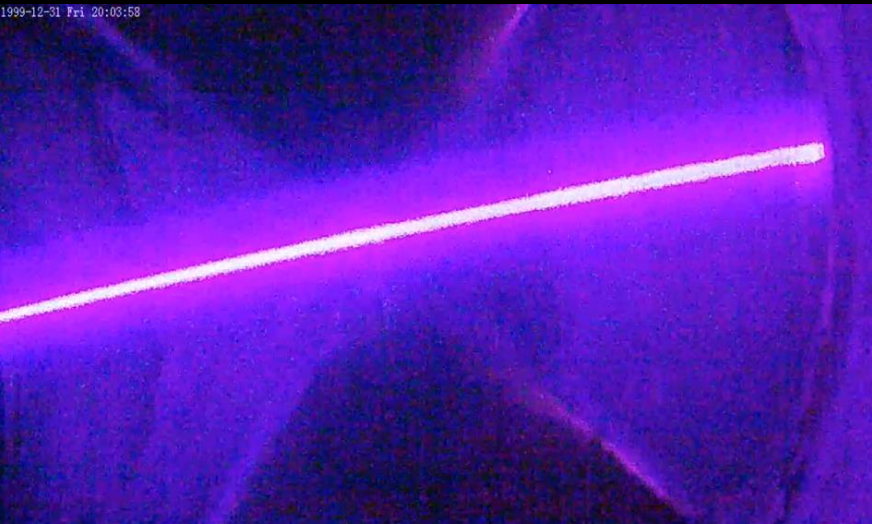


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# The SHINE Path to a Reliable Domestic Supply of Mo-99

Moly-99 Topical Meeting June 27<sup>th</sup>, 2014

# Introduction to SHINE Medical Technologies

## *Health. Illuminated.*

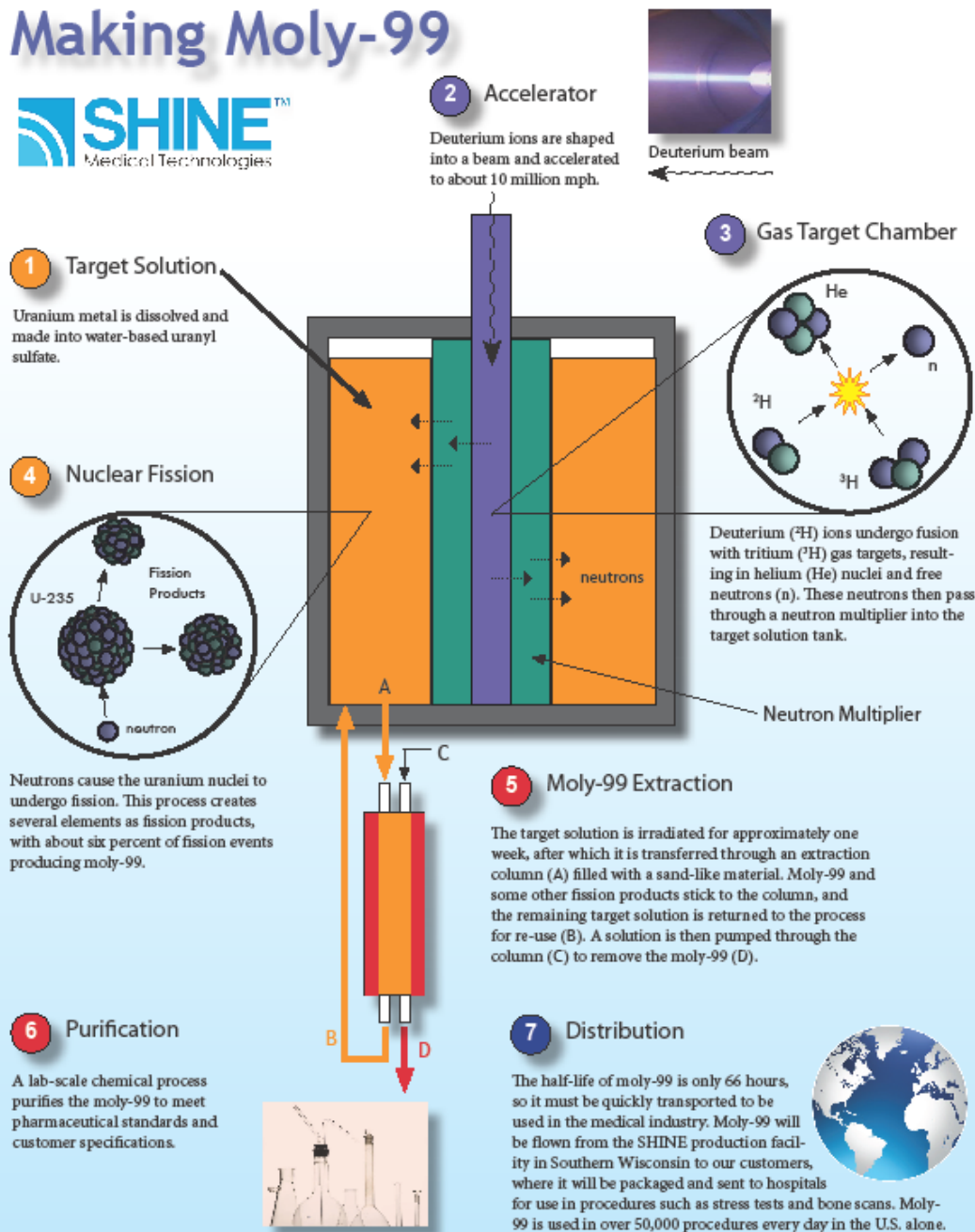
- SHINE Medical Technologies™ is dedicated to being the world leader in the safe, clean, affordable production of medical tracers and cancer treatment elements
- Highest priority is safely delivering a highly reliable, high-quality supply of the medical ingredients required by nearly 100,000 patients each day

# SHINE Snapshot

- Prototype facility located at 2555 Industrial Drive, Monona, WI
  - Includes about 7,000 sqft. office and prototype space
- 26 employees



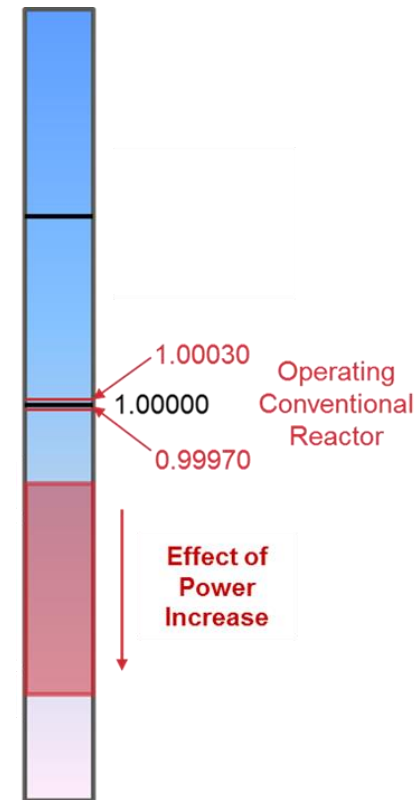
# Making Moly-99



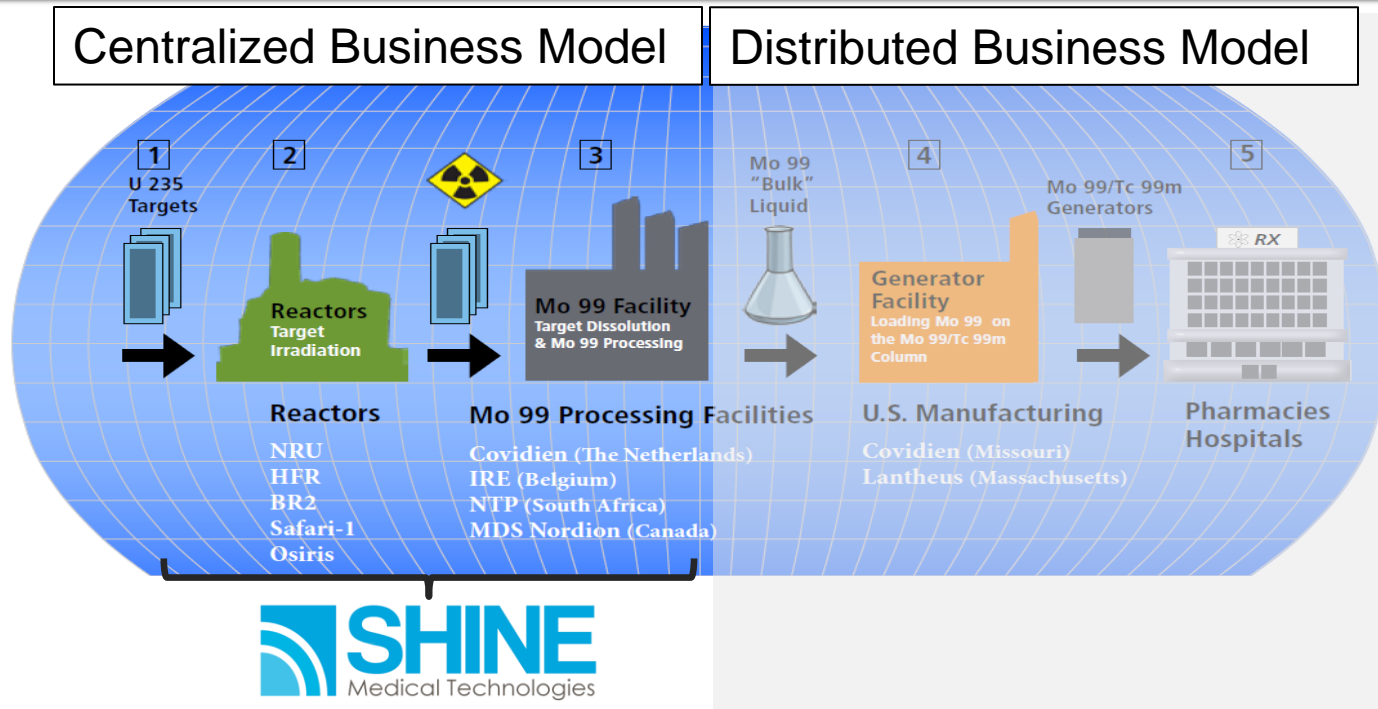
- Deuterium beam hits tritium target creating primary neutrons
- Neutrons induce fission in sub-critical uranium sulfate solution
- Simple column extraction process feeds into demonstrated purification process
- Uranium solution returned to production system after extraction for reuse

# Technology Advantages

- Technology merges positive aspects from accelerators and AHRs, eliminates negatives
- DT accelerator advantages
  - Demonstrated technology, very high yield
  - Efficient and inexpensive, not self sustaining
- Subcritical aqueous target advantages
  - High multiplication while keeping safely away from critical
  - Small, bounded power changes in response to void and temperature
  - No potential for control system “chasing” on instability
  - Easy separation, very low waste production
  - Minimal decay heat after shutdown; less than a hair dryer



# SHINE's Mo-99 Supply Chain



- SHINE produces and purifies Mo-99 equivalent to what is currently in use
- Bulk product is packaged for sale to radiopharmacies by existing distributors → no change
- Allows distribution through existing approved NDAs via sNDA process

# SHINE Has Made Strong Progress

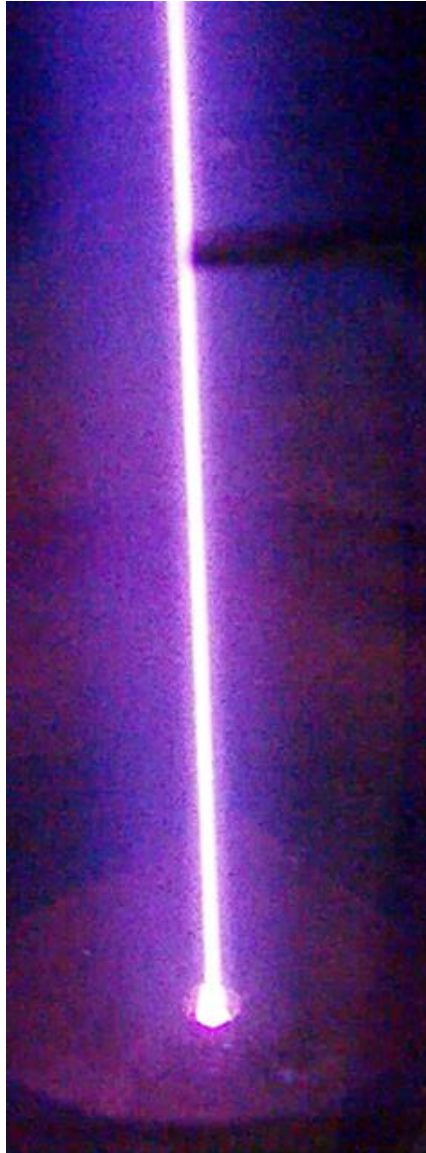
- Excellent progress on many fronts
  - Technical
  - Facility design
  - Regulatory
  - Commercial
- SHINE continues to retire most significant risks
- Current activities focused on obtaining construction permit from NRC
- Seeking balance of project financing in parallel
  - Fundraising now on critical path

# Fundamental Technical Principles Demonstrated

- Demonstration of accelerator performance at full scale
- Extensive subcritical target modeling
- Extraction of moly from SHINE target demonstrated at high efficiency
- Purification chemistry demonstrated with sulfate target
- Various other systems demonstrated
  - Off-gas system
  - Tritium purification
- Additional technical work continues to be done at Nat'l laboratories (ANL, LANL, SRNL, and ORNL)







# Exceptional Progress on Facility Design



- Conceptual design completed
- Preliminary design completed
  - Forms cornerstone of NRC preliminary safety analysis report, sets baseline for final design
- Facility size ~ 55,000 ft<sup>2</sup>
- Will house 8 production units, 3 extraction and purification hot cell trains, solution cleanup and other systems

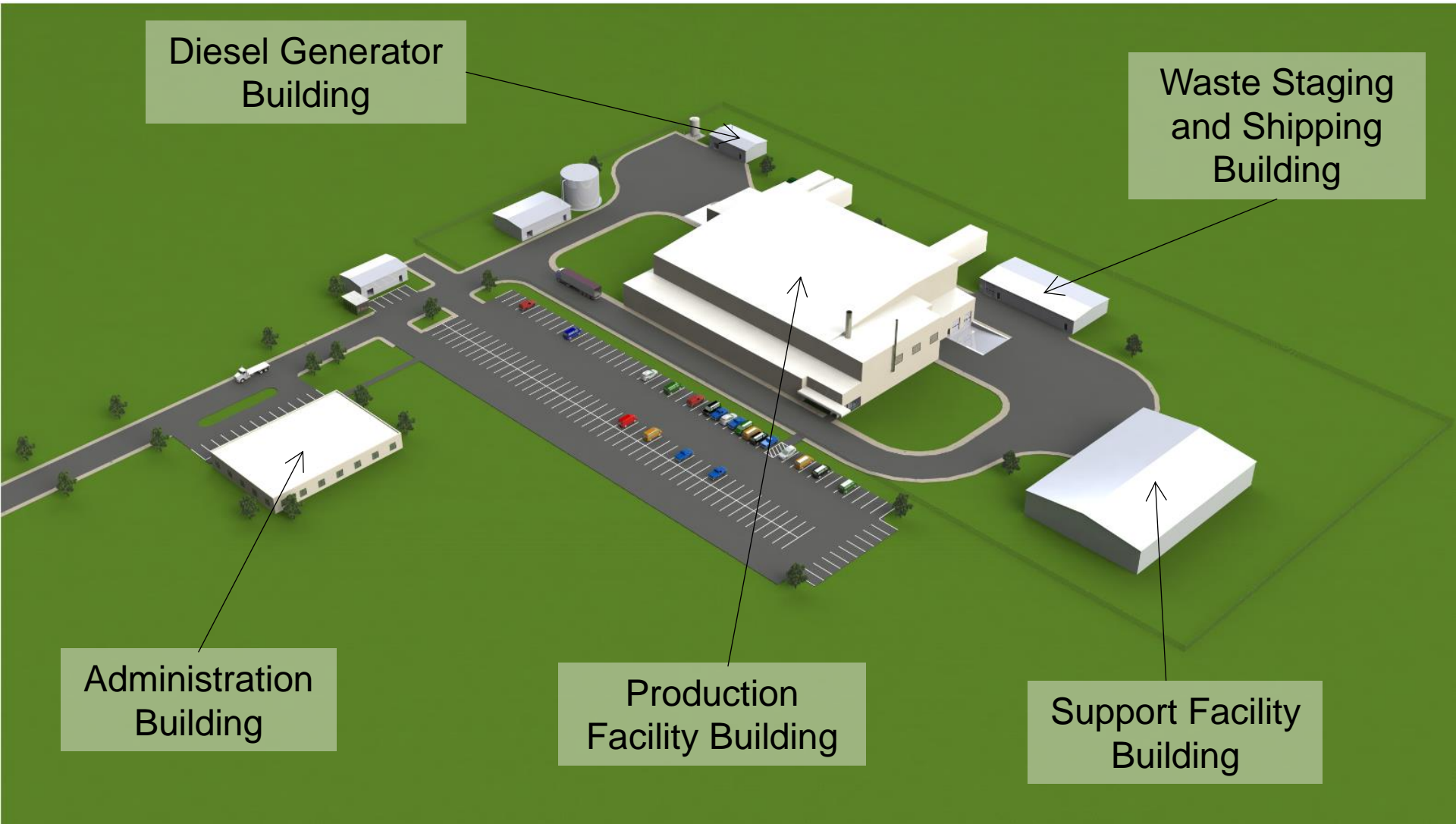
Diesel Generator Building

Waste Staging and Shipping Building

Administration Building

Production Facility Building

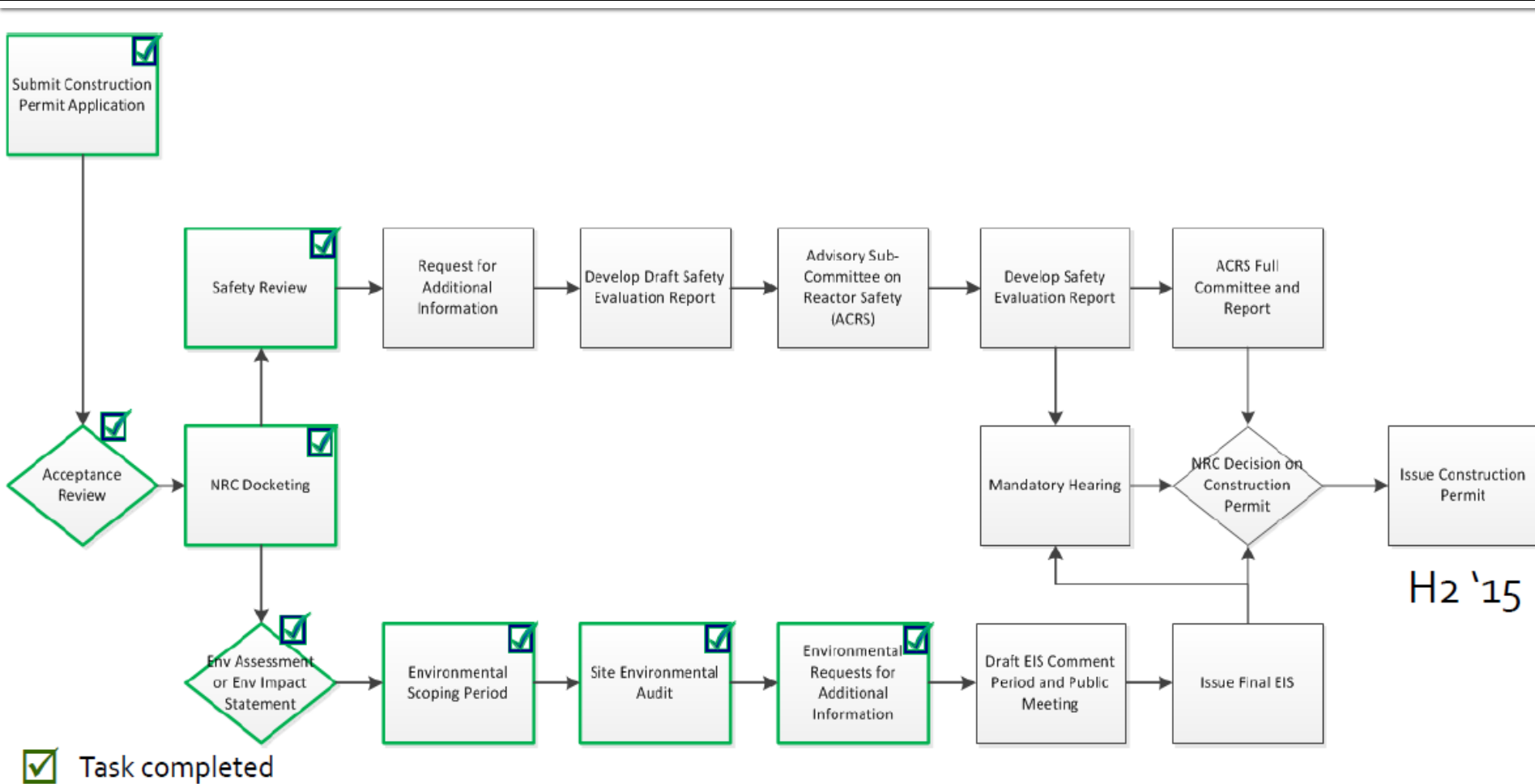
Support Facility Building



# Environmental Report and PSAR Submitted and Docketed

- First application for a fission-based U.S. medical isotope production facility in approximately 50 years
- Environmental Report
  - Submitted March 2013
  - Represents 18 months of extensive data collection and analysis
  - RAI responses and site audit completed
- Preliminary Safety Analysis Report
  - Submitted May 2013
  - Considers wide range of bounding accident scenarios
- On track for permit to build 2<sup>nd</sup> half of next year

# NRC Construction Permit Flowchart



# Substantial Strategic and Commercial Progress has Been Made

- Supply agreement with GE Healthcare signed early 2014
  - Result of years of diligence by GEHC, GE currently tracking over 15 different projects
  - First agreement with a U.S.-based producer
  - First supply agreement with a non-government producer
- MOU signed with Indonesian Mo-99 producer INUKI
  - Exploring collaboration on U.S. facility
  - Further considering expansion into Asia-Pacific markets



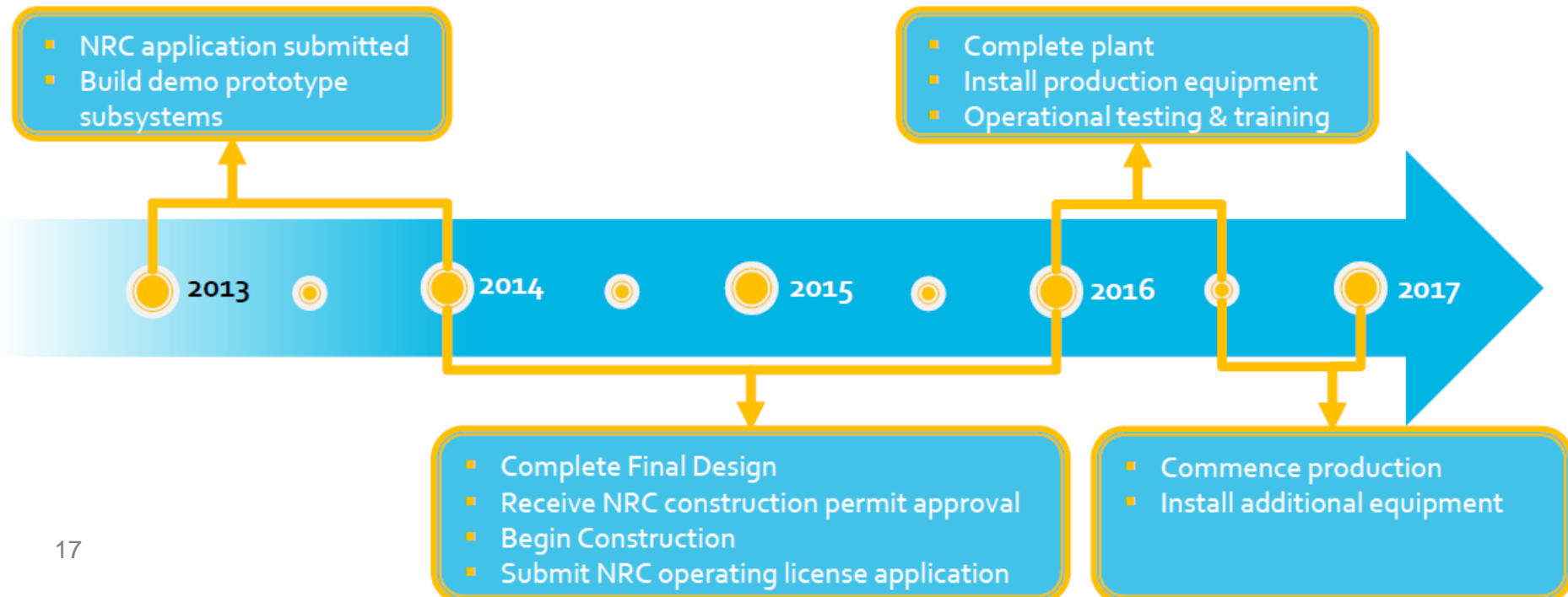
# SHINE Well-positioned to Become Major Industry Participant

- Additional supply agreements under negotiation
- SHINE has overcome many challenges new entrants have yet to face
  - Difficult fund-raising environment
  - 8 years of technology development
  - 3 years of significant investment in a production facility
- Track record of accomplishment



# SHINE Schedule: Production 2<sup>nd</sup> Half of 2017

- Resources have been wisely appropriated to risk reduction, however, not doing everything in parallel that we could be
- Estimated production date now in 2<sup>nd</sup> half of 2017, subject to funding availability



# Next Steps (2014-2015)

- Secure remaining project funding
  - Pursuing comprehensive financing structure: additional government support, commercial partnerships, financial investors
- Demonstrate accelerator reliability
- Obtain construction permit
- Complete final design
- Start construction
- Prepare Final Safety Analysis Report (FSAR) and submit operating license application

# Summary

- Excellent progress continues on many fronts:
  - Technology: major production systems demonstrated
  - Design: Preliminary design complete
  - Regulatory: Construction permit application filed and docketed
  - Commercial: GE supply agreement signed, others in progress
- Expecting commercial sales in 2<sup>nd</sup> half 2017

# Thank You! Questions?

Katrina Pitas  
SHINE Medical Technologies, Inc.

[www.SHINEmed.com](http://www.SHINEmed.com)  
Katrina.pitas@shinemed.com