Intro to SHINE and Experiences Creating a Nuclear Startup

Health. Illuminated.™

About the Speaker

- Wisconsin native
  - University of Wisconsin—Madison education
  - PhD Nuclear Engineering, BS Physics, BS Electrical Engineering and Computer Engineering
- Private sector experience
  - 14 years experience as an executive at technology companies
  - Cofounded Gillware Data Recovery (2004), three years as CTO—now a global leader
  - Founded Phoenix Nuclear Labs (2006), 5 years as President—now on rapid growth trajectory
  - Founded SHINE Medical Technologies (2010), CEO since inception
- Personal Mission: Commercialize peaceful nuclear technology, with and end vision for clean, abundant energy

The **Plan**

4 Clean Energy Generation

Producing cleaner, cheaper, more abundant energy while ensuring energy security and protecting the air & climate

3 Large-Scale Transmutations

Recycling, mitigation of nuclear waste, space reactors & propulsion, nuclear batteries

2 Small-Scale Transmutations

Converting one chemical element into another, most notably the production of medical isotopes

1 Non-Destructive Testing

Ensuring the safety and quality of lightweight aerospace, defense & civilian components

The Approach

Each element needed in a factor of 10 to 100 more at each step

1. Continue to build a team capable of addressing increasingly difficult challenges
2. At every step, develop nuclear technology that is an economic engine for future company growth
3. Create new technologies that fulfill our vision and promote human, environmental and economic health
4. Provide maximum social value by helping people while building a world-class business

Step 2: SHINE Medical Technologies

- Dedicated to becoming the World leader in the production of medical isotopes
- Located in Janesville, WI
  - Headquarters located in downtown Janesville—currently employ ~80 people FT
  - Building One—Advanced prototyping / technology development center complete, construction on production facility to start this year
  - Mo-99 commercial production facility will be online in 2020
- Current focus is delivery of a hybrid fusion-fission medical isotope business
  - Technical approach uses a DT fusion neutron source driving a highly multiplying but subcritical aqueous uranyl sulfate target
  - Now focused on delivery after demonstrating key aspects of technology, regulatory approvals, and customer validation
  - ~$100 M in development so far, with capital commitments of over $300 M

Introduction to Medical Isotopes

- Medical isotopes are radioactive materials that allow physicians to quickly and accurately diagnose or treat patient illnesses
  - Bond to chemical compounds that seek out disease in the body
    - Can target specific areas of the human body
  - Administered by injection, inhalation or orally
- Broad scope of applications:
  - Heart
  - Bones
  - Thyroid
  - Liver
  - Multiple other parts of the body

- Short half-life allows scanning procedures to collect data rapidly while keeping total patient radiation exposure low
- Molybdenum-99 (Mo-99) is the most commonly used medical isotope in nuclear medicine

50+ million

Global procedures requiring medical isotopes

25+ million

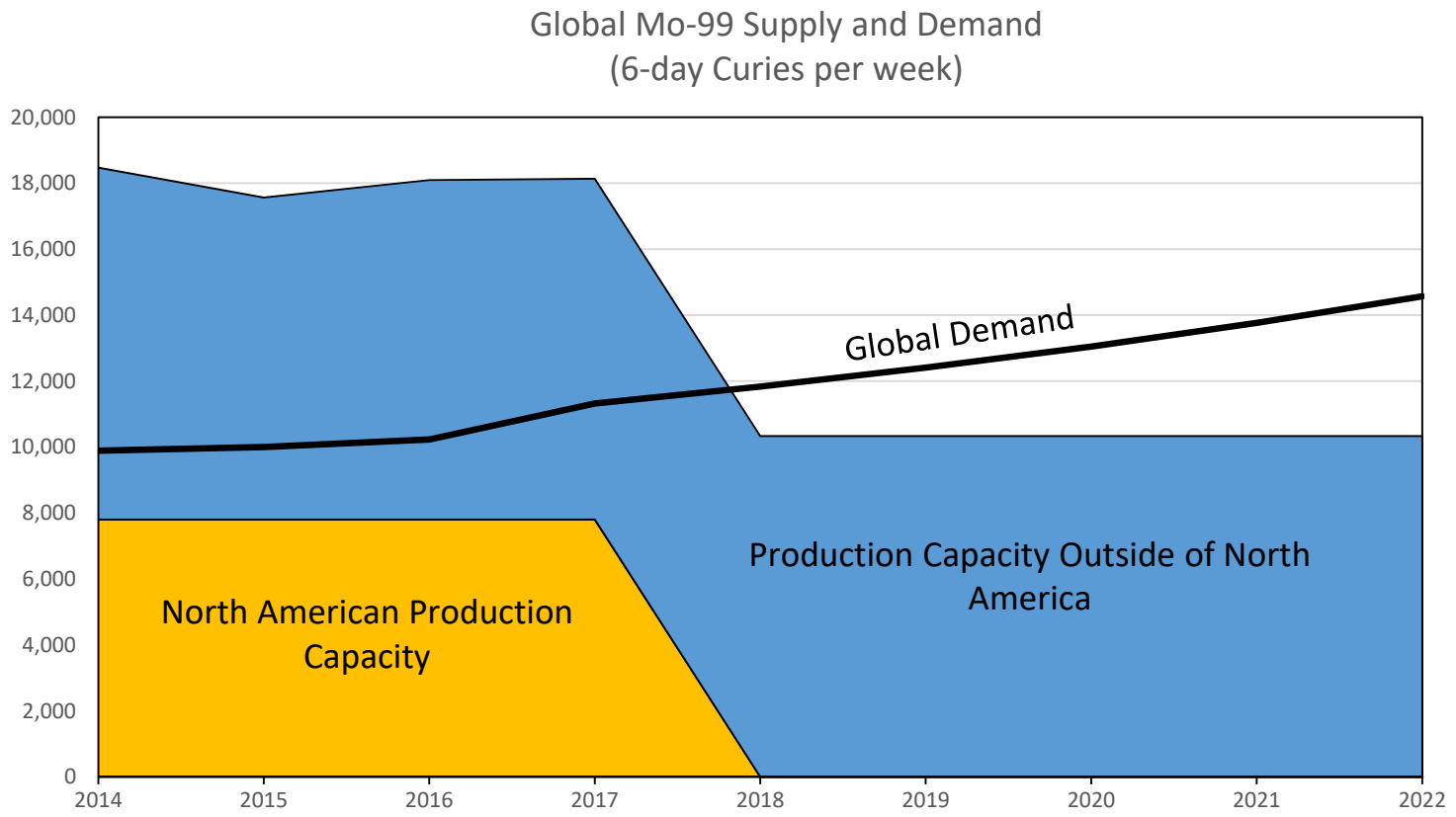
Procedures requiring medical isotopes in the U.S. alone

40+ million

Global procedures requiring Mo-99

Source: Management
Note: Number of procedures statistics provided on an annual basis

National Academy of Sciences Predicts Shortages



"The committee judges that there is a substantial (>50 percent) likelihood of severe molybdenum-99/technetium-99m supply shortages after October 2016…"

—National Academy of Sciences Report "Molybdenum-99 for Medical Imaging" (2016)

Making Moly-99

SHINE™ Medical Technologies

2 Accelerator

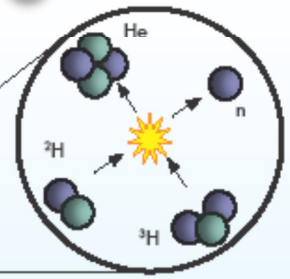
Deuterium ions are shaped into a beam and accelerated to about 10 million mph.

Deuterium beam

1 Target Solution

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

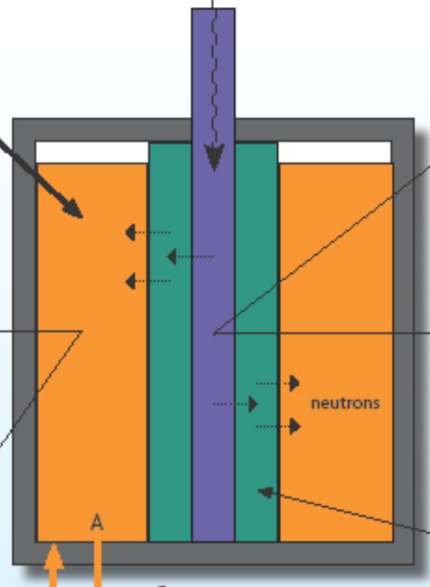
3 Gas Target Chamber



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.

4 Nuclear Fission

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).

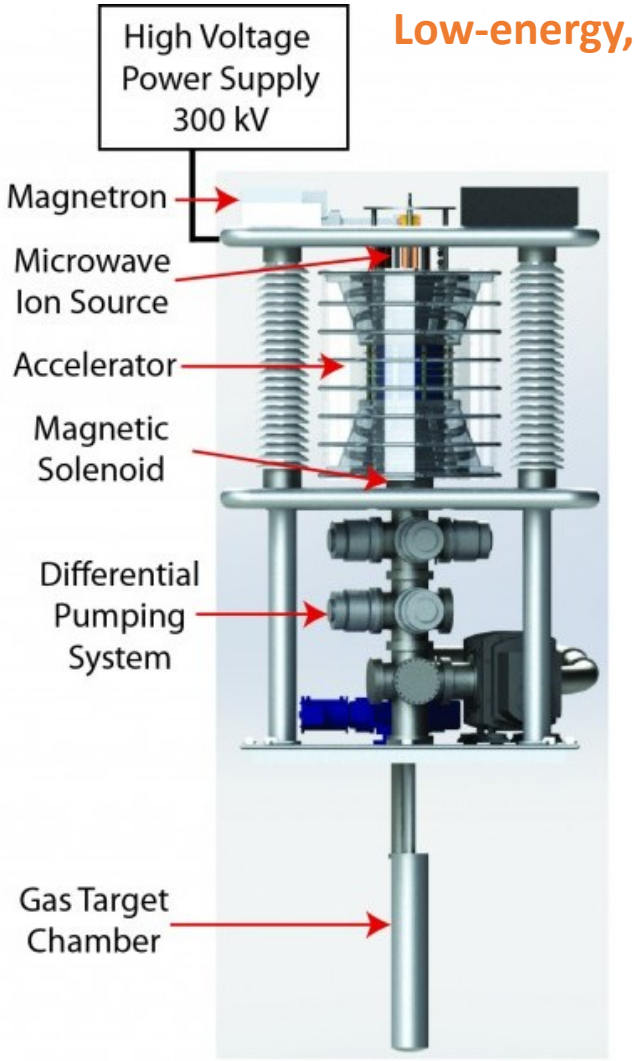
6 Purification

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.

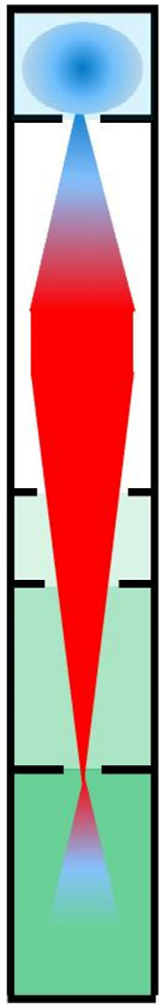
Neutron Generator



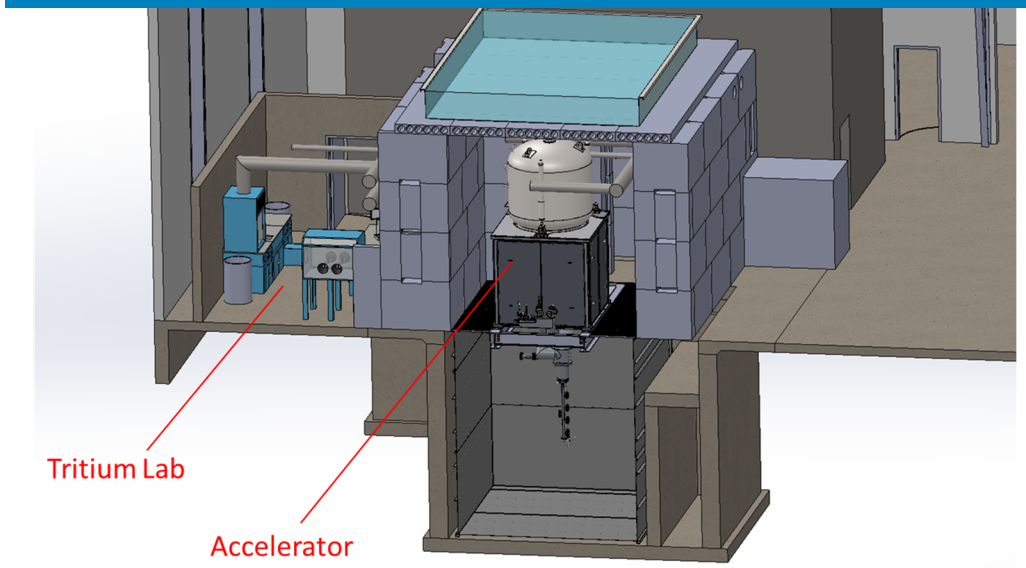
Low-energy, accelerator-based neutron generator drives fission

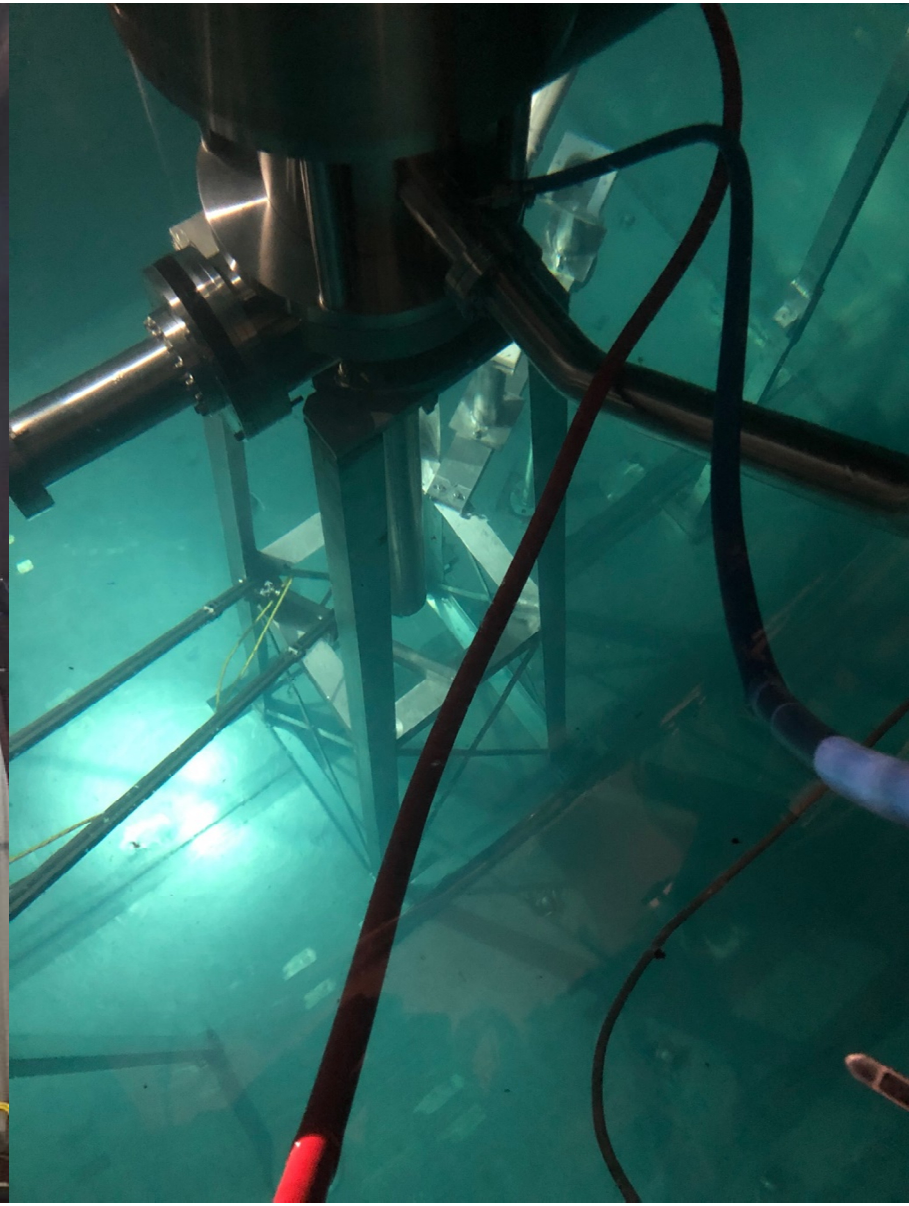
- Microwave ion source creates dense deuterium plasma
- Simple DC accelerator extracts deuterium ion beam (~300 keV, ~60 mA)
- Magnetic field focuses ion beam
- Differential pumping system keeps gas out of accelerator
- Beam strikes tritium gas target and generates neutrons
- 5 x 10^{13} neutrons/second total neutron output

Beam Profile



Full-Scale Accelerator System Demonstration





Starting a Company: The Beginning

- Legal mechanics of starting a company are easy, actually building a successful company is difficult, particularly in nuclear
- Companies should provide clear value proposition
  - What need is the product or service of the company addressing
  - What value does the business provide to the customer or stakeholder?
- Often entrepreneurs develop a “cool” technology for a specific purpose, then try to leverage it into a business
  - Need a clear vision / plan for how the business will grow, become “profitable” and achieve a significant impact on the market
  - Does the advantage you bring allow you to “disrupt” the current paradigm?
  - Without this, it may be better to sell / license technology
- Planning should focus on path to dominance of a market segment—game theory and customer conversations are more important than technology when considering starting a company

For the Entrepreneur

- With successful scrutiny of business idea, the entrepreneur should assess their risk-reward tolerance before getting started
- Essential to recognize that starting a business, even with a great plan is fraught with challenges that can take down the enterprise
  - Technology commercialization almost always costs far more and takes far longer than expected
  - Changing competitive landscape
  - Changing market conditions
  - Changes in demand (nuclear has been especially susceptible)
  - Challenging / changing regulatory landscape
- Entrepreneurs should expect to run on very low funding, face significant uncertainty around compensation, need to go to great lengths to be lean
  - Family situation, financial status, etc. should all be considered when starting a company
  - The upside often looks good, but most ventures fail—must be ready and willing to accept this trade-off

Fundraising 101

- It's likely you'll need outside capital to continue to grow your business; in exchange for this you'll need to sell part of your company
- Several important considerations when doing this:
  - Finding the right financial partner—this can be very important depending on the nature of your needs and risks. If long term support needed, passion for the business in the investor is highly valued
  - Structure of the deal—what are the hooks and control provisions
  - Valuation—what your company is worth
- Raising sufficient capital
  - Raising insufficient capital is one of the biggest mistakes entrepreneurs make
  - Raise money when things are going well even if you don't need it!

Building the Company

- Recognize that a good company is not just:
  - A technology
  - A product or service
  - A vision, idea, or plan
- A good company is a collection of essential ingredients covering all important facets required for mastery of a business, including
  - Technology, products, services
  - Sales channels and agreements
  - Brand and external relationships
  - Assets (IP, facilities, equipment, inventory)
  - The company's team, culture, and chemistry
  - Growth plans and vision
- Focusing too much on any one of these while neglecting the others will cause the company to fail! You must develop them all

Building the Company (continued)

- Culture of the company is essential, and is driven from top leadership
  - Often the leader is a founder in an early stage company—this is good if the leader is willing and able to adopt the broad principles needed to grow the company
  - If the founder prefers to focus on a single aspect (ie. technology), another leader should be sought
- In startups, a lean, innovative and problem solving culture is essential
  - Do inexpensive things that can develop or derisk the business plan as fast as possible
  - Always consider whether or not things “make sense”. Keep perspective. Challenge those (especially outsiders) who tell you things must be done a certain way if it seems illogical—especially important in nuclear!
- Hire good people, and fire people quickly when you know you’ve made mistakes

When Things go Wrong

- Things will go wrong, and this will hurt the business
  - Damage can be mitigated by techniques already discussed
  - The right financial partners can also help minimize the impact of this
- If the business is still viable, anchor yourself in that and what you've been able to accomplish thus far.
- Create a strategy to move forward. This may not be what you planned, but can still cause a very positive outcome
- Be transparent and sincere with your team and partners who may have been hurt by the setback. If you can outline your strategy, the risks and the benefits of your plan versus simple failure, they are likely to support you

Specific Challenges in the Nuclear Space

- Funding companies in nuclear is especially challenging, despite the clear need for innovation
  - Few investors have a mandate to invest—creates personal risk for fund managers
  - Limited pool of investors with expert networks who can understand the risks associated with nuclear
  - Regulatory environment is complex, expensive and slow, which decreases a key investor metric: IRR (internal rate of return)
  - Historical experience with nuclear projects suggest high probability of cost-overruns or outright failure
  - Thus, investors must be convinced of very high upside to help offset these risks
  - FOCUS on developing the minimum viable product and building credibility. We need to show investors that we are changing the game not just from a technology standpoint, but that we can create returns in the space

Specific Challenges in the Nuclear Space (continued)

- Most companies in the nuclear space will require extensive use of subcontractors to meet regulatory, design, and testing requirements
- The culture of the industry has been compromised by decades of cost-plus contracts
  - Cost overruns are ultimately passed on to taxpayers or ratepayers resulting in upside for contractors!
  - Incentives for high overhead, multiple layers of management, slow performance, and mistakes—these things are antimatter to a startup company!
- Remedies aren't always great and take time
  - Hire people internally as often as possible when there is a significant role. Our experience is that our internal staff are 3-5x more efficient in terms of work done per dollar
  - When you must use contractors, avoid cost plus contracts wherever possible—encourage contractors to share in upside and/or create penalties for downside. They will resist, but look around and try to find good contractors who are hungry

Specific Challenges in the Nuclear Space (continued)

- The regulatory environment is complex and expensive
  - Establish an early relationship with regulators who may impact your business
  - In particular, we have found the NRC to be forthcoming when we talk to them about our plans early
  - This helps establish a common understanding on cost and schedule impacts of the regulatory process
  - Important to recognize the NRC's purpose is to ensure safety of workers, the public, and the environment—this is in synergy with the needs of your business. Establishing this understanding early with the regulator will develop trust
- Quality can drive cost excessively, especially when applied excessively
  - Ensure that you are not adopting quality standards that are defined for a different kind of hazard / threat (we run into this a lot)
  - The goal of quality is to ensure safety and operability of an operation. If requirements are being pushed that are not needed to ensure these things, they are likely excessive. This can drive cost and cause a business to lose viability

So Nuclear is Hard—Should I Give Up?

- The good news is that if you can find patient investors, nuclear investments can reap tremendous long term rewards
- Social and environmental impacts are tremendous
- Successful startup ventures involving nuclear innovation will have:
  - Extremely high barriers to entry—it will be very difficult for competition to do what you have done and will take time
  - Greatly advantaged cost-structures—the inefficiency that has developed in the industry will struggle to keep up with new ventures as they've been culturally compromised. This can take a long time to change
  - Strong, innovative teams that can overcome difficult challenges together that will fuel future growth
  - A high sense of accomplishment and satisfaction for achieving difficult and important objectives, and a chance to build a new nuclear industry that can thrive in the modern era
- Stick with it if you have a good plan!