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80FR 27710

**Mendiola, Doris**

**Subject:** FW: SHINE Draft EIS - USEPA comments  
**Attachments:** 20150133.pdf

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**From:** Poole, Elizabeth [mailto:Poole.Elizabeth@epa.gov]  
**Sent:** Thursday, July 02, 2015 5:39 PM  
**To:** Moser, Michelle  
**Cc:** Bethaney Bacher-Gresock; Waldschmidt, Jay - DOT; 'Rosanne.Meer@dot.wi.gov';  
alice.halpin@wisconsin.gov; Ian Chidister; freitagm@ci.janesville.wi.us; smithr@ci.janesville.wi.us;  
Randy.Howell@nnsa.doe.gov; Jim Costedio (Jim.Costedio@shinemed.com)  
**Subject:** [External\_Sender] SHINE Draft EIS - USEPA comments

Hi Michelle,

Attached you'll find USEPA's comments on the SHINE Draft EIS. Please let me know if you have any questions, or would like to schedule a call with our technical reviewers to discuss comments. Hard copy went to NRC only.

Thanks in advance,  
Elizabeth

Elizabeth Poole  
US EPA - Region 5  
NEPA Implementation Section  
Detailed to the Environmental Justice Program  
312-353-2087

RECEIVED

2015 JUL 17 AM 10:53

RULES AND DIRECTIVES  
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US EPC

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Template = ADM - 013  
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Add= m. Moser (mrm1)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5  
77 WEST JACKSON BOULEVARD  
CHICAGO, IL 60604-3590

JUL 02 2015

REPLY TO THE ATTENTION OF:

E-19J

Michelle Moser  
Division of License Renewal  
Nuclear Regulatory Commission  
Office of Nuclear Reactor Regulation  
Mail Stop O-11F1  
11555 Rockville Pike  
Rockville, Maryland 20852

Re: **Draft Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility, Janesville, Wisconsin – NUREG-2183 – CEQ #20150133**

Dear Ms. Moser:

The U.S. Environmental Protection Agency has reviewed the Draft Environmental Impact Statement (EIS) for the above-mentioned project prepared by the Nuclear Regulatory Commission (NRC). Our comments are provided pursuant to the National Environmental Policy Act (NEPA), the Council on Environmental Quality's NEPA Implementing Regulations (40 CFR 1500-1508), and Section 309 of the Clean Air Act.


SHINE Medical Technologies, Inc. (the Applicant) applied to the NRC for a construction permit to build and operate a medical radioisotope production facility in Janesville, Wisconsin. The U.S. Department of Energy (DOE) is a cooperating agency and must decide whether to provide cost-sharing financial support to the Applicant under a cooperative agreement, which will accelerate the commercial production of medical radioisotopes without the use of highly enriched uranium. The proposed preferred alternative is for NRC to issue the license.

EPA acknowledges that mitigation measures that are unrelated to nuclear safety and security cannot be included in the NRC license. This includes, but is not limited to, diesel emissions reduction measures. However, because we find these measures to be value-added, we continue to recommend them to the Applicant for any construction activities and include them in our comment letters. We encourage the Applicant to incorporate mitigation measures into the project, wherever possible.

Based on the information provide, EPA assigns a rating of **EC-1, Environmental Concerns – Adequate Information**. However, we have identified some areas where additional information should be provided in the Final EIS and mitigation measures that would reduce environmental impacts. Our summary of ratings is enclosed.

Thank you in advance for your consideration of our recommendations to reduce environmental impacts of the project and to improve the quality of the document. Please be aware that we reserve the right to provide additional comments or recommendations under other permitting stages. If you have any questions, please feel free to contact Elizabeth Poole of my staff at 312-353-2087 or [poole.elizabeth@epa.gov](mailto:poole.elizabeth@epa.gov).

Sincerely,



Kenneth A. Westlake  
Chief, NEPA Implementation Section  
Office of Enforcement and Compliance Assurance

Cc (via email):      Randy Howell, Department of Energy  
                             Jim Costedio, SHINE Medical Technologies, Inc.  
                             Mark Freitag, City of Janesville  
                             Bethaney Bacher-Gresock, Federal Highway Administration - Wisconsin  
                             Ian Chidester, Federal Highway Administration - Wisconsin  
                             Jay Waldschmidt, Wisconsin Department of Transportation  
                             Roseanne Meer, Wisconsin Department of Transportation - Southwest  
                             Rebecca Smith, Janesville Transit System  
                             Alice Halpin, Department of Agriculture, Trade, and Consumer Protection

Enclosure (2):      Detailed Comments  
                             Summary of Ratings Definitions

**EPA's Detailed Comments on the Draft EIS for the Construction Permit for the SHINE  
Medical Radioisotope Production Facility, CEQ #20150133**

**July 2015**

**Radiation**

EPA has reviewed the Draft EIS and cited reference materials regarding radioactive solid wastes. Table 11.2-1 "Waste Stream Summary" (reference SHINE 2013a Chapter 11 – *Radiation Protection Program and Waste Management* of the Preliminary Safety Analysis Report) provides the destinations of the solid, resin, and liquid wastes. Zeolite Beds and another proprietary waste stream are said to be generated as greater-than-class-C (GTCC) with Waste Control Specialists listed as a destination. Waste Control Specialists has GTCC storage capability, but not GTCC disposal capability. The Draft EIS states that if a disposal pathway for GTCC waste does not exist, the Department of Energy (DOE) will be responsible for its safe storage and disposal in accordance with the American Medical Isotopes Production Act of 2012<sup>1</sup>. There is currently no disposal path for GTCC waste and DOE is currently evaluating alternatives for GTCC disposal<sup>2</sup>.

**Recommendation:** The Final EIS should clarify whether DOE or the Applicant will be responsible for the storage of the facility's GTCC wastes at Waste Control Specialists. The Final EIS should state that once DOE establishes a disposal pathway for GTCC, it should promptly facilitate the disposal of the Applicant's GTCC wastes. EPA also recommends that the Applicant clarify whether a radioisotope production process can be engineered so as to eliminate the generation of GTCC waste for which there is no current disposal path, and otherwise reduce or limit the generation of other waste streams to Class A levels.

UREX process raffinate is listed as a Class B liquid waste with Energy Solutions as the destination. Energy Solutions is not authorized to receive Class B and Class C waste according to its waste acceptance criteria document<sup>3</sup>.

**Recommendation:** The Final EIS should clarify how Energy Solutions can be a destination for Class B UREX process raffinate waste.

The Draft EIS lists three isotopes currently slated for production at the facility (molybdenum-99, iodine-131, and xenon-133). The Draft EIS is unclear if the Applicant anticipates needing to add additional isotopes to the facility's production capabilities (based on market conditions or technological advancements, for example).

**Recommendation:** The Final EIS should clarify whether the Applicant anticipates needing to add additional isotope production capabilities (other than the ones listed). If the Applicant anticipates needing additional production capabilities, the Final EIS should identify potential expansion locations and resultant impacts, including anticipated management of waste streams associated with additional isotope production.

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<sup>1</sup> 42 U.S.C. 2065(c)(3)(A)(ii) - <https://www.law.cornell.edu/uscode/text/42/2065>

<sup>2</sup> <http://www.gtccsis.anl.gov>

<sup>3</sup> <http://www.energysolutions.com/wp-content/uploads/2014/11/BWF-WAC-Rev-93.pdf>

The Draft EIS includes several determinations about whether a potential impact is based on models. In most instances, the name of the model and specifics about model inputs and assumptions are not included in the Draft EIS. EPA is aware that this information could be proprietary or included in other documents.

**Recommendation:** EPA recommends that the Final EIS include the name of the models, inputs, and assumptions identified in the Draft EIS for the following determinations, with locations in the Draft EIS given in parentheses. If this information is provided elsewhere, please provide specific locations. Or, if this information is proprietary, please contact us to discuss comment resolution in the Final EIS.

- Estimate values for gaseous radioactive effluents and determination for exposure potential to an individual(s) off site. (Table 2-2, page 2-16);
- Determining compliance with regulatory requirements for public exposure to radiation (Section 3.8.1.2, page 3-54, lines 1-5; Section 4.8.2.1, page 4-36 lines 44-46 and page 4-37, lines 1-2; Section 4.11.1, page 4-47, lines 18-25; Section 4.13.8, page 4-70, lines 38-46; Section 5.2.2.13, page 5-46 lines 21-47 and page 5-47, lines 1-2; Section 5.2.3.8, page 5-71, lines 5-10; Section 5.2.3.13, page 5-91, lines 28-44);

The Applicant will employ three separate water treatment processes: a demineralization process, a cooling water treatment process, and a facility heating water treatment process. Rock County, Wisconsin is a Zone One Radon County<sup>4</sup>, meaning there are relatively high concentrations of naturally occurring radiation in the soil and groundwater in this area. Water treatment and demineralization will have a tendency to concentrate naturally occurring radioactive materials.

**Recommendation:** The Final EIS should address plans for monitoring and subsequent handling and disposal of wastewater and wastewater treatment residuals should high concentrations of radium or other radionuclides be encountered during the production process.

Agreement States and NRC regulated facilities are to keep all exposures of the public to as low as reasonably achievable (ALARA). In order for EPA to rescind regulation of airborne dose exposure from NRC-licensed or Federal facilities, NRC and any delegated program would meet the requirements of Title 40 of the Code of Federal Regulations Part 61, Subpart I requirements, as outlined in the 1998 Memorandum of Understanding between NRC and EPA.

**Recommendation:** The Final EIS should clarify how the Applicant plans to achieve ALARA to the airborne dose exposure to radionuclides as agreed to between NRC and EPA in the 1998 MOU regarding 40 CFR Part 61, Subpart I, prior to the rescission.

The facility will produce more than 500,000 Curies per year of radioactive material. EPA recognizes that the probability of an accident is low, given the type of technology used at the facility. However, given the large amount of radioactive material produced and since this is the

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<sup>4</sup> <http://www.epa.gov/radon/zonemap.html>

first of its kind in the area, the section detailing accidents and response should be strengthened (Section 4.11 *Accidents*).

**Recommendation:** EPA recommends the Applicant provide additional details on accident preparedness plans. We recommend including reference to any agreements with local, state, or Federal emergency responders. We also recommend the Final EIS include details of public outreach specifically related to emergency response (such as handouts sent to adjacent property owners).

### **Green Infrastructure**

The Draft EIS details the locations of permanent structures, buildings, and roads required for the facility, including an estimate of the type and amount of construction materials required. Structures and building includes an administrative building, water and fuel tanks, production facility, and other various support buildings. This site would also include an entrance road and parking lots. Overall, approximately 41 acres would be disturbed, of which 15 acres would be temporary.

EPA commends the Applicant for already identifying several ways to reduce environmental impacts, such as committing to conversion of unused, temporarily disturbed lands to native prairies. EPA has several recommendations regarding immediate site land use planning and green infrastructure. Please note that we are aware of NRC's limited ability to include the following recommendations in the license; however, we find these measures to further reduce environmental impacts and would encourage the Applicant to incorporate them into site planning.

- The Final EIS should clarify to what extent the DOE (as a cooperating agency and prospective provider of funding to the Applicant under a cooperative agreement) would require energy efficiency measures, greenhouse gas reductions, and other sustainability measures, per Executive Order 13693.
- Any locations on the site which are not planned for operations should be considered for conversion to native habitats, increasing the area which can be beneficially used for wildlife, infiltration or stormwater retention, and aesthetics, among other functions.
- The Final EIS should include more information on the sources of the required construction materials, as listed in Table 2-1 (*Estimated Construction Material Requirements*). Please outline whether this material can be made of second-sourced material (i.e., reclaimed aggregate). EPA understands there are specific safety codes that may prevent this; however, we recommend that any auxiliary buildings, new roads, and other non-safety related structures be constructed with materials that are recycled, if possible. If you need more information about this, please see our website about environmentally responsible purchasing at [www.epa.gov/epp](http://www.epa.gov/epp).
- Any roads, parking lots, sidewalks, or other surfaces slated for driving or walking should be constructed using permeable pavement to reduce runoff
- EPA recommends staggering construction schedules of the new facilities so that no additional undisturbed land is permanently disturbed. This could mean having one temporary laydown area (that is ultimately slated for a permanent use) serving the construction of new permanent facilities.

- EPA encourages the Applicant to construct all buildings to Leadership in Energy and Environmental Design (LEED) standards. If LEED standards are pursued, this information should be included in the Final EIS. Any potential use of Energy Star appliances, EPA's WaterSense program, or other similar programs should be identified in the Final EIS. In lieu of including this commitment in the license, the Applicant should report to EPA once these measures have been implemented, if applicable.

### **Climate Change and Greenhouse Gases**

On December 18, 2014, the Council on Environmental Quality released revised draft guidance for public comment that describes how Federal departments and agencies should consider the effects of greenhouse gas (GHG) emissions and climate change in their NEPA reviews. The revised draft guidance supersedes the draft GHG and climate change guidance released by CEQ in February 2010. This guidance explains that agencies should consider both the potential effects of a proposed action on climate change, as indicated by its estimated GHG emissions, and the implications of climate change for the environmental effects of a proposed action.

**Recommendation:** As discussed above under "Green Infrastructure," EPA recommends that the Applicant identify opportunities to minimize GHG emissions associated with construction and operation of the facility to the extent feasible. For example, clean energy options, such as energy efficiency and renewable energy, can be considered in the purchase of maintenance equipment, new equipment and vehicles. We also recommend any measures that may reduce the facility's carbon dioxide (CO<sub>2</sub>) footprint, particularly from fuel combustion during the life of operations. Finally, EPA recommends that the applicant consider the need to develop adaptation measures to address impacts from climate change on the facility, such as increased intensity and frequency of storm and flood events.

EPA notes that our diesel emissions reduction measures, as recommended in our August 14, 2013 scoping letter, were included in the Draft EIS. EPA commends NRC for including this language and continues to encourage the Applicant to incorporate these measures into their construction planning.

### **Transportation**

The Draft EIS states that the Beloit-Janesville Express operates weekdays between Beloit and Janesville (Section 3.9.1 - *Roads*); the closest stops to the facility are Kellogg Ave (to the north) and Sunny Lane (to the south). At this time, there are no plans to include a new stop on this route serving the facility.

**Recommendation:** EPA recommends the Applicant and the Janesville Transit System determine whether a stop at the facility would benefit employees of the facility and help to alleviate potential degradation to traffic patterns along U.S. Highway 51.

The Applicant anticipates an additional 1000 vehicle trips daily associated with the facility (or an approximately 11% increase from current conditions) in traffic volumes on U.S. Highway 51 during construction activity (Section 4.10.1 *Transportation – Construction*). EPA commends the Applicant for already committing to staggered work schedules during construction and demolition, during which an increase in the number of trucks and vehicles would be highest. We

also commend the Applicant for planning to implement a carpooling program for employees during operation to minimize worker vehicle emissions.

**Recommendation:** EPA recommends on-going coordination with local traffic authorities to ensure levels of service remain appropriate and that users of the road are kept updated of closures and delays. Any anticipated system or infrastructure upgrades deemed necessary as a result of the facility should be identified in the Final EIS.

### **Editorial**

The Draft EIS states that the Applicant does not intend to treat or permanently store hazardous wastes on site, meaning it will not require a hazardous waste treatment or storage permit under the Resource Conservation and Recovery Act (RCRA) (Section 2.7.2 *Nonradioactive Waste*, page 2-17, lines 38-42).

**Recommendation:** EPA recommends this section be clarified to indicate that Wisconsin Department of Natural Resources is the permitting authority for hazardous waste treatment and storage per RCRA.

To facilitate the review, EPA continues to recommend figures be provided in color, where appropriate and where color gradient is used in analyzing the information.

EPA continues to recommend clear and objective metrics or thresholds be identified for the three significance levels (SMALL, MODERATE, and LARGE), particularly for where there are ranges.



## **\*SUMMARY OF RATING DEFINITIONS AND FOLLOW UP ACTION\***

### **Environmental Impact of the Action**

#### LO-Lack of Objections

The EPA review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

#### EC-Environmental Concerns

The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce the environmental impacts. EPA would like to work with the lead agency to reduce these impacts.

#### EO-Environmental Objections

The EPA review has identified significant environmental impacts that must be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

#### EU-Environmentally Unsatisfactory

The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. EPA intends to work with the lead agency to reduce these impacts. If the potential unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the CEQ.

### **Adequacy of the Impact Statement**

#### Category 1-Adequate

The EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis or data collecting is necessary, but the reviewer may suggest the addition of clarifying language or information.

#### Category 2-Insufficient Information

The draft EIS does not contain sufficient information for the EPA to fully assess the environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses, or discussion should be included in the final EIS.

#### Category 3-Inadequate

EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the NEPA and/or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.

\*From EPA Manual 1640 Policy and Procedures for the Review of the Federal Actions Impacting the Environment