

**From:** [Lynch, Steven](#)  
**To:** ["Jeff Bartelme"](#)  
**Subject:** Issuance of Request for Additional Information Related to the SHINE Medical Technologies, LLC Operating License Application (EPID No. L-2019-NEW-0004)  
**Date:** Tuesday, May 26, 2020 3:33:00 PM  
**Attachments:** [SHINE Request for Additional Information Related to Operating License Application.pdf](#)

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Jeff,

By letter dated July 17, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19211C044), as supplemented by letters dated November 14, 2019 (ADAMS Accession No. ML19337A275), and March 27, 2020 (ADAMS Accession No. ML20105A295), SHINE Medical Technologies, LLC (SHINE) submitted to the U.S. Nuclear Regulatory Commission (NRC) an operating license application for its proposed SHINE Medical Isotope Production Facility in accordance with the requirements contained in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities."

During the NRC staff's review of SHINE's operating license application, questions have arisen for which additional information is needed. The enclosed request for additional information (RAI) identifies information needed for the NRC staff to continue its review of the SHINE final safety analysis report (FSAR), submitted as part of the operating license application, and prepare a safety evaluation report. Specific chapters and technical areas of the SHINE operating license application covered by this RAI include the following:

- Chapter 1, "The Facility"
- Chapter 4a2, "Irradiation Facility Description"
- Chapter 7, "Instrumentation and Control Systems"
- Chapter 8, "Electrical Power Systems"
- Emergency Plan
- Quality Assurance Program Description
- Material Control and Accounting Plan

It is requested that SHINE provide responses to the enclosed RAI within 30 days from the date of this electronic mail. In accordance with 10 CFR 50.30(b), "Oath or affirmation," SHINE must execute its response in a signed original document under oath or affirmation. The response must be submitted in accordance with 10 CFR 50.4, "Written communications." Information included in the response that is considered sensitive or proprietary, that SHINE seeks to have withheld from the public, must be marked in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding." Any information related to safeguards should be submitted in accordance with 10 CFR 73.21, "Protection of Safeguards Information: Performance Requirements." Following receipt of the additional information, the NRC staff will continue its evaluation of the subject chapters and technical areas of the SHINE operating license application.

As the NRC staff continues its review of SHINE's operating license application, additional RAIs for other chapters and technical areas may be developed. The NRC staff will transmit any further questions to SHINE under separate correspondence. If you have any questions, or need additional time to respond to this request, please contact me at 301-415-1524, or by electronic mail at

[Steven.Lynch@nrc.gov](mailto:Steven.Lynch@nrc.gov).

Steve Lynch, Project Manager

Non-Power Production and Utilization Facility Licensing Branch

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