



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

January 14, 2016

Mr. Kenneth A. Westlake, Chief
NEPA Implementation Section
US EPA - Region 5
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Chicago, IL 60604

SUBJECT: RESPONSE TO ENVIRONMENTAL PROTECTION AGENCY COMMENTS
REGARDING THE FINAL ENVIRONMENTAL IMPACT STATEMENT FOR THE
CONSTRUCTION PERMIT OF THE PROPOSED SHINE MEDICAL
RADIOISOTOPE PRODUCTION FACILITY

Dear Mr. Westlake:

On November 30, 2015, the Environmental Protection Agency (EPA) Region 5, provided comments on the final Environment Impact Statement (FEIS) for the SHINE Medical Technologies, Inc. (SHINE) application for a construction permit for a medical radioisotope production facility (NUREG-2183) (October 2015) (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15288A046). Appendix A of the FEIS, includes U.S. Nuclear Regulatory Commission (NRC) staff responses to EPA Region 5 comments on the draft EIS that was published for comment in May 2015 (ML151527A241). Your November 30, 2015, letter (ML15335A205) states that EPA has no further information or clarifications on its comments labeled 6-2 through 6-13 in the FEIS, but retains a comment and recommendation as to its Comment 6-1, restating concerns about the generation and disposal of greater than class C (GTCC) waste. This letter responds to your November 30, 2015, letter.

It is the NRC staff's view that the information provided in Comment 6-1 in your November 30, 2015, letter, is already addressed in the published FEIS. The NRC staff notes that Comment 6-1 quotes, in part, a non-public draft of the FEIS that was shared with EPA. That text was revised in the published FEIS.

Specifically, Comment 6-1 (on FEIS pages A-36 to A-37) recommended that, because of the lack of a disposal pathway and offsite storage capacity for GTCC waste, (1) the FEIS should clarify who would be responsible for storage of GTCC waste generated by SHINE, (2) the FEIS should state that the Department of Energy (DOE) should promptly facilitate disposal of such GTCC waste once a disposal pathway is established and (3) SHINE should clarify whether it can engineer its process to eliminate generation of GTCC waste and otherwise reduce waste streams. FEIS, Appendix A, page A-36 to A-37.

The NRC staff's response (on FEIS page A-37) states that the American Medical Isotopes Production Act of 2012 (AMIPA) requires DOE to establish a Uranium Lease and Take Back (ULTB) Program and to be responsible for the final disposition of radioactive waste generated by a medical isotope producer that does not have access to a disposal path. The response indicates that, because the ULTB Program has not yet been established, DOE "cannot yet

describe the process through which wastes would be accepted or disposed.” However, further NRC staff evaluation of the programs and controls related to SHINE’s waste management would occur during the review of SHINE’s Final Safety Analysis Report in support of an operating license application” and the NRC staff must “prepare a supplement to the EIS” to address “any new or updated information provided in the operating license application or identified during the NRC staff’s independent review.” In addition, the FEIS states (on page 2-15) that operation of the SHINE facility would generate wastes up to GTCC waste and notes (on pages 2-16 and 4-42) DOE’s responsibility to provide a disposal pathway for GTCC waste created from irradiation, processing or purification of uranium DOE leases to medical isotope producers. The FEIS (on page 2-15) also notes that SHINE would accumulate and temporarily store Class A to GTCC wastes, and that wastes would be transported offsite for storage or final disposal.

The NRC staff also concludes that your recommendation (on page 4 of the November 30 letter) that “NRC and SHINE should ensure the minimization of GTCC generation and should avoid generating waste without a clear treatment and disposal path” is addressed in the FEIS and by the obligations that AMIPA imposes on DOE. In particular, pages 2-16, 4-42, and A-37 of the FEIS state that DOE is required by AMIPA to provide a disposal pathway. As indicated on page A-37 of the FEIS, if SHINE submits an operating license, the NRC staff will further evaluate the SHINE programs and controls related to waste management and update its analysis of potential environmental impacts of the operation of the SHINE facility based on information identified at that time.

After publication of the FEIS, SHINE provided additional information regarding the generation and minimization of GTCC waste. During the December 15, 2015, mandatory hearing held on the SHINE construction permit application, Commissioners asked about the availability of a national disposal pathway for GTCC waste that might be generated during SHINE operations and whether DOE would physically take possession of such waste. Transcript of Hearing on Construction Permit for SHINE Medical Isotope Production Facility (December 15, 2015) (ML15355A440) Tr. 158-59, 206-07. SHINE stated that its designation of small waste streams of GTCC waste is based on its preliminary design and conservative assumptions, and indicated that refinement of its design may limit or eliminate GTCC waste streams. Tr. 158. SHINE also indicated that under the DOE ULTB program, DOE would dispose of any radioactive waste that does not have a commercial disposal path, as required by AMIPA, and that the program could be in place in early 2016. Tr. 158-59, 206-208.

The NRC staff contacted SHINE to confirm that SHINE received your November 30 letter. The NRC staff also reminded SHINE of its responsibility to comply with applicable Federal, State, and local permit requirements. If you need further information, please contact Ms. Michelle Moser, Environmental Project Manager, by telephone at 301-415-6509 or by e-mail at Michelle.Moser@nrc.gov.

Sincerely,

/RA/

James G. Danna, Chief
Environmental Review and Guidance
Update Branch
Division of License Renewal
Office of Nuclear Reactor Regulation

Docket No. 50-608

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K. Westlake

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Sincerely,

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ADAMS Accession Nos. ML15355A421

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Letter to K. Westlake from J. Danna dated January 14, 2016

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