February 26, 2021

2021-SMT-0027
10 CFR 50.30

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

References: (1) SHINE Medical Technologies, LLC. letter to NRC, dated July 17, 2019, "SHINE Medical Technologies, LLC Application for an Operating License" (ML19211C143)

SHINE Medical Technologies, LLC Overview of Phased Approach to Initial Facility Operations

Pursuant to 10 CFR 50.30, SHINE Medical Technologies, LLC. (SHINE) submitted an application for an operating license for a medical isotope facility located in Janesville, Wisconsin (Reference 1). SHINE intends to pursue a phased approach to initial operations of the SHINE medical isotope production facility in order to help meet the national need for molybdenum-99 production as soon as possible while also ensuring all requirements related to public health and safety are met.

The phased approach to initial facility operations consists of four phases of process equipment installation and operation. The facility structure will be completed in its entirety prior to the completion of Phase 1. Process equipment will be installed as soon as practical when it arrives at the SHINE facility.

Phase 1 consists of the equipment necessary to support operation of irradiation units 1 and 2. The anticipated equipment to be installed during Phase 1 includes:

- all auxiliary and support systems, except as noted below for the instances of primary closed loop cooling system (PCLS), light water pool system (LWPS), and radiological ventilation zone 1 recirculating subsystem (RVZ1r);
- all radioisotope production facility (RPF) systems except the capability of iodine and xenon purification and packaging (IXP) and radioactive liquid waste immobilization (RLWI) selective removal;
- irradiation units 1 and 2, including the associated instances of the subcritical assembly system (SCAS), neutron flux detection system (NFDS), target solution vessel (TSV) off-gas system (TOGS), PCLS, LWPS, and RVZ1r; and
- tritium purification system (TPS) train A.

Phase 2 adds the equipment necessary to support operation of irradiation units 3, 4, and 5. The anticipated equipment to be installed during Phase 2 includes:

- irradiation units 3, 4, and 5, including the associated instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r; and
- TPS train B.

Phase 3 adds the equipment necessary to support operation of irradiation units 6, 7, and 8. Phase 3 also adds the capability for selective removal in the RLWI system and waste staging. The anticipated equipment to be installed during Phase 3 includes:

- irradiation units 6, 7, and 8, including the associated instances of the SCAS, NFDS, TOGS, PCLS, LWPS, and RVZ1r;
- TPS train C;
- RLWI selective removal components; and
- the material staging building.

Phase 4 adds the IXP capability.

The estimated timing of completion of construction and beginning of operation for each phase is defined below.

- Phase 1
  - Construction substantially complete: August 2022
  - Commercial operation: April 2023
- Phase 2
  - Construction substantially complete: August 2022
  - Commercial operation: April 2023
- Phase 3
  - Construction substantially complete: February 2023
  - Commercial operation: May 2023
- Phase 4
  - Construction substantially complete: April 2023
  - Commercial operation: August 2023

Modifications to the SHINE facility structures and footprint are not expected to be required to support phased construction and operation. Additional construction laydown area or warehousing space for materials or equipment outside of what was presented in the supplement to the environmental report is not anticipated because process equipment will be installed as soon as practical after arrival at the SHINE facility.

SHINE intends on submitting a stand-alone application supplement describing each phase of the phased approach to initial facility operations in detail. The supplement will identify any new or different information from that described in the final safety analysis report (FSAR) specific to each phase and will analyze any unique hazards resulting from the phase-specific configuration of the facility from that presented in the FSAR. As the phased approach application supplement will be a stand-alone description of the approach, SHINE does not anticipate any impacts to the full facility descriptions provided in the FSAR or the supplement to the environmental report.

In order to facilitate an efficient review of the phased approach application supplement, SHINE anticipates engaging with the NRC staff to discuss the phased approach during a March 2021 public meeting, and again engaging with the NRC staff to discuss the technical, licensing, and administrative details of the application supplement prior to submittal of the supplement in June 2021.

While unrelated to the phased approach application supplement, SHINE intends on seeking NRC approval to receive and possess certain radioactive materials to support the construction of the SHINE facility and to support preparedness for initial facility operations upon issuance of the operating license. Initially, SHINE will seek approval to receive and possess certain byproduct and source material pursuant to 10 CFR Parts 30 and 40, respectively, in connection with the construction of the SHINE facility. Following this initial request, SHINE will seek approval to receive and possess certain byproduct, source, and special nuclear material pursuant to 10 CFR Parts 30, 40, and 70, respectively, in connection with initial operations of the SHINE facility. SHINE anticipates submitting the initial request to receive and possess certain radioactive materials in April 2021, and the subsequent request to receive and possess additional radioactive materials in Q4 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
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SHINE Medical Technologies, LLC
Docket No. 50-608

cc: Project Manager, USNRC
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