



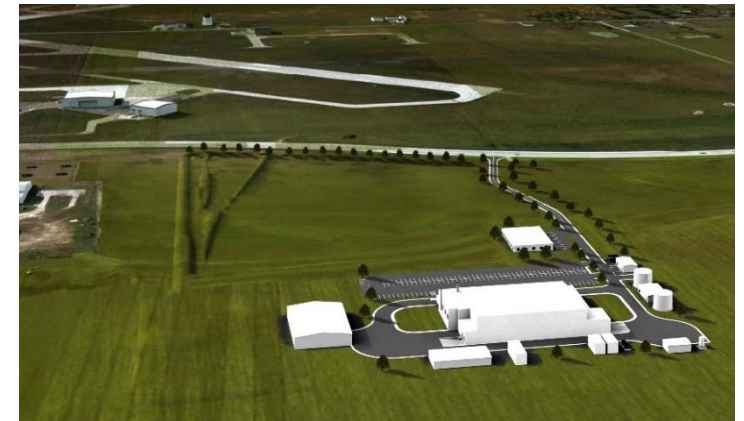
Health. Illuminated.™

# SHINE Snapshot

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## *SHINE is building new irradiation and processing infrastructure*

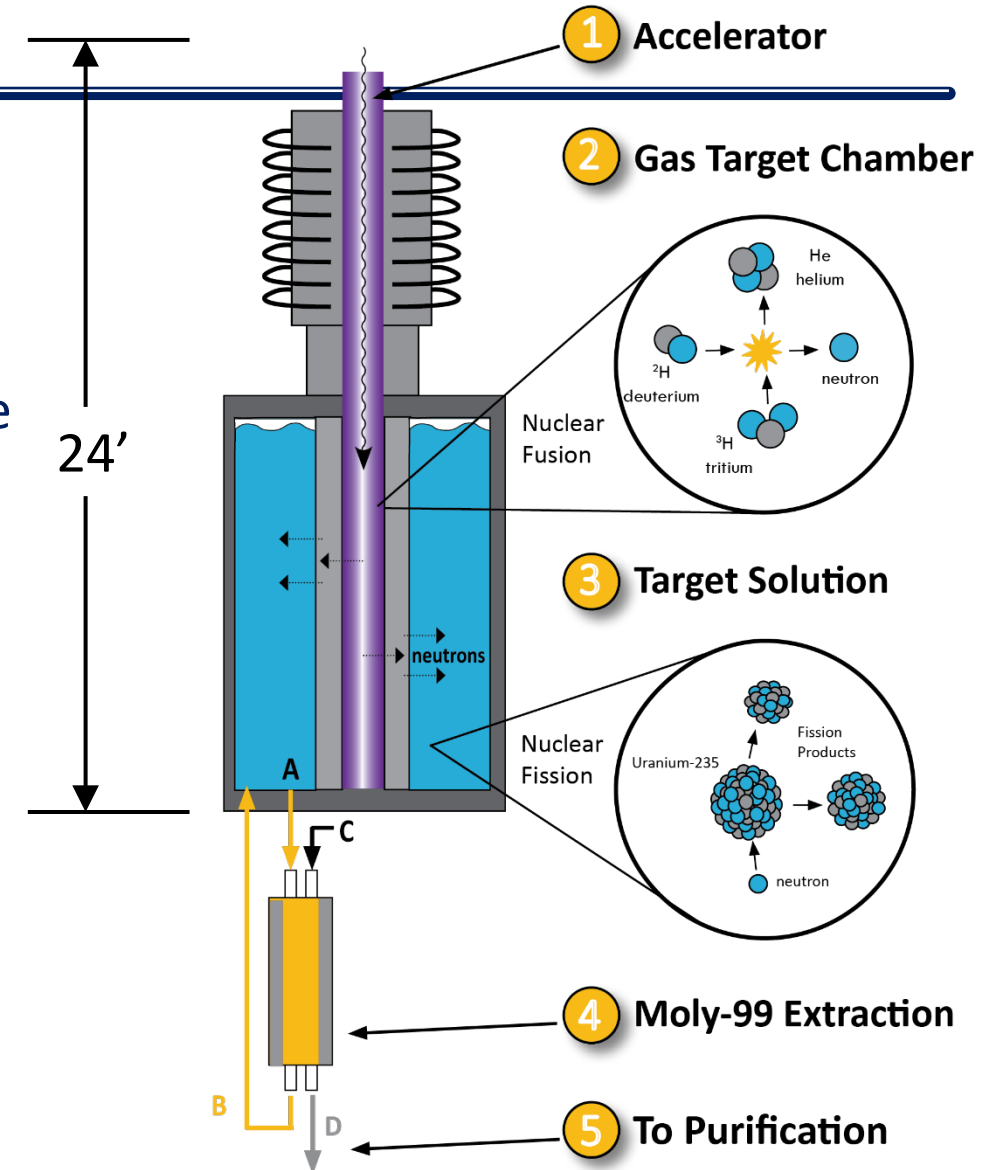
- Dedicated to being the world leader in the safe, clean, affordable production of medical isotopes
- One of few projects aggressively pursuing new irradiation and processing infrastructure
- Since last year:
  - GE tested SHINE Mo-99 in November 2015 and found it met all specifications
  - US Nuclear Regulatory Commission construction permit issued in February 2016
  - HTA agreement
- Over \$50M invested to date in technology and regulatory process
- Leading efforts to establish domestic fission-based isotope supply



# SHINE Technology

## *A modernized approach to making Mo-99*

- Integrated production and refining
- SHINE irradiation unit is a hybrid
  - Accelerator creates D-T neutrons that drive reactions in the target
  - Neutrons multiply in subcritical uranium sulfate solution, allowing for very high yield
- **100% LEU**
- Cost effective approach
  - Elimination of reactor results in 100s of times less waste than conventional production
  - Reusable target

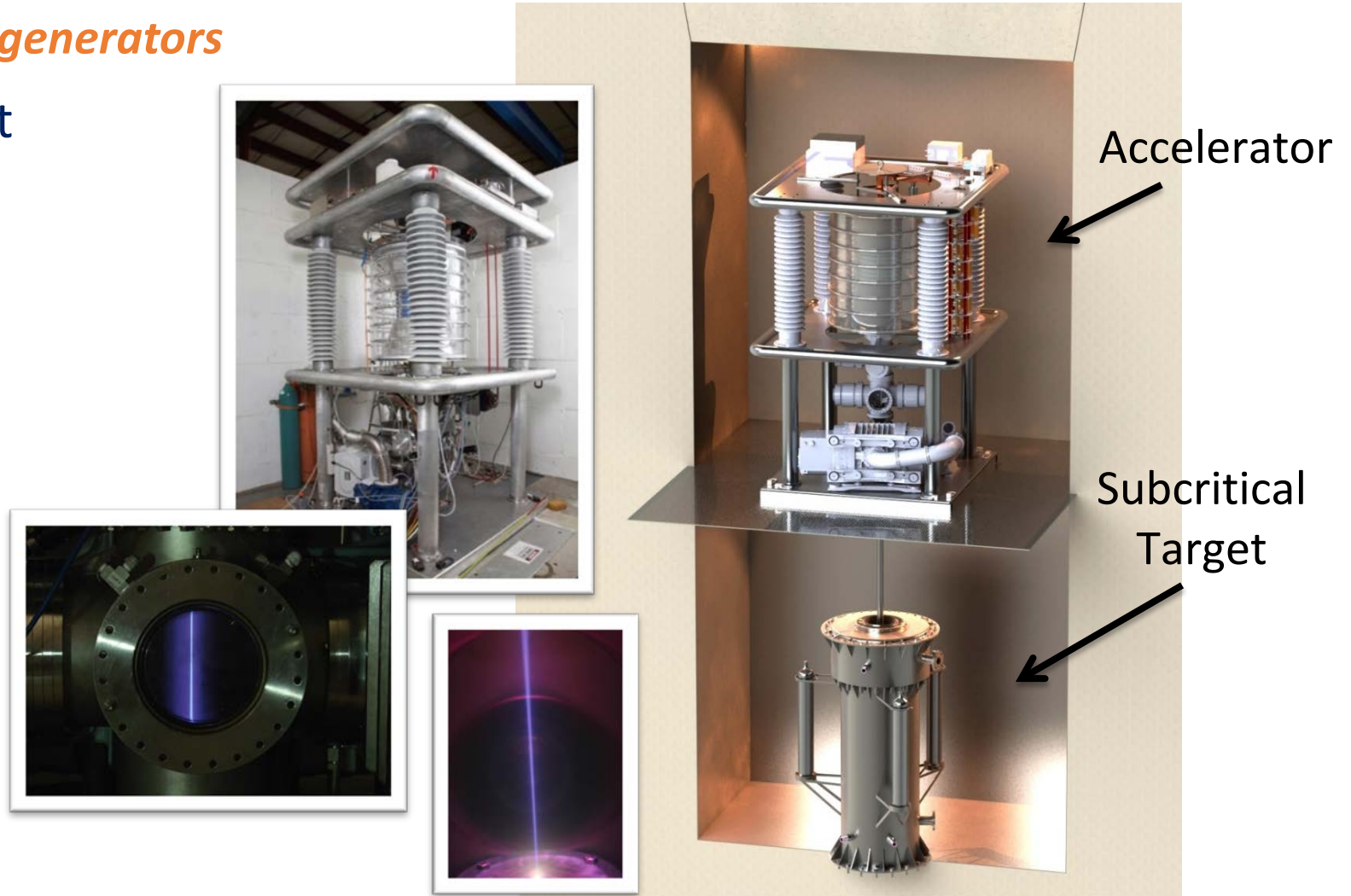




# Demonstrated Technology

## *The world's strongest neutron generators*

- Plant-scale accelerator at Monona, Wisconsin facility
- March 2016 demonstration
  - 132 consecutive hours of operation
  - 97% uptime
- Thousands of hours of operation logged on similar accelerators



# Demonstrated Technology

*Every part of the process demonstrated*

Process Step	Demonstrated?	Details
Irradiation	✓	<ul style="list-style-type: none"><li>• Plant-scale neutron driver operational</li><li>• Operation at plant cadence demonstrated</li></ul>
Target	✓	<ul style="list-style-type: none"><li>• Many SHINE-specific uranyl sulfate irradiations performed at ANL and LANL</li><li>• Uranyl sulfate solutions routinely used in critical reactors at 2x power density (Argus)</li></ul>
Processing	✓	<ul style="list-style-type: none"><li>• Separations demonstrated from sulfate solutions (Argus, LANL, ANL)</li><li>• Cintichem process was used for decades</li></ul>

# Market Acceptance

## *Supply chain compatibility*

- Fission-based, high-specific activity
  - No changes to pharmacy practices
  - Ensures access to other isotopes, including I-131 and Xe-133
- Supply agreements
  - 2014 - GE Healthcare and Lantheus Medical Imaging
  - June 2016 - HTA Co., Ltd.



Mr. Guo Chunsheng, President of HTA and Dr. Greg Piefer, CEO of SHINE

# GE Drytec Generator and Kit Test

*Mo-99 produced by the SHINE process met all GE quality requirements*

- Mo-99 produced by the SHINE process at Argonne National Laboratory was loaded on a GE DryTec generator
- Eluted Tc-99m was used with Myoview and Ceretec kits
- Mo-99, Tc-99m and both drugs met all GE specifications
- Demonstrates SHINE chemistry is compatible with DryTec generators and drugs

**It Takes Two: GE Healthcare and SHINE team up to solve longstanding radiopharmaceutical supply concerns in medical imaging**

By Patti McLean on November 9th, 2015



*Successful generation of Tc-99m is a supply chain advancement that can help ensure patient access to critical medical imaging scans.*

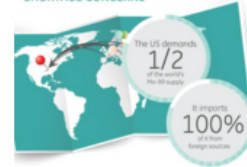
**CHALFONT ST. GILES, UK – 9 November 2015** – Technetium-99m (Tc-99m) is used in more than 40 million medical imaging procedures each year, primarily stress tests to assess heart disease, and bone scans to determine the stage of cancer progression. This essential medical isotope is generated in pharmacies and hospitals from another isotope—molybdenum-99 (Mo-99). Despite using half of the world's supply of Mo-99, the United States does not produce any domestically and imports 100 percent of its supply from foreign nuclear reactors. Many of these reactors are beyond their originally intended lifespans and outages have

caused major shortages of Mo-99.

Today, SHINE and GE Healthcare announced they have successfully demonstrated the use of SHINE-produced Mo-99 in DRYTEC Tc-99m generators for the production of Sodium Pertechnetate (Na<sup>99m</sup>TcO<sub>4</sub>) For the Production of Sodium Pertechnetate (Na<sup>99m</sup>TcO<sub>4</sub>) results of this test confirm that Mo-99 produced by the SHINE process can be used in DRYTEC Tc-99m generators for use in medical imaging scanning procedures. SHINE is expected to begin commercial production of Mo-99 to supply two-thirds of the US patient population.

## SUPPLY CHAIN ADVANCEMENT

### SHORTAGE CONCERNS



"We have been confident from the start that the SHINE process is a cleaner, safer technical approach. GE greatly appreciates the help of Argonne National Laboratory for making this test possible, who have provided important insights."

After successfully producing Tc-99m, the team is now working on it in preparation of finished radiopharmaceuticals.





# NRC Construction Permit Issued

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## *SHINE noted as model applicant*

- NRC issued SHINE Construction Permit February 2016
  - Culmination of over four years of work
  - Only U.S. medical isotope producer with NRC approval to construct



SHINE Testimony at the NRC Hearing (photo by NRC)



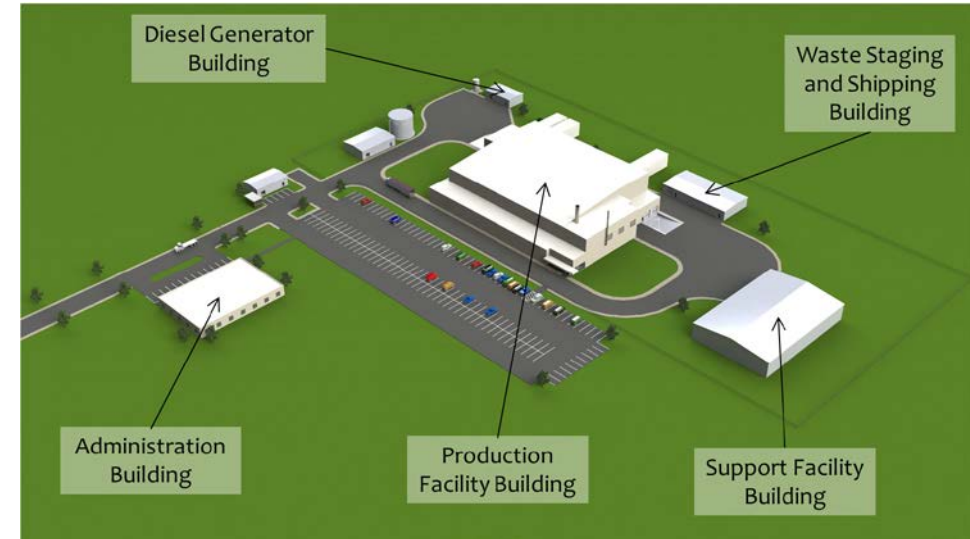
SHINE Construction Permit Signing Ceremony (photo by NRC)



# Production Facility Design

## *Designed for logistical efficiency*

- SHINE facility to be built in Janesville, Wisconsin, USA
- 57,000 ft<sup>2</sup> production facility
- Plant capacity of 4000 6-day Ci/week
  - Over 1/3 global demand
- 8 independent irradiation units – ensures high reliability, flexible production schedule
- Independent hot cell chains further increase reliability and flexibility

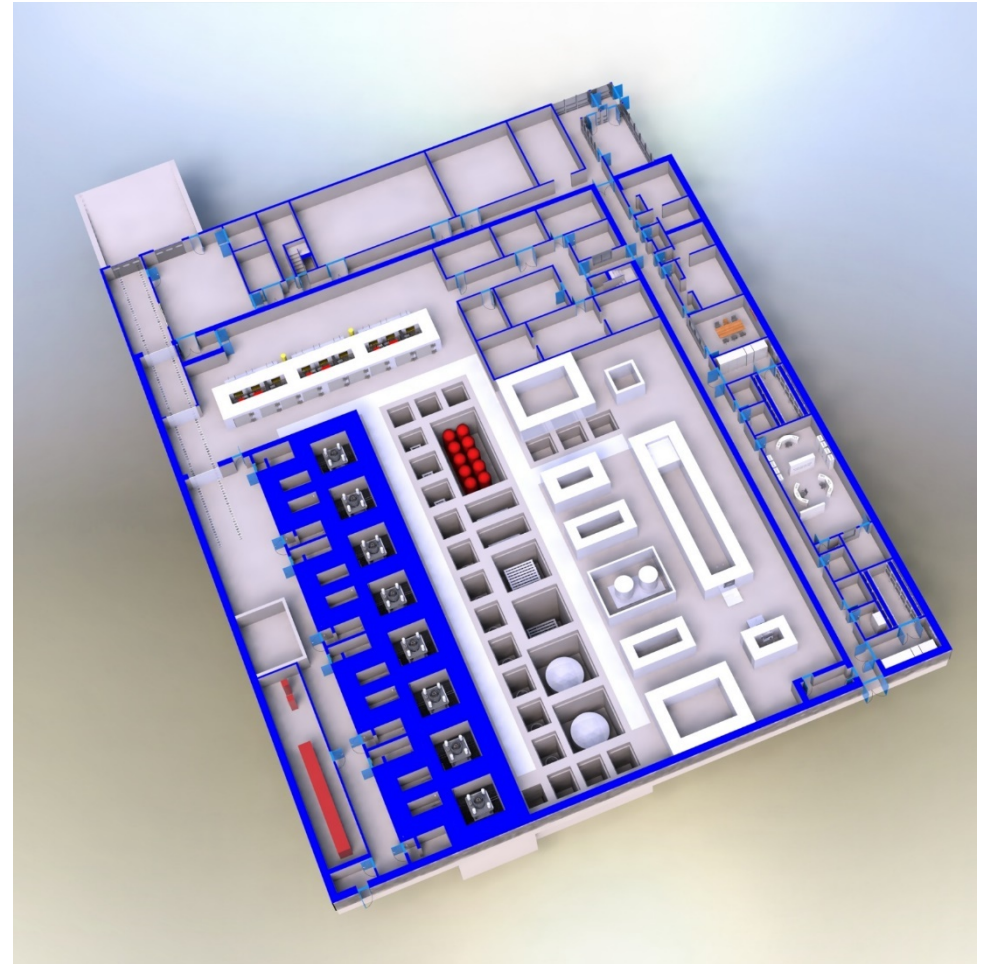


# Next Steps

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## *Industry-leading progress*

- Current key activities
  - Construction team selected
  - Preparing operating license
  - Completing detailed design
  - Negotiating additional supply agreements
- Construction to begin early 2017
- Commercial production in 2019



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