



September 2, 2021

2021-SMT-0113
10 CFR 50.30

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

- References:
- (1) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Application for an Operating License," dated July 17, 2019 (ML19211C143)
 - (2) NRC letter to SHINE Medical Technologies, LLC, "SHINE Medical Technologies, LLC – Update to Operating License Application Technical Review Schedule (EPID No. L-2019-NEW-0004)," dated August 3, 2021 (ML21209A997)
 - (3) SHINE Medical Technologies, LLC letter to the NRC, "SHINE Medical Technologies, LLC Overview of Phased Approach to Initial Facility Operations," dated February 26, 2021 (ML21057A340)

SHINE Medical Technologies, LLC Schedule Update

Pursuant to 10 CFR Part 50.30, SHINE Medical Technologies, LLC (SHINE) submitted an application for an operating license for a medical isotope production facility to be located in Janesville, WI (Reference 1). Via Reference 2, the NRC staff requested SHINE provide updated submission dates for the phased approach supplement and subsequent request to receive and possess radioactive material, as well as the current expected completion dates for each phase of construction, to enable the staff to establish a revised review schedule for the SHINE application.

SHINE previously provided an overview of the phased approach to initial facility operations, including identification of the four phases of process equipment installation and operation, the estimated dates when construction associated with each phase would be substantially complete, the anticipated submittal date associated with the application supplement for the phased approach to initial facility operations, and the anticipated submittal dates for requests to receive and possess certain radioactive materials to support construction and to support preparedness for initial operations of the SHINE facility (Reference 3).

The estimated submission date for the application supplement for the phased approach to initial facility operations described in Reference 3 is January 2022. Ahead of the submittal of the application supplement, SHINE intends to submit a revision to the Supplement to the Environmental Report describing environmental impacts related to the phased approach to initial facility operations.

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SHINE is currently re-baselining the project schedule, and additional time is needed to accurately represent the estimated submission date for the request to license certain byproduct, source, and special nuclear material to support initial facility operations and the estimated construction completion dates for each phase of process equipment installation. SHINE will provide these requested dates by October 15, 2021.

If you have any questions, please contact Mr. Jeff Bartelme, Director of Licensing, at 608/210-1735.

Very truly yours,

DocuSigned by:

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James Costedio
Vice President of Regulatory Affairs and Quality
SHINE Medical Technologies, LLC
Docket No. 50-608

cc: Project Manager, USNRC
SHINE General Counsel
Supervisor, Radioactive Materials Program, Wisconsin Division of Public Health