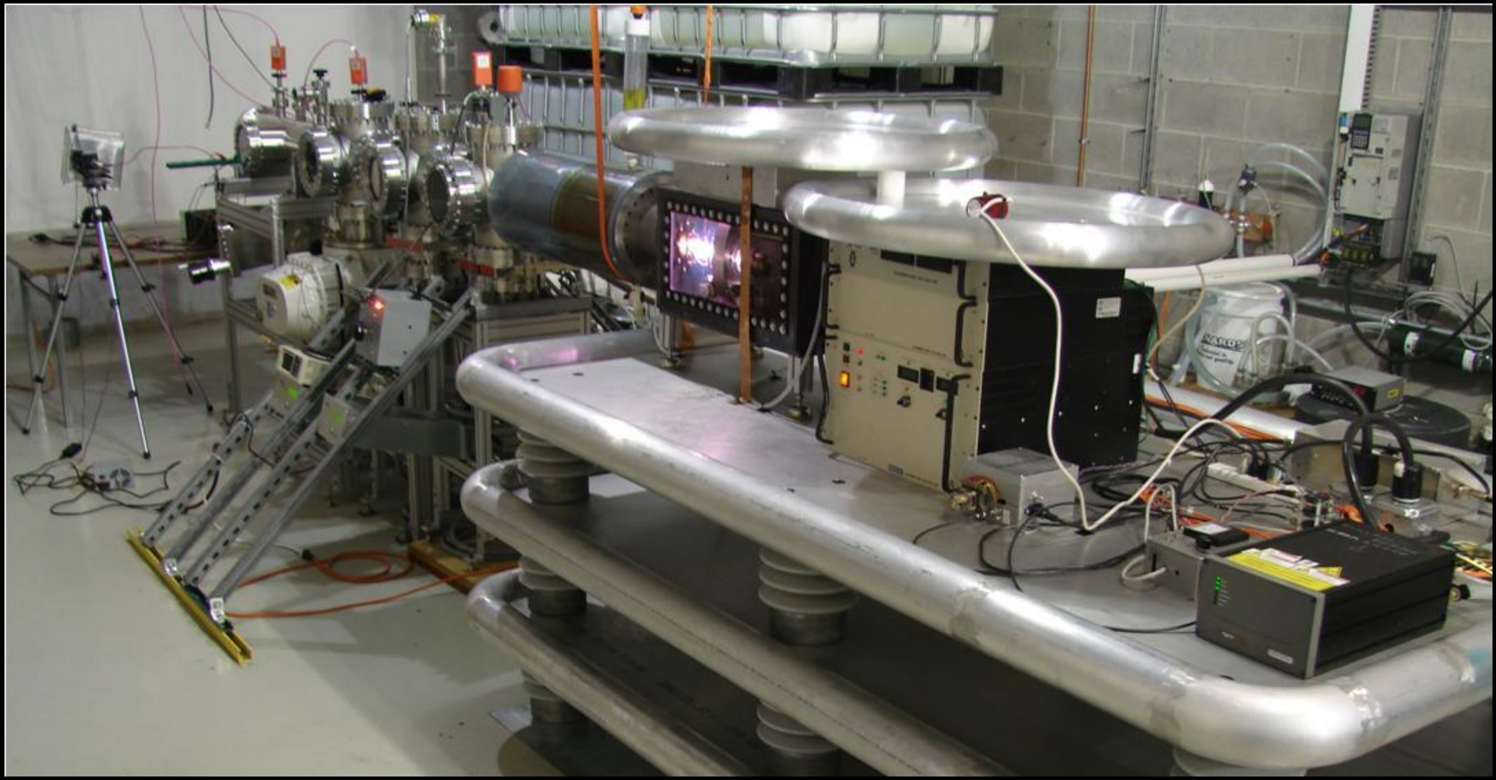
SHINE Medical Technologies



Technology Introduction

NRC Kickoff Meeting

March 7, 2011

SHINE Medical Technologies

Introductions

- Dr. Richard Vann Bynum – SHINE Medical Technologies
- Ms. Katrina Pitas – SHINE Medical Technologies
- Dr. Ross Radel – Phoenix Nuclear Labs
- Dr. Thad Heltemes – Morgridge Institute for Research
- Mr. Jim Freels – EXCEL Services Corporation

Introduction to SHINE Medical Technologies
Health. Illuminated.

- SHINE Medical Technologies™ is dedicated to being the world leader in 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
- Products fit seamlessly into the existing medical tracer supply chains, but does not rely on a nuclear reactor.

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SHINE Medical Technology's Key Collaboration Partners

- Phoenix Nuclear Labs
- Morgridge Institute for Research
- National Nuclear Security Administration
- Wisconsin Alumni Research Foundation
- Los Alamos National Lab
- TechSource
- University of Wisconsin
- EXCEL Services Corporation
- Lawrence Berkeley National Lab
- Argonne National Lab
- State of Wisconsin

SHINE Medical Technologies

Overview

- SHINE Medical Technologies, and its partners, are developing a system that can produce reactor grade medical isotopes without a nuclear reactor
- System is capable of ending the cycle of medical isotope shortages quickly and relatively inexpensively
- Technology has two key aspects
  - Primary neutrons created by high output D-T source
  - Neutrons enter an LEU solution where they multiply sub-critically and create medical isotopes
- Initial construction will produce nationally relevant quantities of ^{99}Mo and other medical isotopes (50% of U.S. ^{99}Mo demand)

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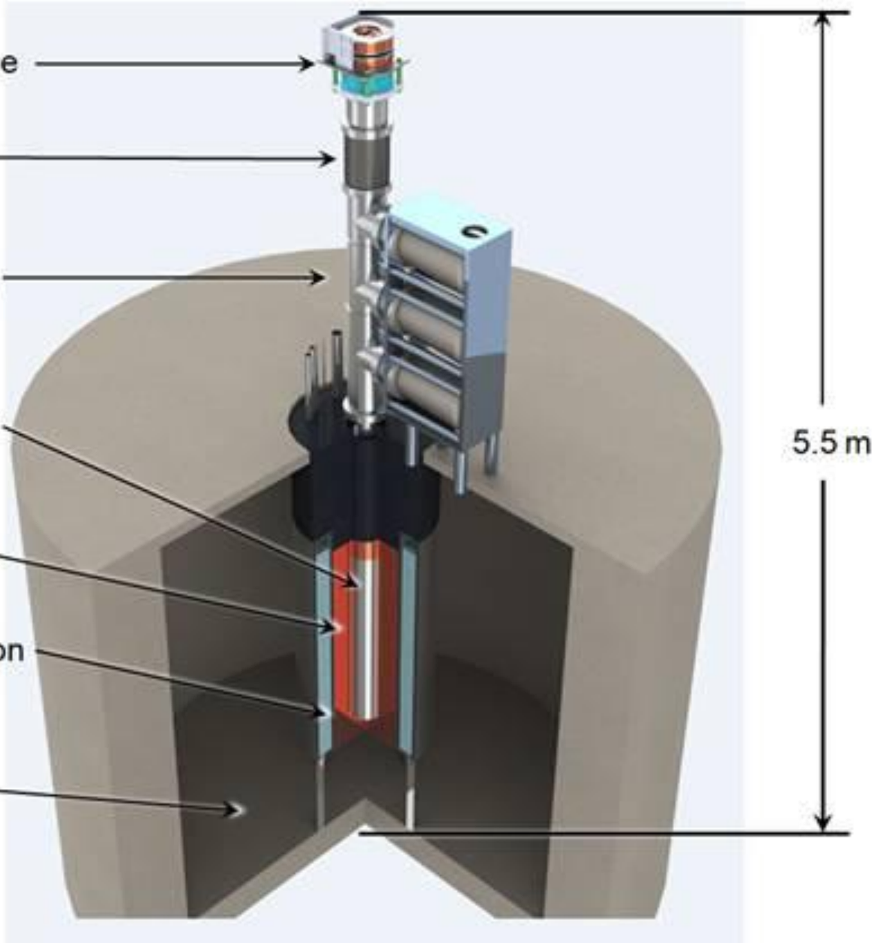
Aqueous Subcritical Assembly Boosts Neutron Flux and Generates Medical Isotopes



- D-T source in center
- Be multiplier
- Annular Geometry
- LEU Solution
- Externally moderated
- No active control elements
- Fission power:
  ~ 75 kW per device
- ^{99}Mo production rate:
  500 6-day Ci / wk

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SHINE Technology Overview

- SHINE (Subcritical Hybrid Intense Neutron Emitter)
  - Consists of an aqueous pool of uranium nitrate or sulfate
  - Subcritical assembly driven by a single D-T beamline
  - Beryllium surrounding driver target provides neutron multiplication
  - Isotopes made from fissioning of uranium in solution
  - Uranium concentration and solution height limits ensure subcriticality
  - Six devices will generate 50% of US ^{99}Mo demand

- Key Benefits
  - Sub-critical
  - Inherent safety; needs to be driven to operate, large negative feedback
  - Utilizes low enriched uranium (19.5%)
  - Greatly reduced nuclear waste – no reactor, recyclable solution
  - Aqueous process improves chemical extraction efficiency

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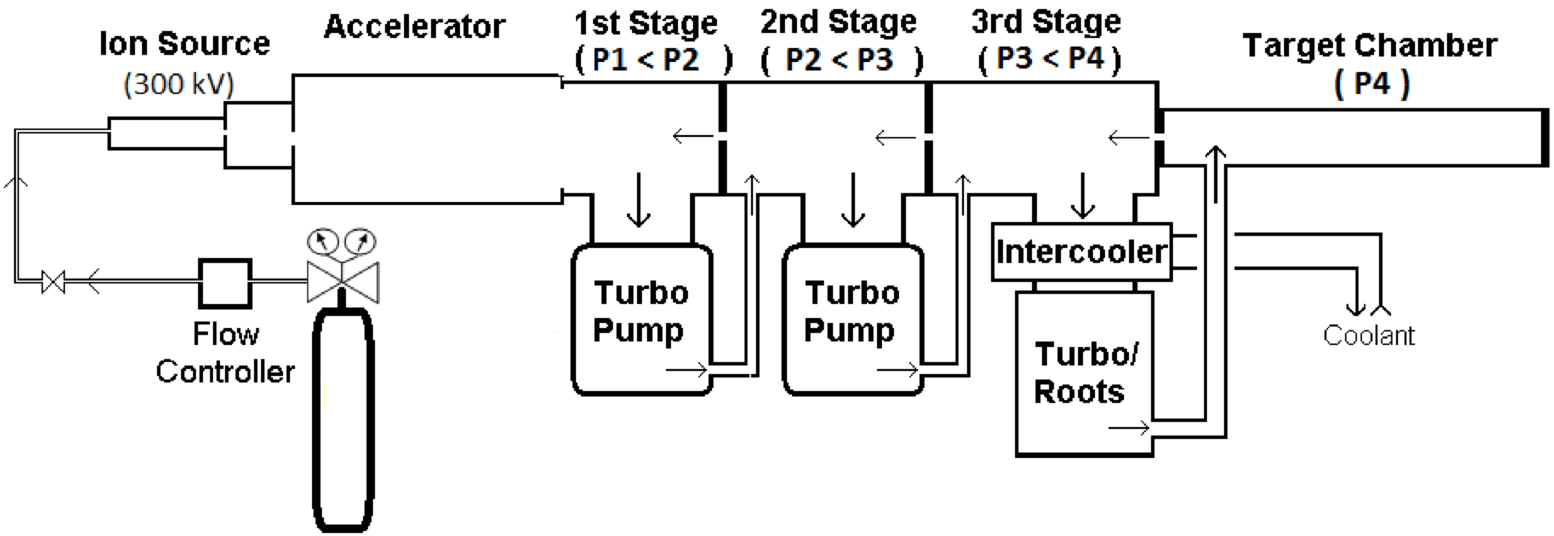
D-T Driver is Based on Demonstrated Technology



- Neutrons are made by reactions between deuterium and tritium atoms
  - Deuterium gas flows into ion source, is ionized by microwaves
  - Simple DC accelerator pushes ions toward target chamber (300 keV)
  - Accelerated deuterons strike tritium gas in target chamber, creating neutrons
  - Proof of high efficiency and yield already demonstrated (> 2 10^{9} n/s per watt)
  - High energy neutrons allow for (n,2n) multiplication on beryllium

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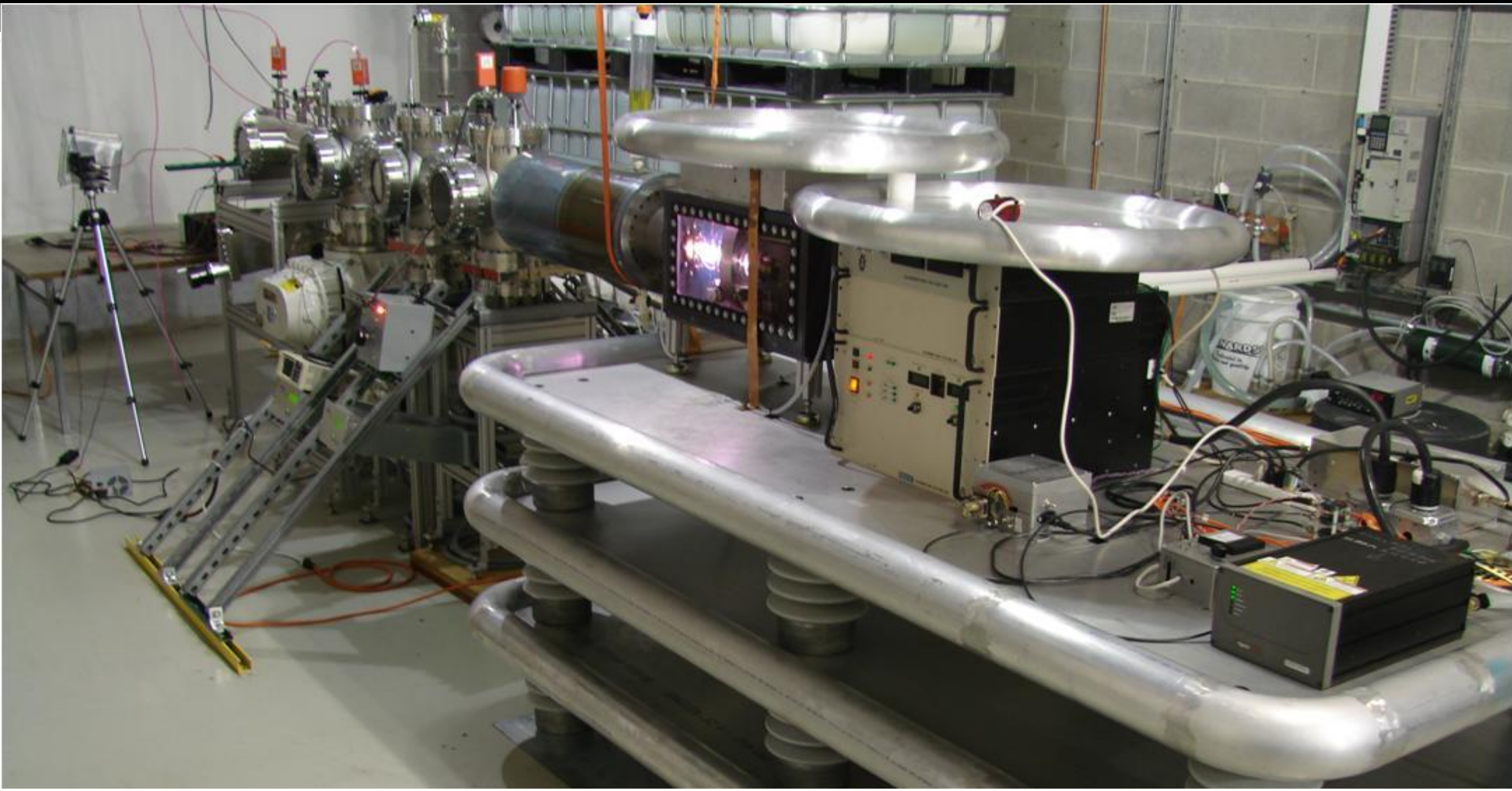
Driver Prototype at Phoenix Nuclear Labs



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SHINE Driver Concept

- Physical
  - Structure held together with aluminum frame
  - Ion source, pumping power supplies, cooling systems fully integrated
  - High voltage delivered externally
- Operational
  - Deuteron current: 100 mA
  - Beam energy: 300 keV
  - Beam power: 30 kW
  - Neutron output: 1×10^{14} n/s (14.1 MeV)
  - Tritium inventory: < 500 Ci per device (< 50 mg)
  - Tritium consumption (per year): ~125 Ci per device
  - Wall power (with pumping): 50 kW

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Off-gas, Fueling and Control

- Off-gas containment and piping
  - System designed to condense entrained water, recombine radiolysis products, and separate gaseous fission products
- Reactivity control
  - Small amounts of uranium solution added to increase reactivity
  - Physical design prevents addition of too much uranium (inherently sub-critical)
- pH control maintained by non-uranium fluid injections
- System shutdown for a few hours every week to allow for medical isotope separation

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Extraction Technology

- Solution moved from production cell to extraction hot cell
- Separated by ion exchange to extract molybdenum
- Other isotopes of commercial interest separated by different scrubbers
- Solution returned to target vessel
- Additional purification steps may be performed on extracted isotopes
- Isotopes shipped to customer following DOT regulations

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Waste Streams

- Separated fission products will either be sold or will be held in storage
- Non-separated fission products will build up in solution until it can no longer be reused
- Actinide buildup will be small due to the relatively short irradiation time, and actinides will remain in solution
- The waste will then be disposed of via available channels

Proposed Operations Facility

- ~$25 million custom facility based on SHINE specifications
- Manufacturing will be focused on safety and redundancy
- Provides low cost, efficient production with flexible capacity and just-in-time delivery

SHINE Medical Technologies Campus

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In Summary.....
Key Operations/Cost Advantages

- Neutron source
  - Simple, efficient, redundant non-reactor source
  - Low cost accelerator, easily and reliably controlled
- Aqueous target
  - No HEU
  - Soluble fission products already dissolved in solution
  - Simple separation process
  - Simple design with redundancy for high uptime
- Separation Technology
  - Separated Mo fits into existing supply chain
  - Other isotopes (Xe, I, etc) can be separated as well
  - SHINE believes that waste can be disposed as LLW

Questions?

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Licensing Topics

- <u>Introduction</u>

Jim Freels, P.E.

Senior Project Manager

EXCEL Services Corporation

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Licensing Topics

- Desired Outcome
  - Determine the regulatory and licensing framework needed to provide a complete, quality license application to the Staff for review

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Licensing Topics

- The simplified system associated with the innovative SHINE technology and facility introduces licensing complexities:
  - No "cookie cutter" regulatory licensing or review framework
  - Unlike other previously proposed technologies:
    - No nuclear reactor
    - No spent nuclear fuel
  - Possession of special nuclear material, source and byproduct material
  - Application of various parts of Title 10
  - Agreement State responsibilities

Licensing Topics

- SHINE Near-term Licensing Strategy
  - A number of the licensing questions were included in our Letter of Intent, submitted February 14, 2011.
    - Engage the Staff early to reach consensus on the appropriate approaches
    - Maintain communications and dialogue with the Staff during reviews
    - Follow-up meeting to discuss Staff positions

Licensing Topics

10 CFR 50 Applicability

Licensing Topics

- 10 CFR 50 Applicability
  - Production facility definition in 10 CFR 50.2
  - Bases and clarification of embedded exemptions and terms within the definition:
    - 1 E-06 gram Pu per gram U^{235} and 0.25 millicuries fission product activity per gram U^{235}
    - Definition of "batch"
    - Definition of "process batch"
    - 100 grams U^{235} and less than 15 grams of other SNM per "batch"

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Licensing Topics

10 CFR 70 Subpart H

Licensing Topics

- 10 CFR 70 Subpart H Applicability
  - Interpretation of “enriched uranium processing”
    - The Atomic Energy Act makes the distinction between “processing” and “separating”
    - We will be separating Moly-99 and other isotopes of commercial interest from a solution containing enriched uranium, not processing enriched uranium
  - Interpretation of general criterion: “significantly affect public health and safety”

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Licensing Topics

10 CFR 51

Licensing Topics

- 10 CFR 51 Applicability
  - Premise: SHINE will be evaluated under Materials License regulations
  - Necessity for Environmental Report- 10 CFR 70.21(f)
    - Proposed rulemaking for 10 CFR 70.21(f)
    - No specific criteria apply to SHINE
    - Interpretation of one general criterion: "activity which the Commission has determined pursuant to Subpart A of part 51 of this chapter will significantly affect the quality of the environment"

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Licensing Topics

- 10 CFR 51 Applicability (continued)
  - 10 CFR 51 Subpart A
    - How does Subpart A apply to SHINE?
      - 10 CFR 51.20 - Environmental Impact Statements
      - 10 CFR 51.21 - Environmental Assessments
      - 10 CFR 51.22 - Categorical Exclusions
      - 10 CFR 51.50 – Environmental report-construction permit, early site permit, or combined license stage
      - 10 CFR 51.60 – Environmental Reports--Materials License

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Licensing Topics

- <u>10 CFR 51 Applicability</u> (continued)
  - Necessity for Environmental Report- 10 CFR 51.60
    - Applicant for a license under specified parts of Title 10 and identified in 10 CFR 51.60(b)(1) through (b)(5) must submit an Environmental Report
    - SHINE does not meet (b)(1) through (b)(5) unless Commission determines an Environmental Report is necessary through general criterion: (b)(5) "Any other licensing action for which the Commission determines an Environmental Report is necessary."

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Licensing Topics

Restricted Data

Licensing Topics

- Restricted Data
  - Defined in 10 CFR 70
  - Concerns production of SNM
  - SNM will be produced as an artifact of the subcritical fission process, consistent with commercial reactor operations
  - Commercial reactors do not possess Restricted Data
  - We believe there will be no Restricted Data necessary to design, build, operate, and maintain the SHINE technology and facility

Licensing Topics

Regulatory Review Framework

Licensing Topics

- <u>Regulatory Review Framework</u>
  - SHINE will fall under multiple parts of Title 10
  - We believe the Staff will review the license application under the following:
    - NUREG-1520, Revision 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility"
    - NUREG-1280, Revision 1, "Standard Format and Content Acceptance Criteria for the Material Control and Accounting (MC&A) Reform Amendment: 10 CFR Part 74, Subpart E"
    - NUREG-1065, Revision 2, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities"

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Licensing Topics

Agreement State Interaction and Responsibility

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Licensing Topics

- <u>Agreement State Interaction and Responsibility</u>
  - Wisconsin became an Agreement State in 2003
  - Article II A of the Agreement does not transfer authority from the Commission to the State for "The regulation of the construction and operation of any production or utilization facility…"
  - SHINE believes the State will regulate the particle accelerator and approve the radiation shielding plans
  - We would like to understand the lines of responsibility for common programs, such as Radiation Protection, and how the interface works between the State and NRC

Licensing Topics

Other Regulatory/Licensing Questions or Topics ?

Licensing Topics

- What is next?
  - We request the Staff to review and consider these issues and develop positions/interpretations
  - Establish and maintain a dialogue between the NRC Project Manager and SHINE Licensing Project Manager to provide an avenue for additional information needs during this review and provide a path for other questions during license application development
  - Schedule a follow-up public meeting within the next 30 days to provide Staff feedback or submit a letter to SHINE identifying the Staff positions/interpretations for these issues

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