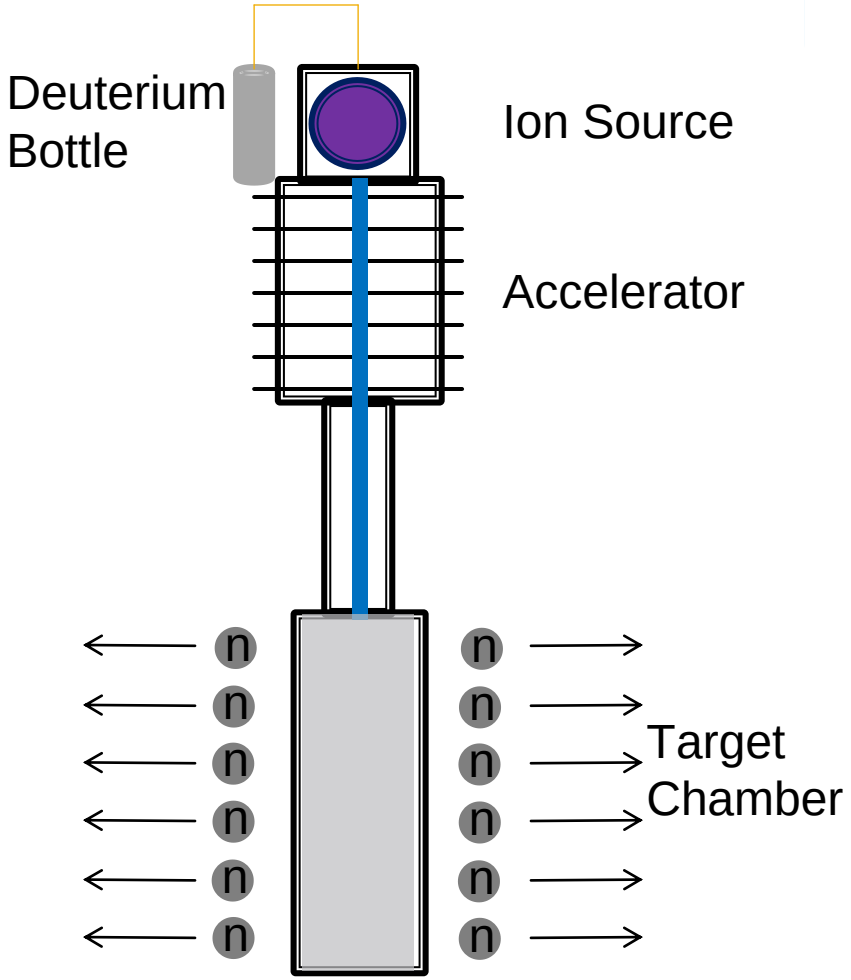
Update on Medical Isotopes (MO-99)

Gregory Piefer, Ph.D.,
Chief Executive Officer,
SHINE Medical Technologies, Inc.

December 16, 2014

Technology Overview

- **SHINE process uses a small particle accelerator to create neutrons**
  - **Beam strikes gas creating primary neutrons**
  - **Neutrons strike multiplying uranium target, creating isotopes**
- **Must be driven to operate**
  - **Subcritical fission process immediately begins to cease if accelerator loses power**
  - **Extremely small amount of decay heat (only a few kW within minutes)**



In Addition to Safety Benefits, Configuration Greatly Improves Efficiency

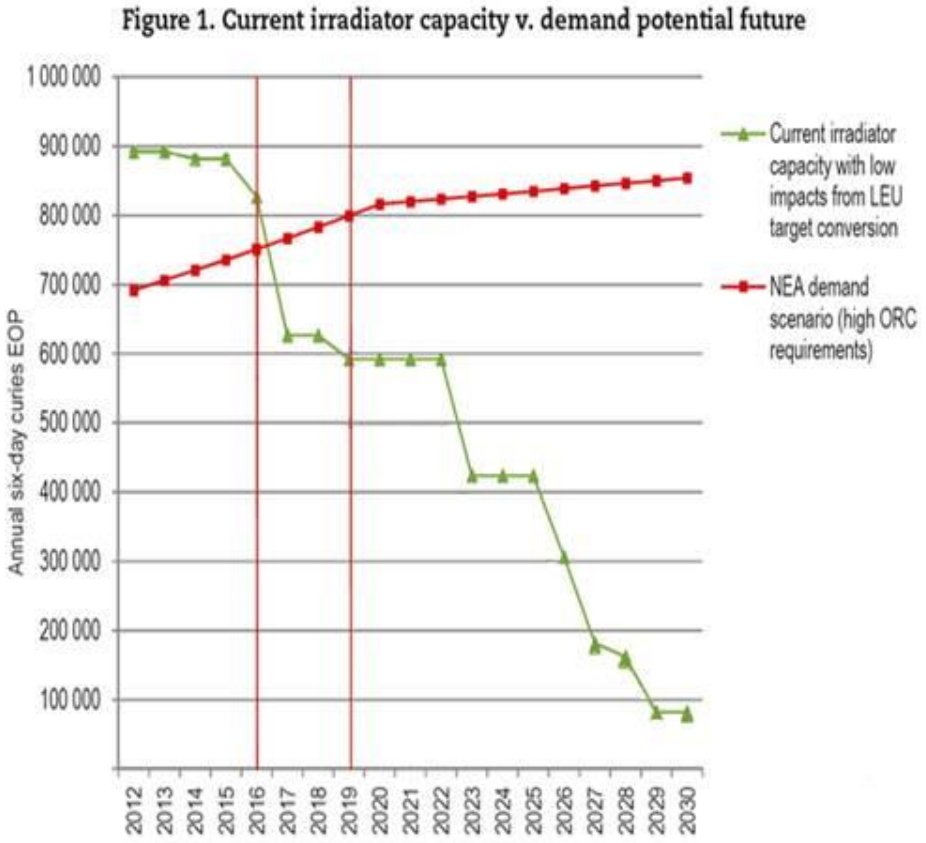
- **Accelerator in center of target → Almost all neutrons used**
- **Target in liquid form → easy processing, reusability**
- **Radioactive byproducts reduced by hundreds of times compared to conventional methods**

Plant Systems Evolved, High Caliber Team Behind Development

- System modeling continues at Los Alamos National Laboratory (LANL); confirms high yield, safety of SHINE approach
- UW system modeling and experiments also verify effective, high yield design
- Demonstrations at Argonne National Laboratory and LANL continue to show efficient, high yield chemical separation
- Plant-scale prototype accelerator has demonstrated full output at Monona facility

Market Situation with No Intervention

- **Mo-99 is an essential component in the global medical diagnostic industry**
- **Market Size**
  - **The worldwide market for Mo-99 is expected to approach $600 million in 2017**
  - **Volume growing at a rate of 3% annually and prices firming**
- **Growth Drivers**
  - **Growing diagnostic imaging procedures**
  - **Price increases**



Medical Need: Replace Aging and Consolidated Supply

- **More than 90% of the world's supply of Mo-99 is produced in five nuclear research reactors**
- **These reactors are old and have recently required major repairs resulting in shortages—largest producer ceasing operations in 2016 (Canada)**

Name	Location	Age in 2016 (years)	Market Share
NRU	Canada	59	30-35%
HFR	Netherlands	55	30-35%
Safari-1	South Africa	51	10-15%
BR-2	Belgium	55	10-15%
Osiris	France	50	5-10%

- **Effects of Mo-99 Shortages**
  - **Medical imaging procedures are postponed, cancelled, or converted to pricier, less-effective alternative tests**
  - **Rationing of Tc-99m has been tried but the lower dosage use means poor image quality and less effective tests**

Construction Permit Application Progress

- March 26, 2013: SHINE submits part 1 of the Construction Permit (CP) Application
- May 31, 2013: SHINE submits part 2 of the CP Application
- June 24, 2013: NRC publishes an intent to prepare an Environmental Impact Statement for the SHINE facility in the Federal Register
- June 25, 2013: NRC accepts part 1 of the SHINE CP Application for docketing
- July 3, 2013: NRC provides SHINE with an Environmental Site Audit Needs List
- July 17, 2013: NRC holds public meeting in Janesville to discuss the CP Application Review Process and Environmental Scoping for SHINE

Construction Permit Application Progress

- Week of July 29, 2013: NRC conducts Environmental Site Audit
- September 11, 2013: SHINE receives Requests for Additional Information (RAIs) for the Environmental Review from the NRC
- October 4, 2013: SHINE submits responses to the RAIS for the Environmental Review
- December 2, 2013: NRC accepts Part Two of the SHINE CP Application for docketing
- September 19, 2014: SHINE receives RAIs for the CP Application from the NRC
- October 15, 2014: SHINE submits responses to approximately 60% of the CP RAIs
- December 3, 2014: SHINE submits remainder of responses to the CP RAIs

Challenges

- **Schedule Risk**
  - **First-of-a-kind (FOAK) facility**
  - **Multiple regulatory reviewers (e.g., Part 70, Part 50, OGC)**
  - **Time to provide licensing path forward (i.e., Revising 10 CFR 50.2 definition)**
- **Investor Risk**
  - **No firm schedule provided to SHINE**
  - **Delays due to FOAK**

Licensing Path Forward

- **Submitted Remainder of Responses to PSAR RAIs**
- **Receive Construction Permit (Expected October 2015)**
- **Complete Final Design (Expected April 2016)**
- **Submit Operating License Application (Expected May 2016)**
- **Construction Complete (Expected May 2017)**
- **Receive Operating License (Expected September 2017)**
- **Ready to Sell Product (Expected January 2018)**

Relationship With NRC

- **SHINE has fostered a good working relationship with the NRC.**
  - **Licensing manager makes frequent contact with the Project Manager**
  - **Numerous visits to present SHINE positions of various issues**
  - **Were given positive feedback on responsiveness and quality of work regarding the ER**

Summary

- Need to work closely with NRC to stay on schedule
- The NRC quickly developed guidance to address the new technology
- SHINE has designed a very safe, environmentally conscious approach to solving a global health issue
- Working with the regulatory community (NRC, FDA, state and local governments), SHINE has made significant progress
- SHINE technology has tremendous benefits
- Progress continues on technology, design, and licensing
- Will create ~150 good-paying jobs in Janesville, WI; add to tax base; become a strong community partner

Questions?

Dr. Gregory Piefer
SHINE Medical Technologies, Inc.
877-512-6554
greg.piefer@shinemed.com