

ENCLOSURE 2

SHINE MEDICAL TECHNOLOGIES, LLC

**MEETING SLIDES FROM THE APRIL 13, 2021 PUBLIC MEETING
BETWEEN SHINE MEDICAL TECHNOLOGIES, LLC AND THE NRC**

**PHASED APPROACH TO INITIAL OPERATIONS OF THE SHINE FACILITY
PUBLIC VERSION**



Phased Approach to Initial Operations of the SHINE Facility

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Outline

- I. Philosophy of Approach**
- II. Description of Phases**
- III. Safety Analysis Impacts**
- IV. Approach to Licensing the Phased Approach**

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Philosophy of Approach

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Overall Philosophy

- Purpose: Meet the national need for Mo-99 production as soon as possible while also ensuring all requirements related to public health and safety are met
 - Provide flexibility for challenges that may arise during procurement, installation, and testing
- Key considerations:
 - Ensure that all design criteria and safety functions can be met
 - Simplify process boundary isolation strategy
 - Simplify confinement boundary isolation strategy
 - Minimize impact on operating portions of the facility



Procurement and Installation Philosophy

- The phased startup plan does not inherently affect how we are approaching procurement and installation
 - Equipment for all eight units being procured at the same time
 - Fabrication for most equipment is naturally being done in sets or batches, resulting in staggered delivery
 - As challenges are encountered in the fabrication process, equipment for Phase 1 will be prioritized
- Equipment will be installed as soon as possible once it is received on site



Operational Considerations to Phased Approach

- Minimize equipment that needs to be installed during operation
- Each irradiation unit (IU) has a dedicated IU cell, target solution vessel (TSV) off-gas system (TOGS) cell, and primary cooling room
 - Installation activities are occurring in an area that is physically separate from operating units
 - Confinement boundaries for operating systems are not impacted by installation activities
- Equipment movement by the facility crane will be conducted by the maintenance organization, in accordance with approved procedures
- Installation workers will be trained as radiation workers



Description of Phases

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Summary of the Four Phases

- Phase 1:
 - All main production facility structure
 - All facility-wide auxiliary systems
 - All radioisotope production facility (RPF) systems, except iodine and xenon purification and packaging (IXP) and radioactive liquid waste immobilization (RLWI) selective removal
 - IU cells 1 and 2
 - Tritium purification system (TPS) train A
- Phase 2: IU cells 3 through 5 and TPS train B
- Phase 3: IU cells 6 through 8, TPS train C, RLWI selective removal, and material staging building
- Phase 4: IXP



Summary of Systems Affected by Phased Startup Plan

- IU Systems
 - Subcritical assembly system (SCAS)
 - TOGS
 - Neutron driver assembly systems (NDAS)
 - Primary closed loop cooling system (PCLS)
 - Neutron flux detection system (NFDS)
 - RVZ1 recirculation units
 - Light water pool system
- TPS
- IXP
- RLWI selective removal



Physical Layout of the Four Phases



SRI



Current Live Schedule Dates

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



Safety Analysis Impacts

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Process of Evaluation

- A hazard evaluation will be performed to assess potential impacts to the SHINE safety analysis
 - Each category of accidents sequences will be evaluated for new or different initiating events
 - Updates to safety analysis calculations (e.g., radiological dose, chemical consequence) will be made, if needed
- Results will be documented in a supplement to the SHINE Safety Analysis summary report and incorporated into the licensing basis, via the application supplement



Preliminary Assessment of Safety Analysis Impacts

- Radiological and chemical inventory in the facility will be reduced in early phases
 - Releases of tritium into multiple IUs or multiple TPS gloveboxes are not applicable for some phases
 - Likelihood of some events related to frequency of operations with radiological hazards would be reduced
- Frequency of lifting operations would be higher during early phases
 - Single-failure-proof crane in IF provides sufficient protection against drop events
- No new safety-related controls are anticipated for the phased approach
- Currently evaluated radiological dose and chemical consequence scenarios are expected to remain bounding for the phased approach



Approach to Licensing the Phased Approach

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Approach to Licensing Individual Facilities

- SHINE intends to seek NRC authorization to operate the eight utilization facilities and one production facility on a facility-by-facility basis
 - While the NRC issued a single construction permit for the SHINE facility (CPMIF-001), the construction permit individually identifies the eight utilization facilities and one production facility as comprising the SHINE facility
- Upon completion of construction of a specific phase, SHINE will notify the NRC of the substantial completion of facilities within the scope of the phase (e.g., utilization facilities one and two and the production facility in the first phase), allowing the NRC to commence the operational readiness review
- SHINE believes NRC authorization of initial facility operations can occur via the initial issuance of the operating license, while authorization of the operation of subsequent phases (i.e., subsequent utilization facilities) can be provided via an amendment to the operating license
 - SHINE has not identified the need to amend the construction permit to support this licensing approach



Phased Approach License Application Supplement

- SHINE intends to prepare a stand-alone supplement to the operating license application, describing each of the four distinct phases for the phased approach to construction and operation of the SHINE facility
- Each of the four phase descriptions within the supplement will include 18 sections, with each section providing a phase-specific comparison to each chapter of the FSAR
- Each of the four phase descriptions in the supplement will identify the extent of system installation to be completed in that phase, identifying any deviations from the system configurations provided in the FSAR
- Where the level of detail provided in the FSAR is consistent with the planned installation scope of a specific system, reference to the FSAR description will be provided in the supplement (e.g., complete installation of a facility-specific instance of a system is planned [PCLS] or complete installation of a shared structure is planned [FSTR])



Phased Approach Licensing Application Supplement

- Each of the four phases will have an analysis of phase-specific hazards, based on the unique configuration of the phase
- Accident analysis sections within the phased approach licensing application supplement will include any unique considerations resulting from the hazard analysis for each accident category considered in Chapter 13 of the FSAR (i.e., those accident categories identified in Section 13a2.1 and Subsection 13b.1.2 of the FSAR)
 - Where the accident scenario described in Chapter 13 of the FSAR bounds the phase-specific hazards considered, the bounding nature of the Chapter 13 accident scenario will be described
 - Should the phased approach hazard analysis identify any unique considerations for an accident category, the supplement will describe the consideration (e.g., unique phase-specific initiating event or phase-specific safety control) and any impact on the resulting determination of consequences
- However, SHINE does not expect the phased approach hazard analysis to result in the identification of any unique phase-specific initiating events or safety controls