



**Commission Mandatory Hearing  
SHINE Construction Permit Application  
Overview  
December 15, 2015**

# SHINE Medical Technologies, Inc. Mission

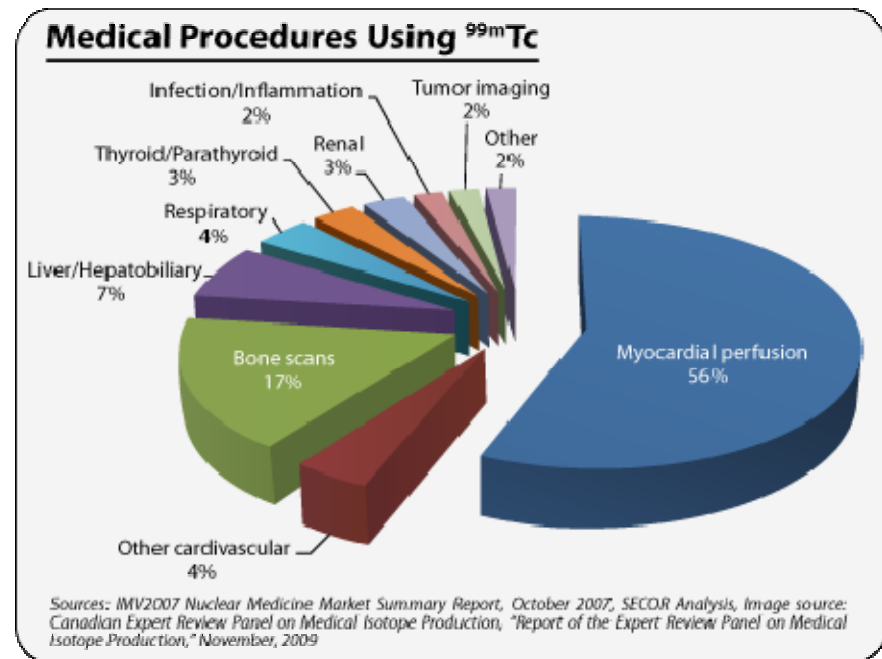
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- SHINE is dedicated to being the world leader in safe, clean, affordable production of medical tracers and cancer treatment elements
- Highest priority is safely delivering a highly reliable, high-quality supply of the medical ingredients required by nearly 100,000 patients globally each day, while maintaining a minimal environmental impact
- Will fill gap in supply chain caused by exiting foreign reactors, and ensure continuity of essential treatments for U.S. patients for decades to come



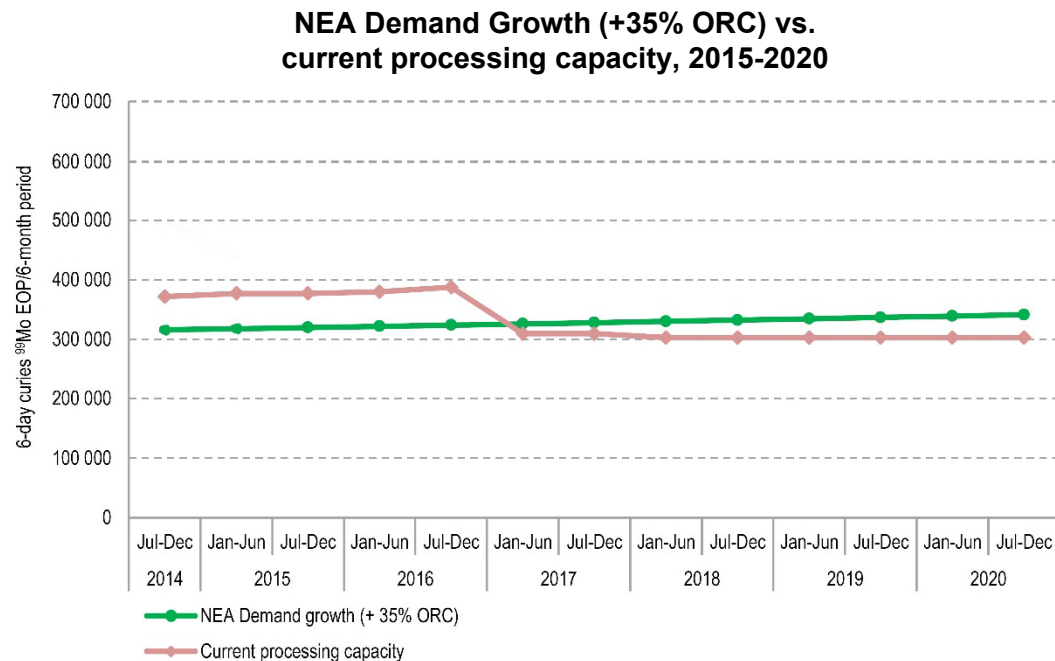
# Medical Isotopes

- Molybdenum-99 (Mo-99), the most widely-used medical isotope, decays into technetium-99m, which is used in more than 40 million doses annually
- Stress tests and bone scans most common of dozens of uses



# Supply Situation with No New Capacity

- Canada will stop operating the NRU reactor in March 2018
- Following Canadian exit, there will be no North American producer
- Highly relevant because Mo-99 decays ~1% per hour
- Domestic supply is necessary to ensure US patient health



# SHINE Medical Technologies, Inc. Core Values

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- SHINE mission driven by our core values
  - Ensure health and safety of the public and our workforce
  - Minimize environmental impacts of medical isotope production
  - Ensure minimal or no disruption to patient supply chain
  - Ensure cost effectiveness and therefore patient access
  - Eliminate need for highly enriched uranium (HEU) reactors or targets in medical isotope supply chain
- SHINE believes each of these points are essential to fulfill our mission



# Technological Approach Reflects Core Values

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- Small systems: Hundreds of times less power than isotope production reactors being used
  - Low source term—helps ensure safety of public and workforce
  - Decay heat per system < 1 kW within 5 hours
  - Minimizes waste nuclide generation compared to reactors
- Low enriched uranium (LEU) reusable target
  - Reduces waste and cost
  - Product compatible with current supply chain
  - Eliminates need for HEU
- Driven by low-energy electrostatic accelerator
  - System must be driven to operate, no criticality
  - Hundreds of times less waste than reactors
  - Electrostatic technology simple, demonstrated and cost effective



# SHINE Medical Technologies, Inc.

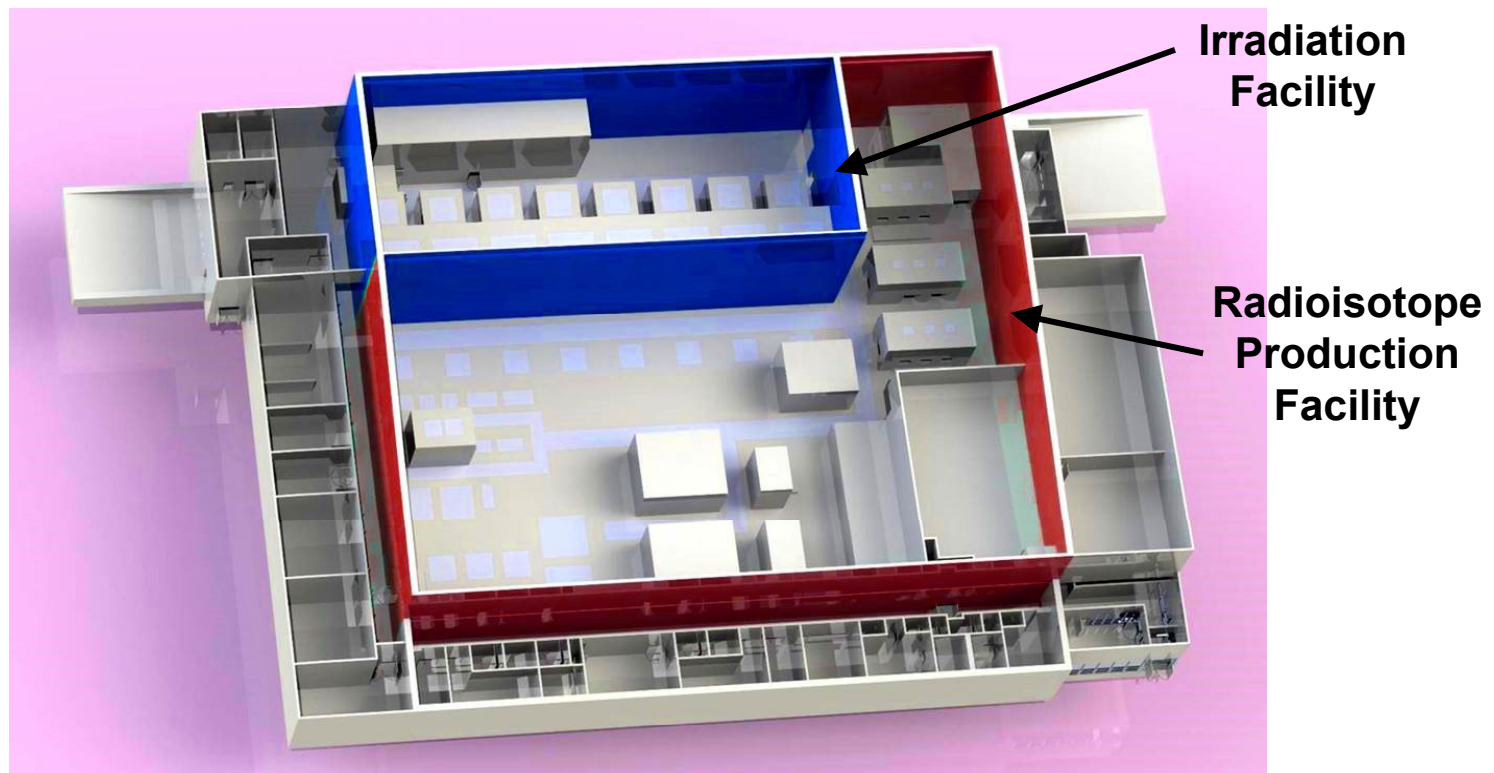
- The SHINE facility is located on a previously undeveloped 91 acre parcel in the southern boundaries of the City of Janesville in Rock County, Wisconsin



# SHINE Facility Layout

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- The SHINE facility consists of an irradiation facility (IF) and a radioisotope production facility (RPF)



# SHINE Irradiation Facility

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- The SHINE IF consists of eight subcritical irradiation units (IUs), which are comparable in thermal power level and safety considerations to existing non-power reactors licensed under 10 CFR Part 50
  - However, due to subcriticality, the IUs did not meet the existing definition of utilization facility in 10 CFR 50.2
  - To align the licensing process with potential hazards, the NRC issued a direct final rule modifying 10 CFR 50.2 definition of utilization facility to include SHINE IUs
- An IU consists of a subcritical assembly, a neutron driver, and supporting systems



# SHINE Radioisotope Production Facility

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- The RPF is the portion of the SHINE facility used for preparing target solution; extracting, purifying, and packaging Mo-99; and the recycling and cleaning of target solution
- Based on batch size (i.e., greater than 100 grams), the RPF meets the definition of a production facility as defined in 10 CFR 50.2



# SHINE Construction Permit Application

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- SHINE submitted the CP Application in two parts, pursuant to an exemption to 10 CFR 2.101(a)(5)
  - Part 1 of the Application submitted March 26, 2013
    - PSAR Chapter 2 (Site Characteristics)
    - PSAR Chapter 19 (Environmental Review)
    - General and Financial Information
  - Part 2 of the Application submitted May 31, 2013
    - Remaining PSAR Chapters
  - A discussion of the preliminary plans for coping with emergencies, in accordance with 10 CFR 50.34(a)(10), provided September 25, 2013
- The SHINE facility will be licensed under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”



# Regulatory Guidance and Acceptance Criteria

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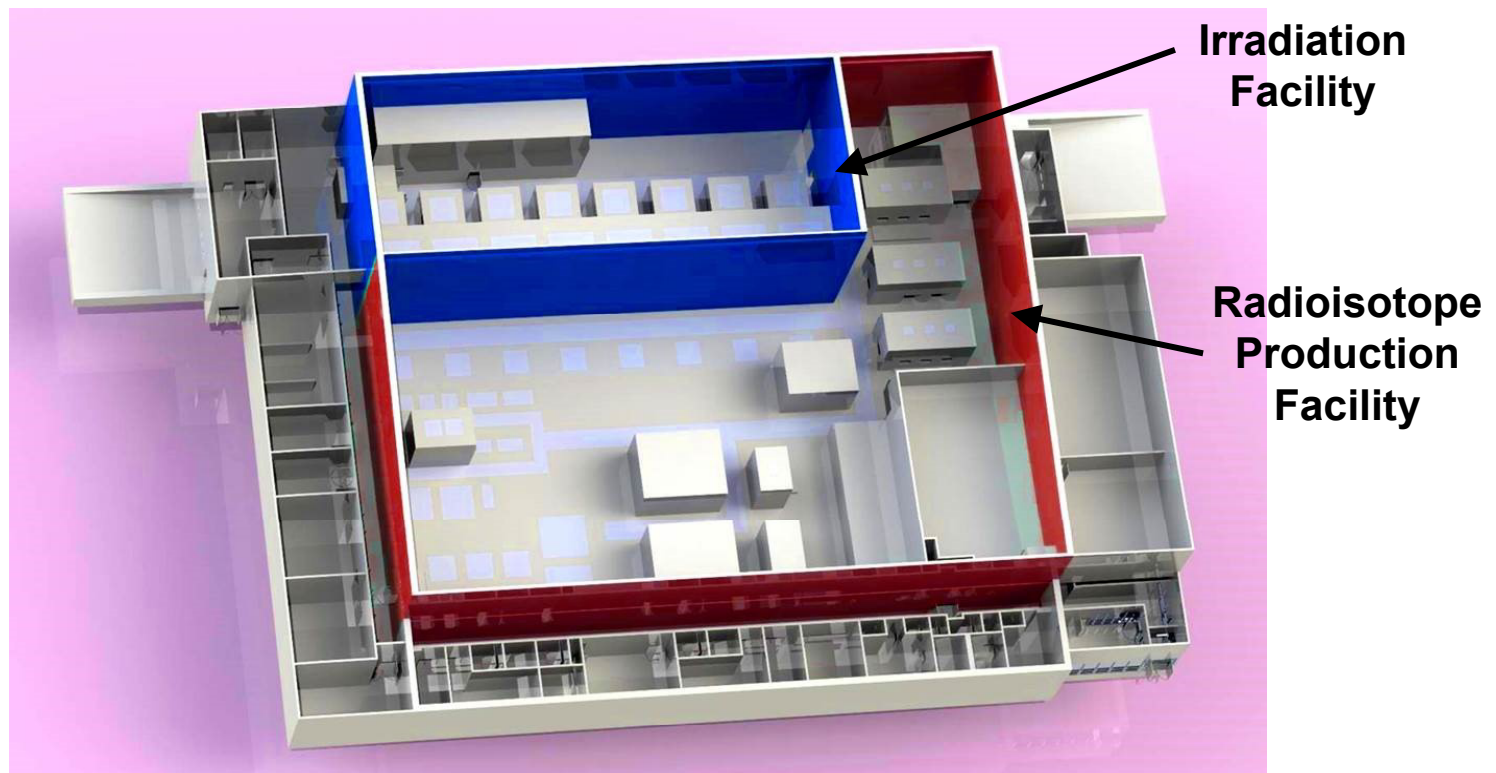
- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
- Interim Staff Guidance augmenting NUREG-1537
  - Incorporates relevant guidance from NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility”
- Additional guidance (e.g., Regulatory Guides, ANSI Standards) used



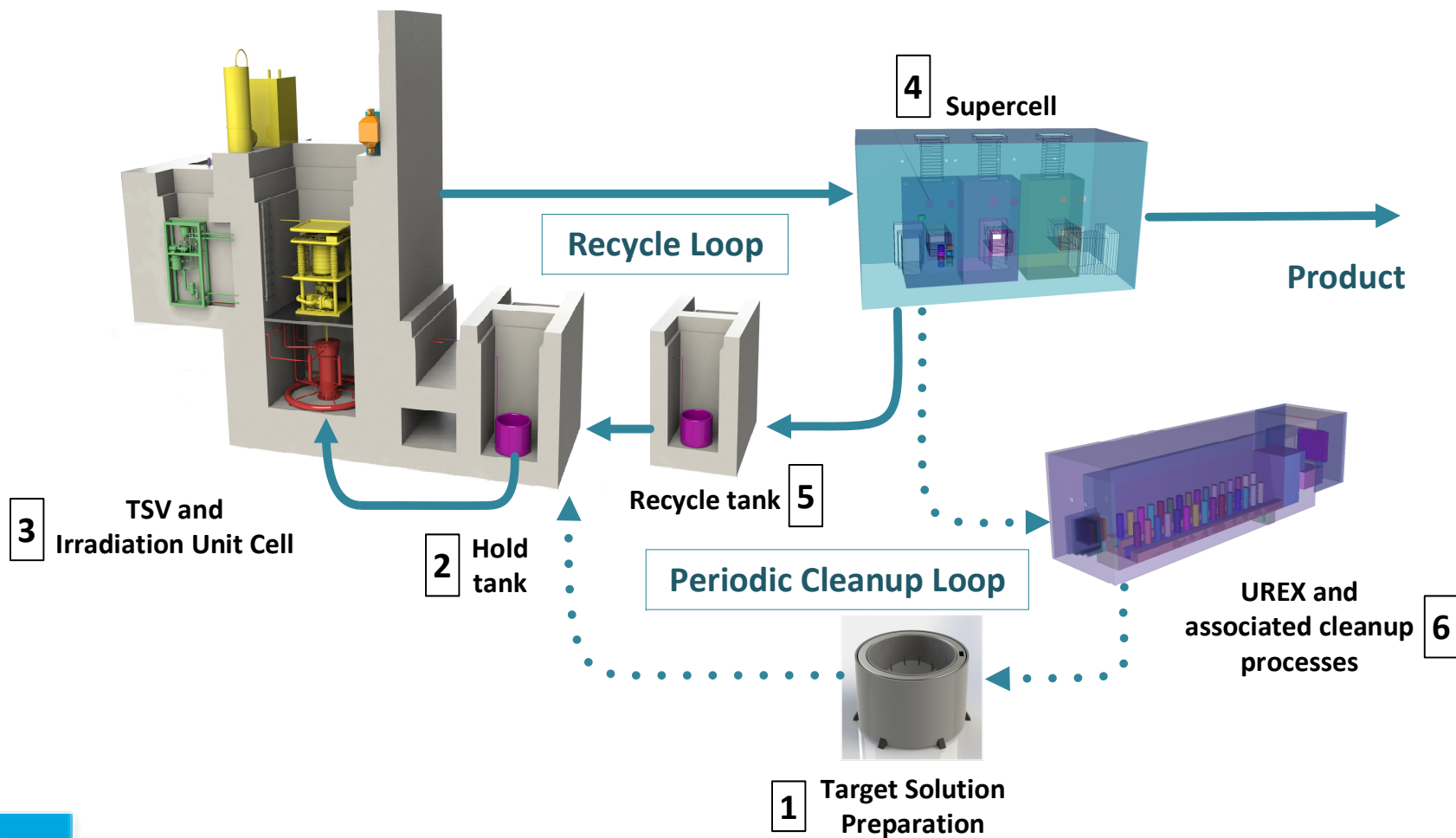
# SHINE Facility Layout

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- Production, processing, and packaging operations located within one controlled, confined area

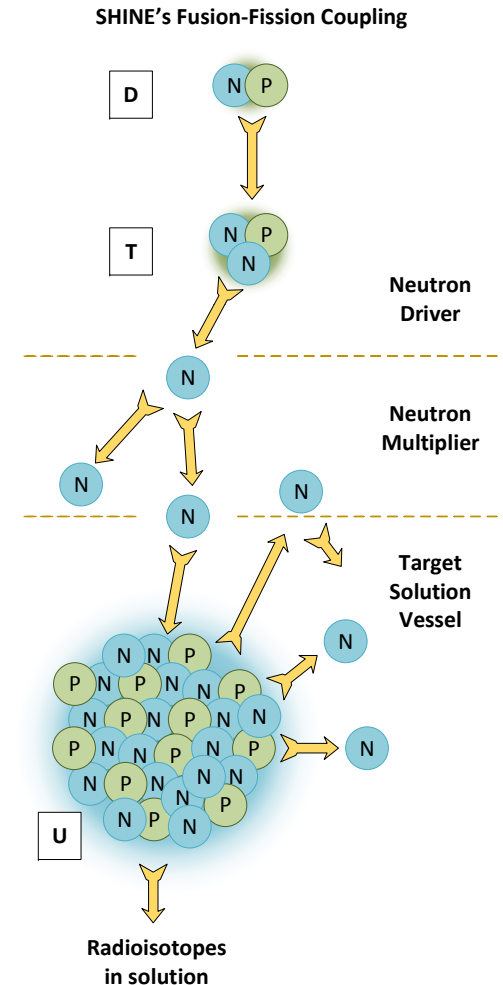


# SHINE Process Overview

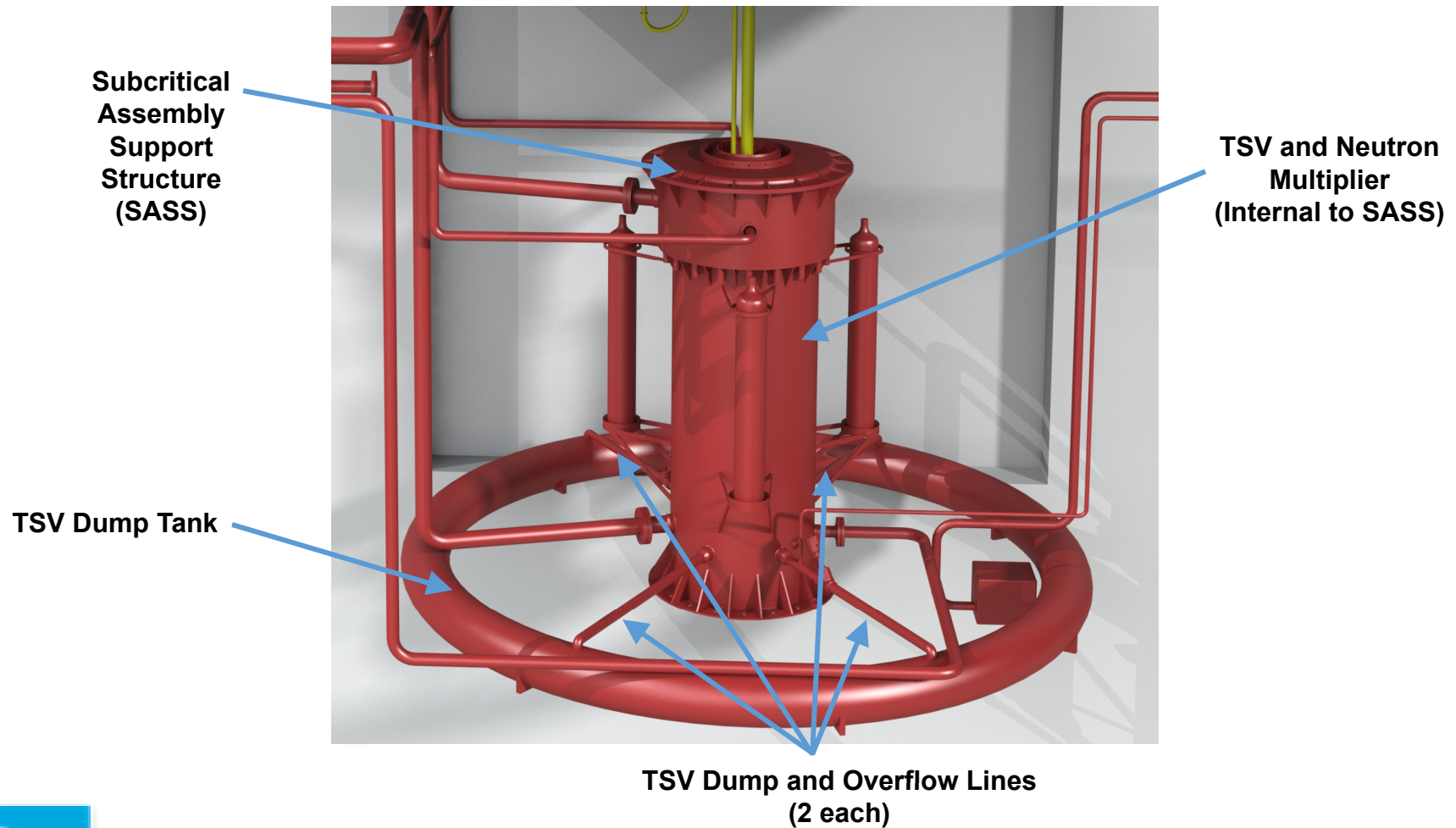


# SHINE Irradiation Facility

- An IU consists of a subcritical assembly, a neutron driver, and supporting systems
- Major supporting systems include:
  - Light water pool system (LWPS)
  - Target solution vessel (TSV) off-gas system (TOGS)
  - Primary closed loop cooling system (PCLS)
  - Tritium purification system (TPS)
- Primary system at near-atmospheric pressure
- Target solution is drained to dump tank via gravity
  - Dump tank is criticality-safe by geometry and passively-cooled
  - Redundant, fail-open dump valves
- TSV is an annular vessel to be constructed of Zircaloy-4
  - Natural convection within TSV

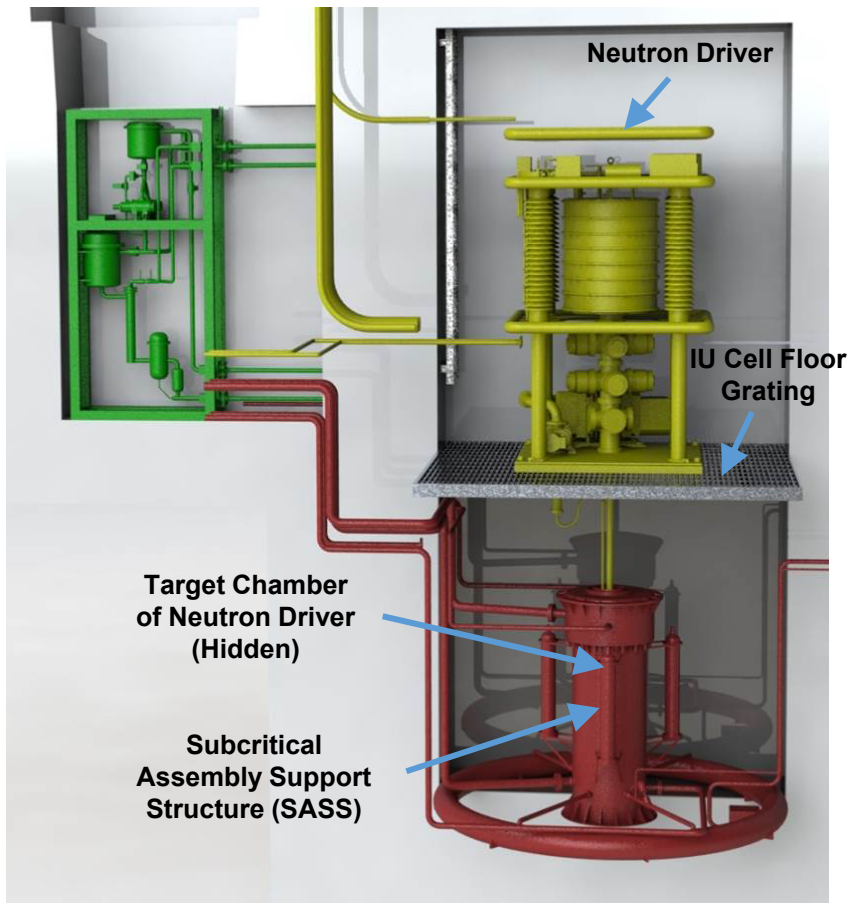


# Subcritical Assembly



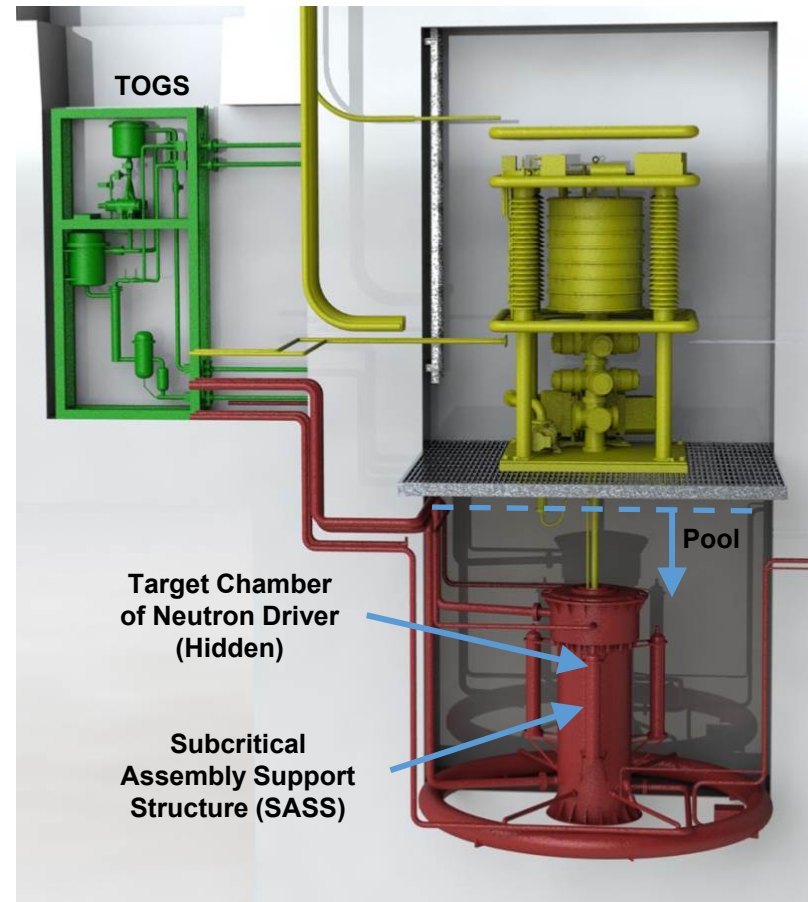
# Neutron Driver and Tritium Purification System

- One Neutron Driver per IU cell
  - Electrostatic accelerator with a gas target
  - D-T fusion reaction generates 14 MeV neutrons that drive the fission process
- Tritium purification system
  - Isotopically separates gases, and supplies clean tritium to neutron drivers
  - Tritium lines and processing equipment in gloveboxes and double-walled pipe



# TSV Off-Gas and Primary Cooling Systems

- TSV off-gas system (TOGS)
  - Contains the fission product gases
  - Removes iodine from the off-gas
  - Recombines hydrogen and oxygen to maintain hydrogen gas below the lower flammability limit (LFL)
- Subcritical assembly submersed in light water pool
  - Provides shielding and heat removal



# Subcritical Assembly Irradiation Process

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- Uranium concentration of solution and any other necessary parameters are measured
- Operators use a 1/M startup methodology to monitor the reactivity increase in the TSV
  - TSV is filled in discrete increments
  - Final fill level is approximately 5% by volume below critical
- Automatic safety systems will be designed to protect the primary system boundary (PSB) and ensure the TSV remains subcritical
  - High flux trips
  - Primary cooling system temperature trips



# Subcritical Assembly Irradiation Process

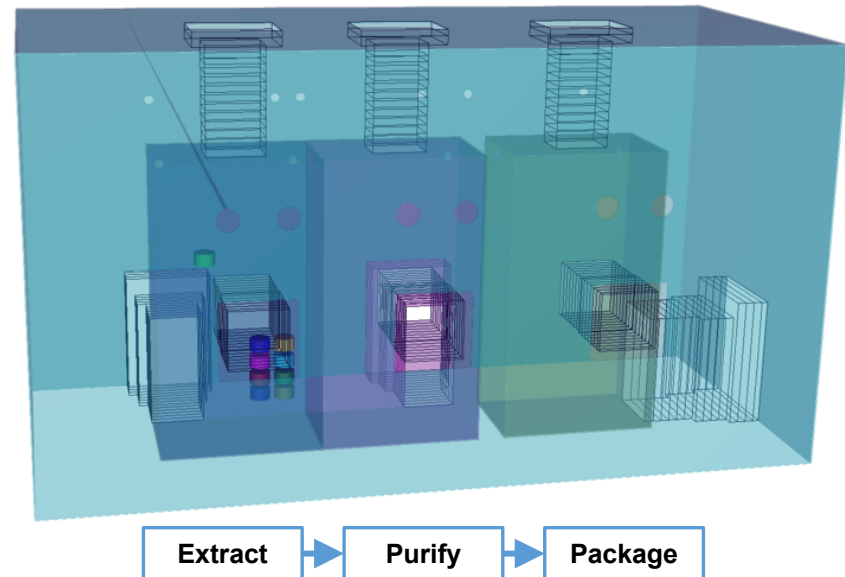
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- When irradiating the TSV:
  - Further solution addition is prevented
  - Tritium is supplied to the target, and neutron driver output is gradually increased
  - Reactivity decreases significantly in the assembly due to the strong negative feedback
- Normal irradiation mode operations are approximately 5.5 days
- Following shutdown, light water pool provides decay heat removal
  - On a loss of off-site power, pool passively removes heat
  - Temperature rise of 12°F (7°C) after 90 days without cooling



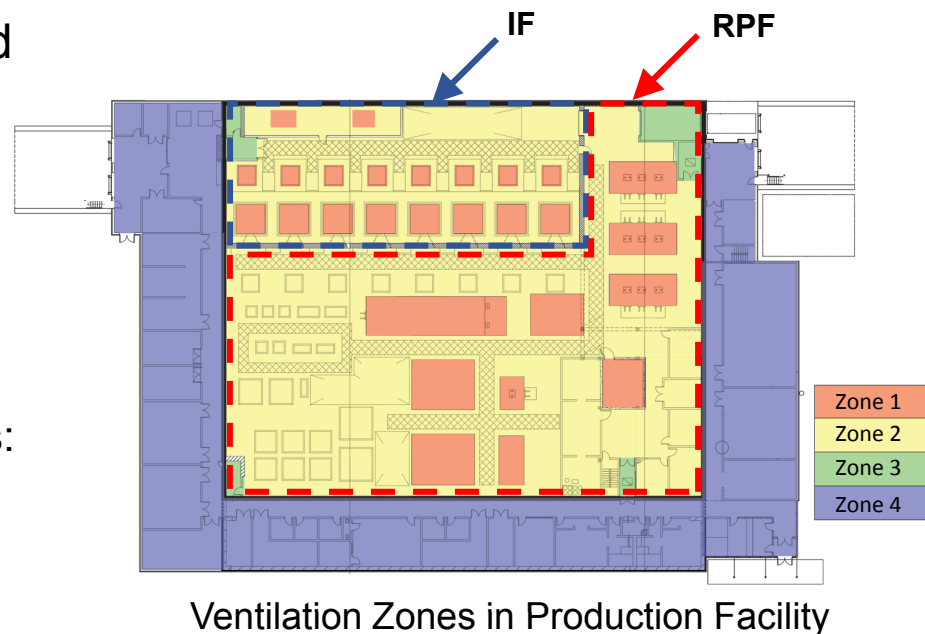
# Radioisotope Production Facility

- Extracting, purifying and packaging Mo-99 in supercells
  - Laboratory scale purification process
- Noble Gas Removal System (NGRS) stores TSV off-gas
  - Held for 40 days of decay prior to sampling for release
  - Released through the Process Vessel Vent System (PVVS)
  - Monitored and filtered discharge to ensure regulatory limits are met
- Recycling and cleaning target solution
  - Uranium extraction (UREX) process separates uranium for reuse



# Engineered Safety Features (ESFs)

- SHINE protects public health and safety during postulated accidents via a confinement system
  - Radionuclide inventory in any one confinement area is approximately 10,000 times less than a power reactor
  - Low dispersion forces in processes
- Confinement functions provided by:
  - Biological shielding (IU cells, hot cells, trenches, tank vaults)
  - Isolation valves on piping systems
  - Ventilation systems
  - Instrument and control systems:
    - Engineered Safety Features Actuation System (ESFAS)
    - Radiological Integrated Control System (RICS)



# Summary

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- Preliminary design described in the PSAR shows the SHINE facility can be constructed such that it meets the applicable regulatory requirements
- Robust engineered and administrative controls have been identified to ensure protection of the public, the environment, and our workers
- The plant is being designed with safety as the primary criterion

