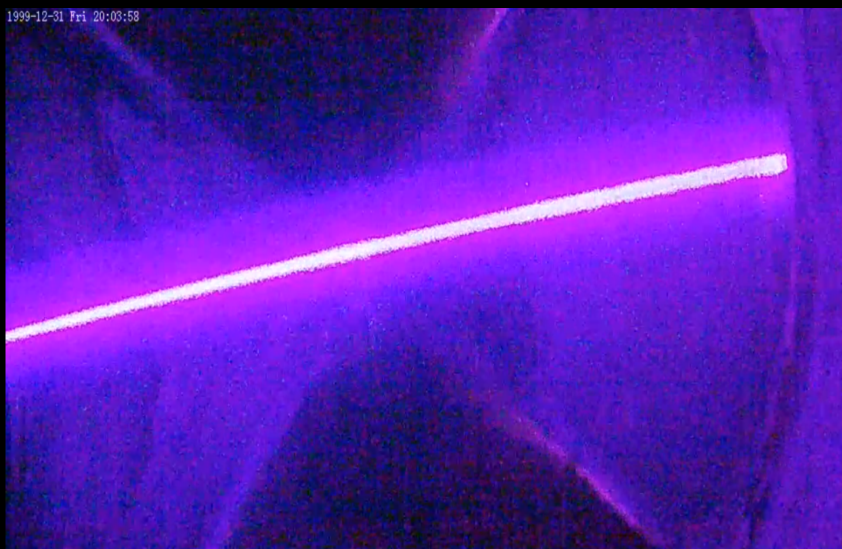
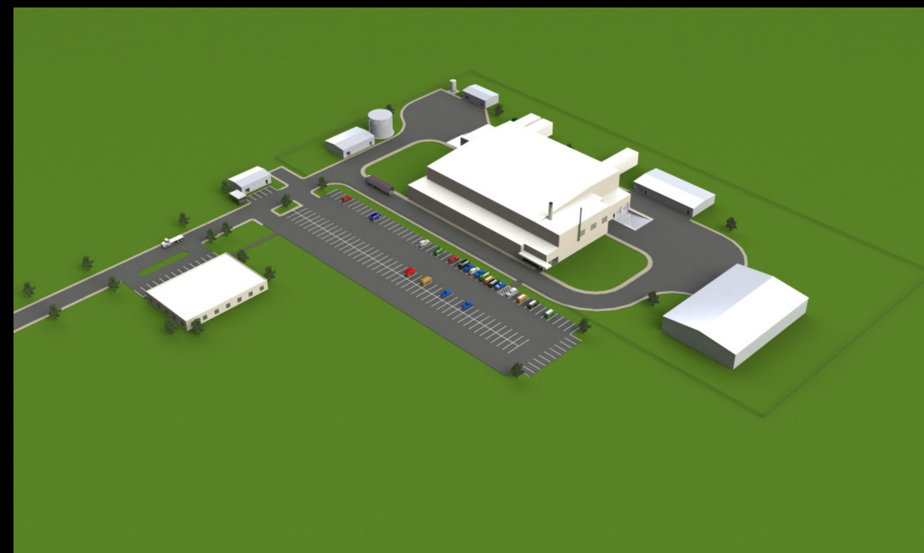
SHINE Medical Technologies





The Future of Medical Isotope Production

September 2014

SHINE Medical Technologies

Agenda

- Overview
- Market Snapshot
- SHINE’s Technology
- Development and Regulatory Plans

SHINE Overview

Corporate Overview

- Founded in 2010
- Headquartered in Monona, WI
- Manufacturer specialized in the production of the medical isotope molybdenum-99 (Mo-99)

Technology

- SHINE's Mo-99 production method:
  - Employs an accelerator as opposed to a nuclear reactor
  - Utilizes low enrichment uranium (LEU) as an alternative to highly enriched uranium (HEU)
  - Combines a series of existing technologies in a novel way

Milestones

- 2010
  - SHINE was selected as one of four Department of Energy (DoE) $25MM grant recipients to develop the capability for U.S.-based Mo-99 production that does not require the use of HEU
- 2012 and 2013
  - The NNSA committed over $16MM in direct funding to the Labs in support of SHINE's project
  - Demonstration of the particle accelerator at production power levels completed by Phoenix Nuclear Labs (PNL)
- 2014
  - GE supply agreement announced

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SHINE Snapshot

- Prototype facility located at 2555 Industrial Drive, Monona, WI
  - Includes about 7,000 sqft. office and prototype space
- 26 employees
- Operating on pre-construction funding, working through NRC approval
- Strong progress continues to position SHINE to be a major player for medical isotope production around the globe

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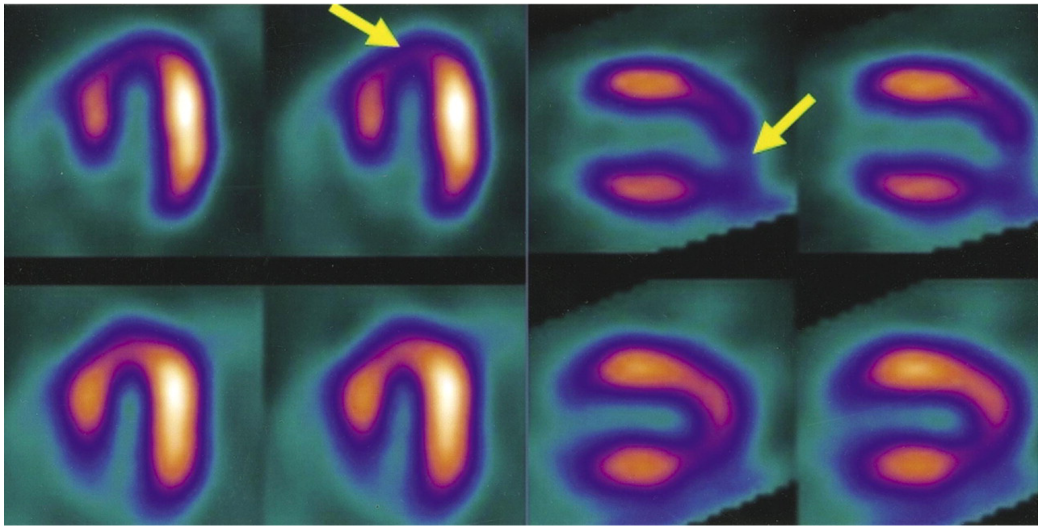
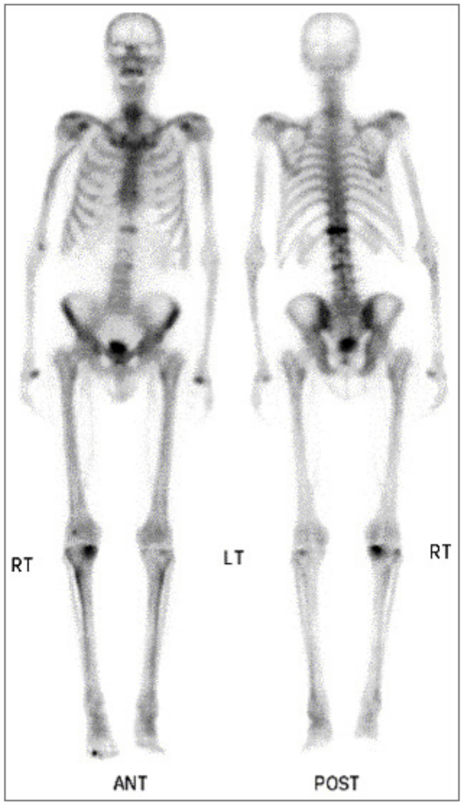
Medical Isotopes Provide Doctors Tools Needed in > 40 Million Procedures / year

- Most common use is diagnosis of heart disease and bone disorders (osteoporosis, bone cancer)



Cardiac stress test shows reduced blood flow under stress



Bone density scan

- Other uses include detection and treatment of cancer as well as many other diseases

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Supply Crisis Create Opportunity

- More than **90%** of the world's supply of Mo-99 is produced in five nuclear research reactors
- These reactors are old and have required major repairs in recent years
  - NRU Reactor (Canada)
    - Canadian government had announced the intention to discontinue production in the NRU reactor by late 2016
  - HFR Reactor (Netherlands)
    - Industry observers anticipate permanent shut down before the end of this decade
  - Safari-1 Reactor (South Africa)
    - Plant shut until an independent review conducted by the National Nuclear Regulator has been completed
- 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
  - The supply chain continues to be challenged from these closures unless a stable, cost-effective supply source can be developed

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%

Source: Management estimates

NRU Reactor in Canada is scheduled to be shut down in 2016

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Market Snapshot

- 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
- **Volume Trends**
  - International markets are growing, especially India and China

Federal Government Understands Problem

The majority of today's Mo-99 production uses HEU in the production process—the same material used to produce nuclear weapons

Each year, the United States exports HEU to Canada and Europe to ensure a stable supply of Mo-99

The U.S. government plans to discontinue that practice due to the potential diversion of that HEU for use in nuclear weapons, but cannot do so until a non-HEU supply for Mo-99 can be assured

Various federal agencies are actively backing the development US-based Mo-99 production that does not require HEU

Department of Energy

SHINE received one out of four $25 million cooperative agreements to develop the capability for U.S.-based Mo-99 production that does not require the use of HEU

United States Congress

- Late 2012, the Congress passes the American Medical Isotope Production Act
- Created a legal imperative for federal assistance to the domestic production of Mo-99 from non-HEU sources
- **SHINE** was actively involved in advocating for its position in the Act

President's Office of Science and Technology

- Holds several meetings each year to follow progress of new domestic producers and transition to LEU
- Requested key regulatory agencies to expedite their review and licensing processes in support of these new entrants, including **SHINE**

Centers for Medicare and Medicaid Services

- Agreed to pay an extra $10 per dose for Mo-99 that is not produced from HEU
- Could nearly double present reimbursement levels if passed on to producers

Making Moly-99

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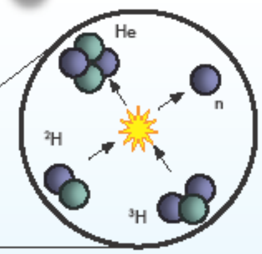
2 Accelerator

Deuterium ions are shaped into a beam and accelerated to about 10 million mph.

Deuterium beam

3 Gas Target Chamber

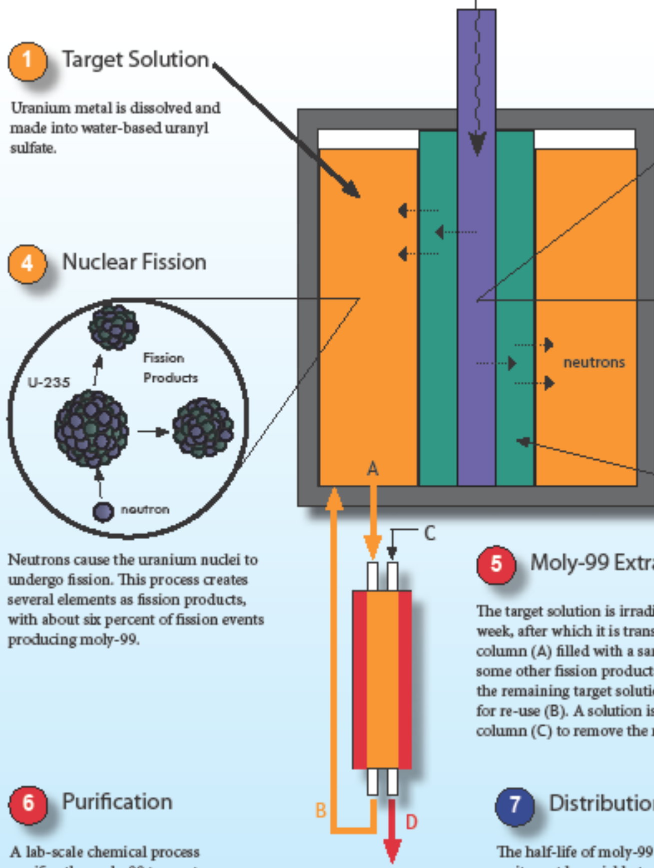


Deuterium (^{2}H) ions undergo fusion with tritium (^{3}H) gas targets, resulting in helium (He) nuclei and free neutrons (n). These neutrons then pass through a neutron multiplier into the target solution tank.

1 Target Solution

Uranium metal is dissolved and made into water-based uranyl sulfate.

4 Nuclear Fission



Neutron Multiplier

Neutrons cause the uranium nuclei to undergo fission. This process creates several elements as fission products, with about six percent of fission events producing moly-99.

5 Moly-99 Extraction

The target solution is irradiated for approximately one week, after which it is transferred through an extraction column (A) filled with a sand-like material. Moly-99 and some other fission products stick to the column, and the remaining target solution is returned to the process for re-use (B). A solution is then pumped through the column (C) to remove the moly-99 (D).

6 Purification

A lab-scale chemical process purifies the moly-99 to meet pharmaceutical standards and customer specifications.

7 Distribution

The half-life of moly-99 is only 66 hours, so it must be quickly transported to be used in the medical industry. Moly-99 will be flown from the SHINE production facility in Southern Wisconsin to our customers, where it will be packaged and sent to hospitals for use in procedures such as stress tests and bone scans. Moly-99 is used in over 50,000 procedures every day in the U.S. alone.

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SHINE Has Made Strong Progress

- Company continues to move forward, retiring most significant risks while seeking construction financing
- Very good progress on many fronts
  - Technical
  - Regulatory
  - Commercial

SHINE Production System

Excellent Technical Progress Demonstrated

- Major technical milestones already accomplished
  - Demonstration of accelerator performance (full power, 24 hour run)
  - Chemistry demonstrated compatible with existing supply chain
  - Many other subsystem technical demonstrations complete
- Technical work continues to be done n collaboration with Nat'l laboratories (ANL, LANL, SRNL, and ORNL)
  - ANL: Uranium solution irradiation and characterization / test batches
  - LANL: Nuclear systems modelling, chemistry support
  - ORNL: Corrosion studies
  - SRNL: Tritium systems

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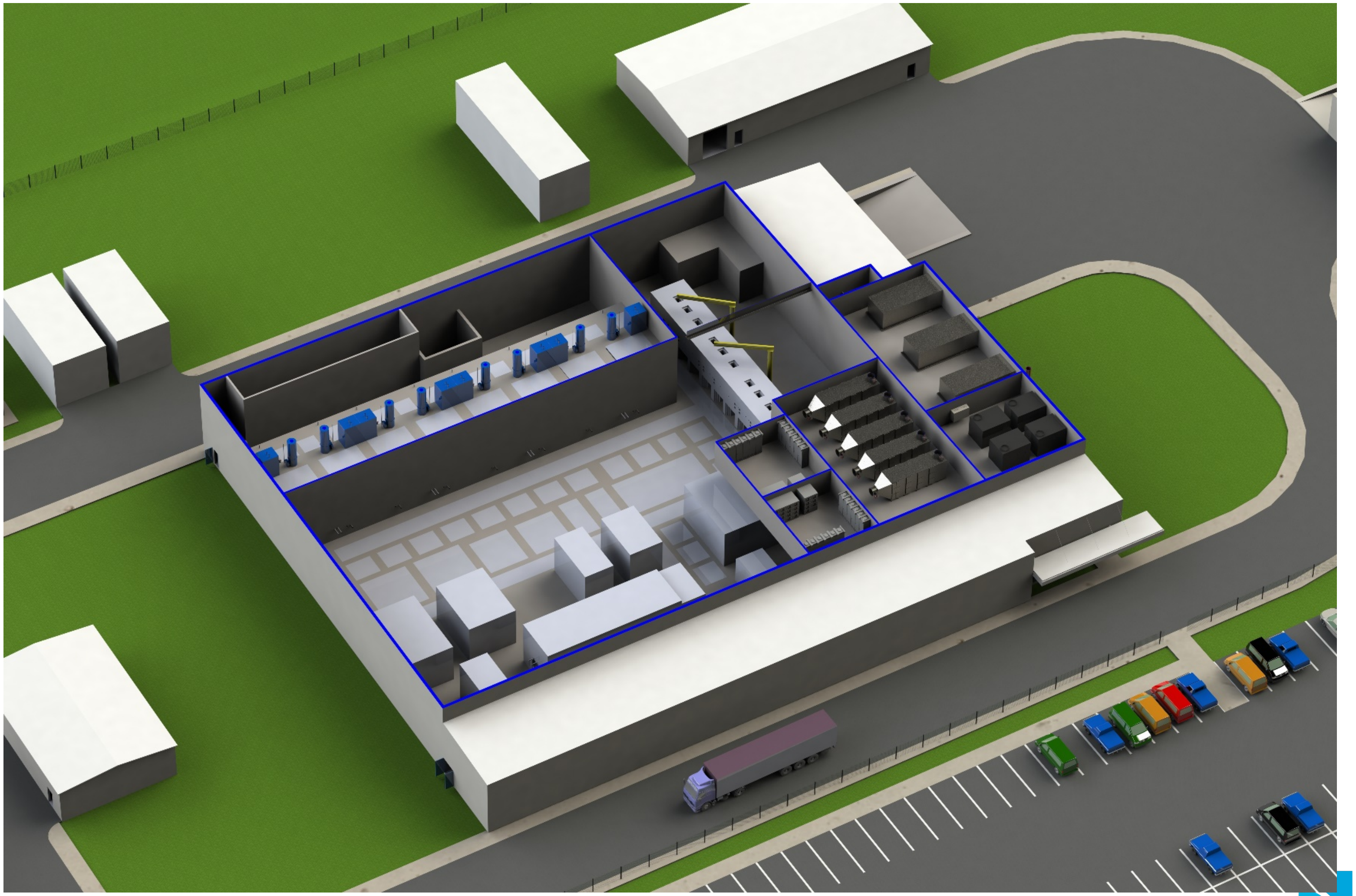
Production System Specifications

- Accelerator
  - 300 keV, 50 mA deuteron beam
  - 10 torr tritium target
  - $5*10^{13}$ n/s
  - >95% uptime
- Target performance
  - Multiplying configuration
  - 100 kW equivalent thermal power
  - 500 6-day Ci ^{99}Mo per week / device
  - I-131, Xe-133, > 1000 Ci / wk

Simplified Facility Design



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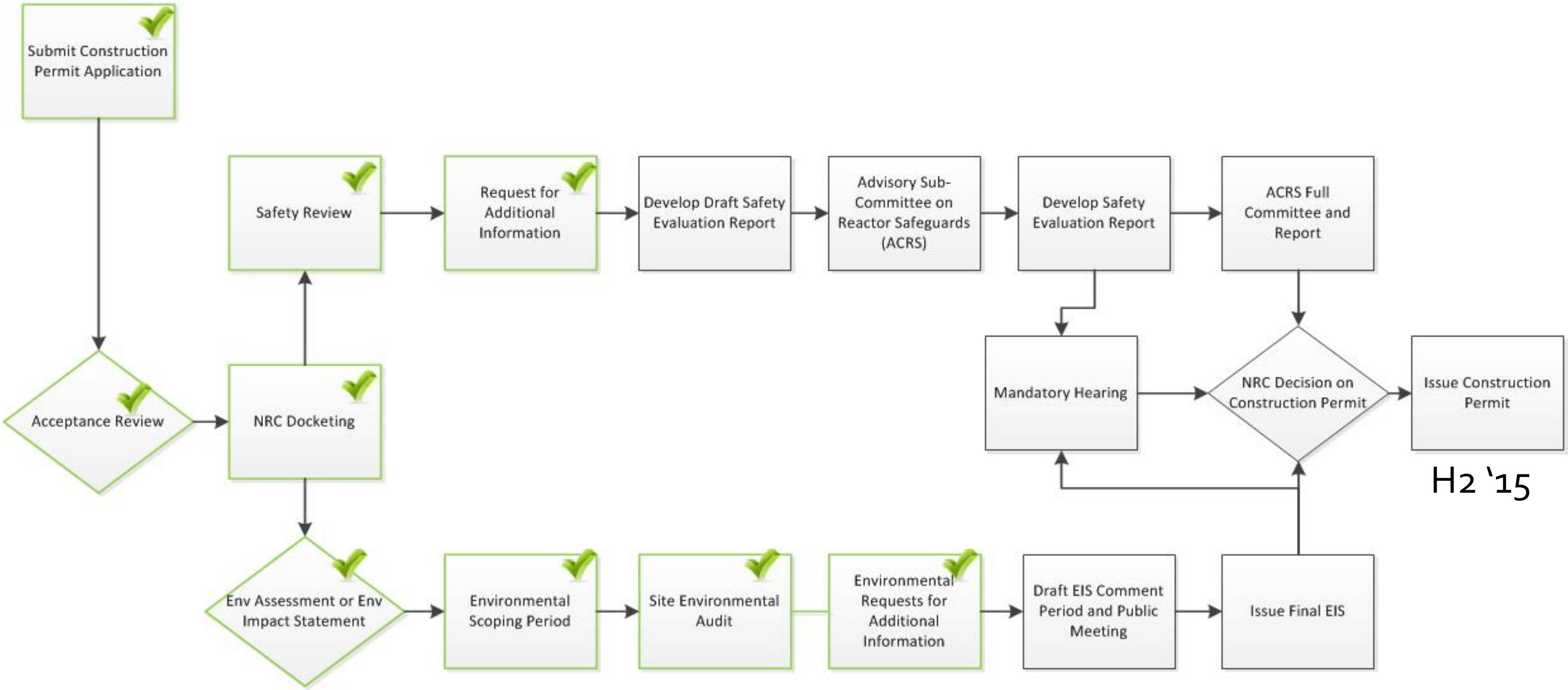
NRC has a well documented, structured path for permit to construct



SHINE staff communicate directly with the NRC Program Manager several times a week.

Recent Statement from Commissioner Magwood (NRC)

While I approve the staff's recommendation in this unique circumstance, I am troubled by the need to reference a specific docket number in any rule. Rulemakings should be structured to provide generic applicability; another facility applying a technically similar approach would require yet another change in the rule to be considered under 10 CFR Part 50. I would prefer for staff to analyze the effect of its proposed rules carefully and craft them to be both generic and evasive of unintended consequences.

That said, sending this proposal back to the staff for further work would take considerable time. I support the present request only out of fairness to applicant, which has submitted its application in good faith and deserves a timely response from the agency, and the important national need to pursue methods of molybdenum-99 production.

William D. Magwood, IV 8/19/14
Date

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Regulatory Risk

- Regulatory Summary: Primary regulatory responsibility lies with the NRC

- Mitigation actions completed:
  - Major commission decision two weeks ago supporting SHINE proposed regulatory path
  - Early and frequent interaction with NRC resulted in guidance documents including recommendations on SHINE specific process

- Remaining risk is related to timing of approvals
  - It is possible that approval could be delayed for unforeseen reasons
  - Not binary, but could affect time to market (up to 6 months)

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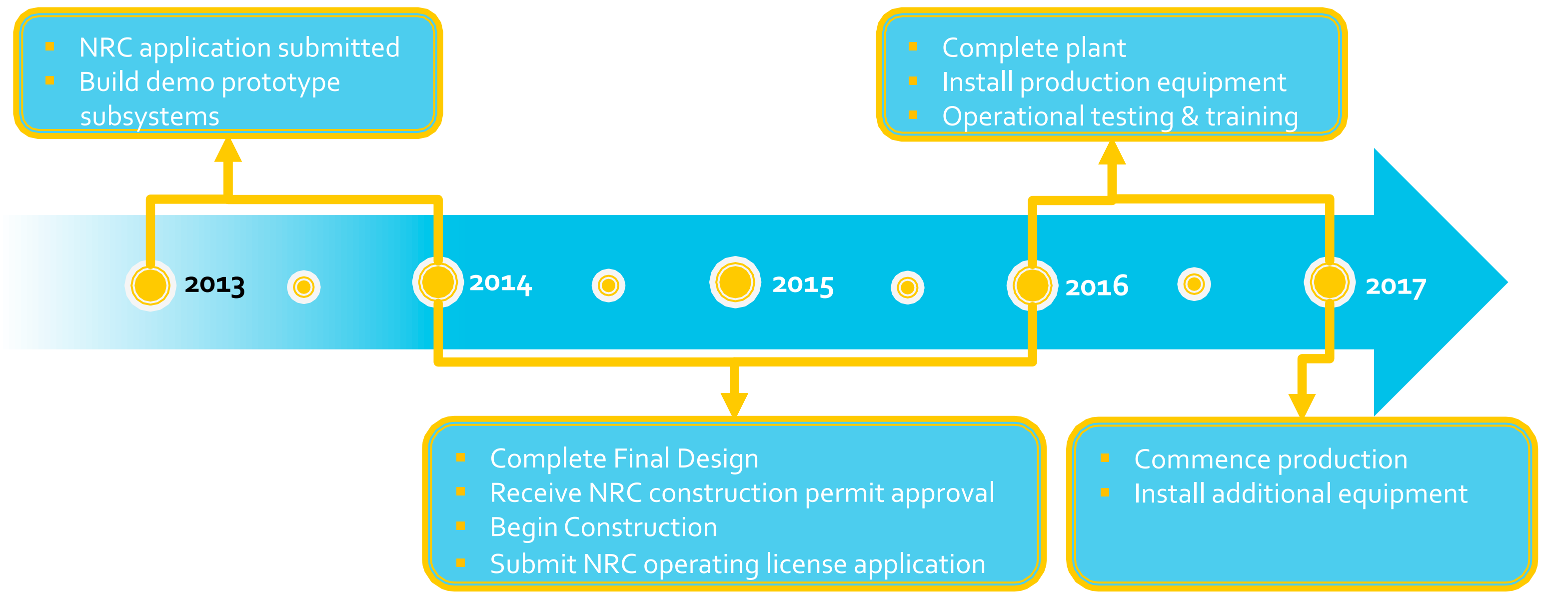
Development Timeline

- **Permit to construct** production facility expected in the second half of 2015
- **License to operate** the facility in early 2017 (subject to funding)
- Commercial sales of Mo-99 and other isotopes is expected to begin in 2018 (subject to funding)



Strategic and Commercial Progress

- Supply agreement with GE Healthcare in early 2014
  - Result of years of diligence by GEHC
  - First supply agreement signed by any U.S.-based producer
- Second U.S. supply agreement imminent
- International markets being pursued
  - MOU with Indonesians to explore U.S. collaboration followed by future Asia-Pacific expansion
  - Multiple active discussions with radioisotope distributors outside the U.S.

Bottom Line: SHINE Story is More Compelling than Ever

- Legacy of reactor problems continues – simultaneous shutdowns of Netherlands reactor and processor, and South African producer in early 2014
- SHINE has a track record of success
  - $40 M invested so far
  - 4 years of system engineering, facility design and license work
  - Technology and regulatory pieces on track for commercial operations in 2018