B&W Medical Isotope Production System

Meeting with USNRC

Presented by B&W TSG
July 2009

Agenda

- Introduction and Background
- Project and Design Update
- Licensing Approach
- Project Schedule
- Actions and Path Forward

B&W Presenters

- Evans Reynolds, MIPS Program Manager
- Don Roy, Reactor Systems Lead
- Dan Glenn, Isotopes Separation Lead
- Steve Schilthelm, Licensing Lead

Introduction and Background

Execution: MIPS Team

B&W TSG
Project Review Board

MIPS Program Manager
WE Reynolds

Technical Review Committee

B&W TSG
QA

Quality Assurance

Deputy Program Manager

Project Administrator

COVIDIEN

Reactor Systems — *DH Roy*
- Reactor Systems
- Waste Management Systems

Licensing — *SW Schilthelm*
- Nuclear Regulatory Commission
- Food and Drug Administration

Isotope Separations — *DE Glenn*
- R&D Subcontractor
- DOE Lab
- Separation Purification Systems Design

Construction Manager
- Construction Subcontractor
- Start-Up and Test

Operations
- Pharmaceutical Operations
- Reactor Operations
- Packaging & Shipping
- Training

Environmental Safety & Health
- Environmental Impact
- Radcon & Waste Management Ops
- Safety

B&W MIPS - History & Market Drivers

- Mid-90s: MIPS invented by Dr. Russell M. Ball – LEU or HEU capable, uranyl nitrate, patented 1997
- 92: Schumer Amendment to Energy Policy Act pushes phase-out of HEU export for isotope production
- 05: Burr Amendment to Energy Policy Act eased earlier restrictions on HEU exports and required study by National Academy of Sciences
- 07 - 09: B&W TSG and Covidien negotiated agreements
- 09: Report by National Academy very favorable for US domestic, LEU sources
- 09: Anticipated legislation promoting Mo-99 production; Rep Markey.

US005596611A

United States Patent [19] **Ball**

[11] **Patent Number:** **5,596,611**
[45] **Date of Patent:** **Jan. 21, 1997**

[54] **MEDICAL ISOTOPE PRODUCTION REACTOR**

[75] Inventor: **Russell M. Ball**, Lynchburg, Va.

[73] Assignee: **The Babcock & Wilcox Company**, New Orleans, La.

[21] Appl. No.: **339,264**

[22] Filed: **Nov. 10, 1994**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 986,939, Dec. 8, 1992, abandoned.

[51] **Int. Cl.**[6] **G21G 1/02**
[52] **U.S. Cl.** **376/189**; 376/186; 376/311; 376/313; 376/358
[58] **Field of Search** 376/186, 313, 376/354–358, 311, 189

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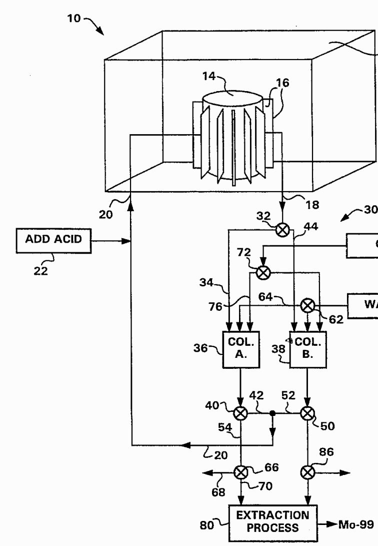
Primary Examiner—Harvey E. Behrend
Attorney, Agent, or Firm—Robert J. Edwards

[57] **ABSTRACT**

Medical isotopes are produced using a lower power, low cost nuclear reactor which permits the use of all the fission products produced in the reactor. Medical isotopes such as Molybdenum-99 are produced in a reactor operating at a power of 100 to 500 kilowatts.

16 Claims, 1 Drawing Sheet



Current Status of ^{99}Mo Production

- Wide domestic and global consumption of Mo-99
  - 70,000 imaging procedures per day in US
- Motivation to convert to LEU technology
  - Congressional mandate
- No domestic source
- Global supply instability – 40+ year old reactors
- B&W core capability
- Leverages existing assets (patents)
- Strategic opportunity for diversification

Previous AHRs – Proven Technology

MIPS based on proven technology

KEWB-1 - ROCKWELL	SANTA SUSANA, CAL	USA
LA 1	LOS ALAMOS	USA
LA 2	LOS ALAMOS	USA
BATELLE PNL CRITICAL MASS LAB	RICHLAND, WASH	USA
SHEBA	LACEF (LOS ALAMOS)	USA
LOPO	LOS ALAMOS	USA
NAA WATER BOILER NEUTRON SOURCE	SANTA SUSANA, CAL	USA
L 3	LAWRENCE LIVERMORE	USA
HYPO	LOS ALAMOS	USA
L 6	ROCKWELL, INT	USA
KING INTENSE NEUT GENERATOR	LOS ALAMOS	USA
SUPO (REBUILT HYPO)	LOS ALAMOS	USA
BRIGHAM YOUNG UNIV	UTAH	USA
ROCKWELL	SANTA SUSANA, CAL	USA
U OF C -SANTA BARBARA	SANTA BARBARA, CAL	USA
U OF NEVADA	NEVADA	USA
IIT	CHICAGO, ILLINOIS	USA
NAA	SANTA SUSANA, CAL	USA
NASA - ZPR-1	CLEVELAND, OH	USA
NASA - ZPR-2	CLEVELAND, OH	USA
ROCKWELL	SANTA SUSANA	USA
U OF WYOMING	WYOMING	USA
NCSTATE	RALEIGH, NC	USA
DR-1	RISO	DENMARK
IIN-3N-HYDRA	KURCHATOV INST.	RUSSIA
ARGUS	KURCHATOV INST.	RUSSIA
WBRL	TAIWAN	TAIWAN
HAZEL	U.K.	U.K.
L-77	PUERTO RICO	PUERTO RICO
L77A ATIBKA	GERMANY	GERMANY
L-54	ITALY	ITALY
PURNIMA	INDIA	INDIA
MIRENE-CEN	VALDUC	FRANCE
SILENE-CEN	VALDUC	FRANCE
L-54 - AI 3739	WALTER REED HOSP, WASH. D.C.	USA
AE-6 WATER BOILER	ROCKWELL	USA

Over 30 AHRs Built and Operated

MIPS Project Update

B&W Covidien Press Release

B&W and Covidien to Develop U.S. Source of Key Medical Isotope

Initiative could supply 50 percent of U.S. demand

LYNCHBURG, VA & ST. LOUIS – January 26, 2009 – Babcock & Wilcox Technical Services Group, Inc. (B&W TSG), a major operating unit of The Babcock & Wilcox Company (B&W), has signed an agreement with Covidien (NYSE:COV, BSX: COV) to develop technology for the manufacture of molybdenum-99 (Mo-99), the parent isotope of technetium-99m (Tc-99m), the most widely used radioisotope in the world for molecular imaging and nuclear medicine procedures. The program has the potential to supply more than 50 percent of U.S. demand for Mo-99. B&W is a subsidiary of McDermott International, Inc. (NYSE: MDR).

Under the agreement, B&W TSG and Mallinckrodt Inc., a subsidiary of Covidien, will collaborate on the development of solution-based reactor technology for medical isotope production. The agreement combines Covidien's expertise in radiopharmaceutical production and global regulatory approvals with B&W's patented liquid phase nuclear technology. This reactor technology uses low enriched uranium (LEU) and generates only about 1 percent of the radioactive waste compared to spent fuel and processing wastes generated by current reactor production of Mo-99, most of which uses highly enriched uranium (HEU).

This collaboration is an initial step toward establishing a large-scale U.S. supply of medical isotopes. Currently, the U.S. imports 100 percent of the Mo-99 supply, which is manufactured at a handful of aging nuclear reactors. Unplanned shutdowns of these reactors for maintenance needs or safety-related issues have led to periodic shortages of medical isotopes. Because Mo-99 has a half-life of only 66 hours, shortages have an almost immediate impact on the ability of physicians to perform critical patient procedures. Besides providing a reliable, domestic supply of the medical isotope, the program will support the U.S. National Nuclear Security Administration's nonproliferation efforts.

"For more than 50 years, B&W has been a leader in developing and deploying technologies that contribute to the nuclear industry through government initiatives and commercial endeavors," said S. Robert Cochran, President of B&W TSG. "This is a significant advancement in technology that B&W is proud to lead. Working in concert with Covidien, we believe this achievement will have a great impact on the medical and nuclear industries."

"Our agreement with B&W is another demonstration of how Covidien's commitment to innovation is laying the foundation for significant advances in medical imaging," said Timothy R. Wright, President, Pharmaceutical Products and Imaging Solutions, Covidien. "We're focused on delivering the critical solutions clinicians need to provide insightful diagnoses and quality treatments for patients. With technology advances such as this, we hope to improve the reliability of medical isotope supply, which is of vital importance to the nuclear medicine industry."

Approximately 16 million U.S. patients benefit annually from nuclear medicine procedures that are performed to diagnose heart disease or to detect and treat cancer and other medical conditions. Tc-99m, which is derived from Mo-99, is used in approximately 80 percent of these medical imaging procedures. Current production methods for imported Mo-99 involve extraction from HEU targets that have been irradiated in a reactor. Mo-99 is used to manufacture generators, which are distributed to hospitals and radiopharmacies as a source of Tc-99m.

DOE Support for MIPS

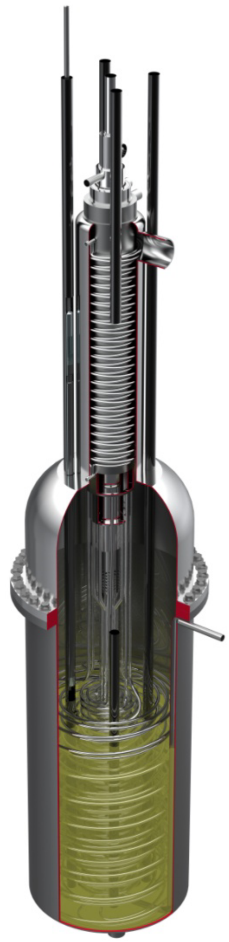
- Argonne National lab
- Los Alamos National Lab
- DOE Cooperative Agreement

MIPS Design Update

B&W Core Technology

200 kW MIPS Reactor

4 ft. tall, 22” diameter



Feature

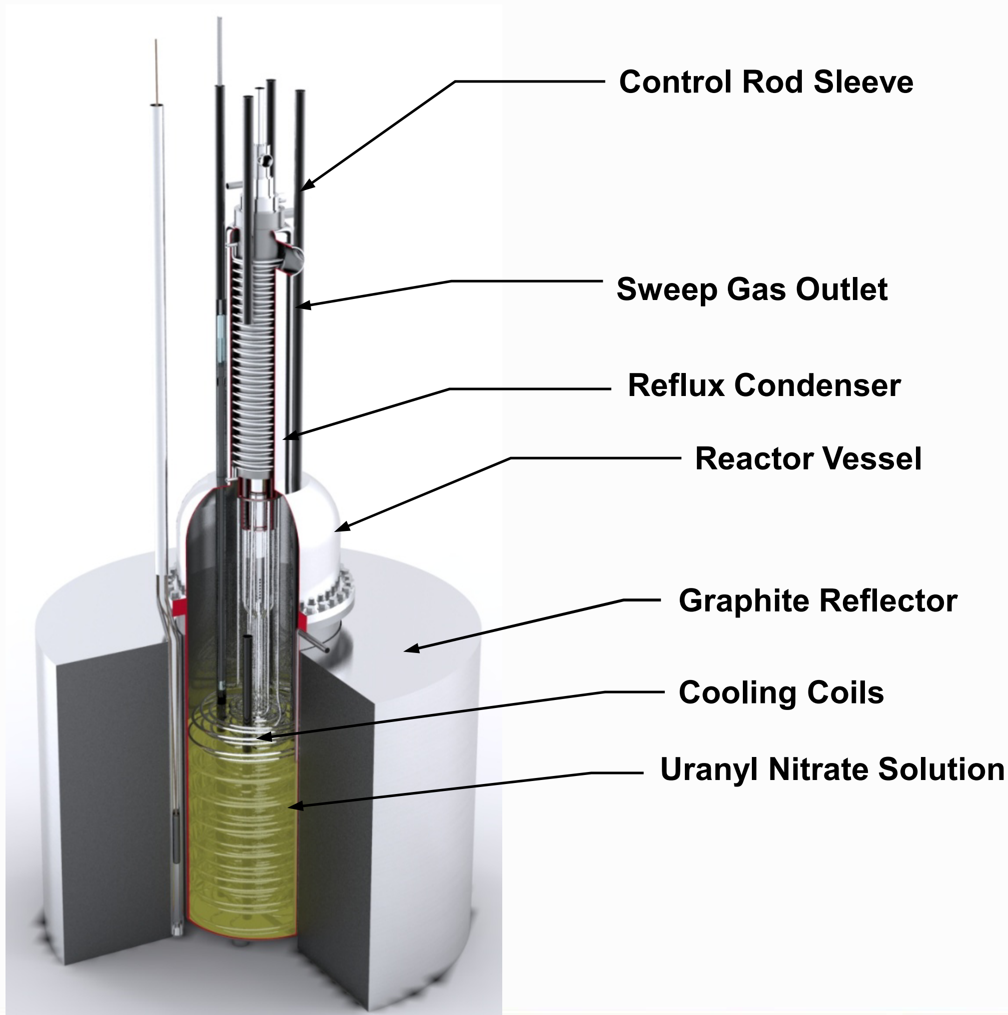
- Aqueous homogeneous reactor
- Low enriched uranyl nitrate solution
- Low power (200 kW) reactor module
- Low power density (1kW/liter)
- Large negative coefficient of reactivity
- Low temperature and pressure (80°C, atmospheric)

Benefit

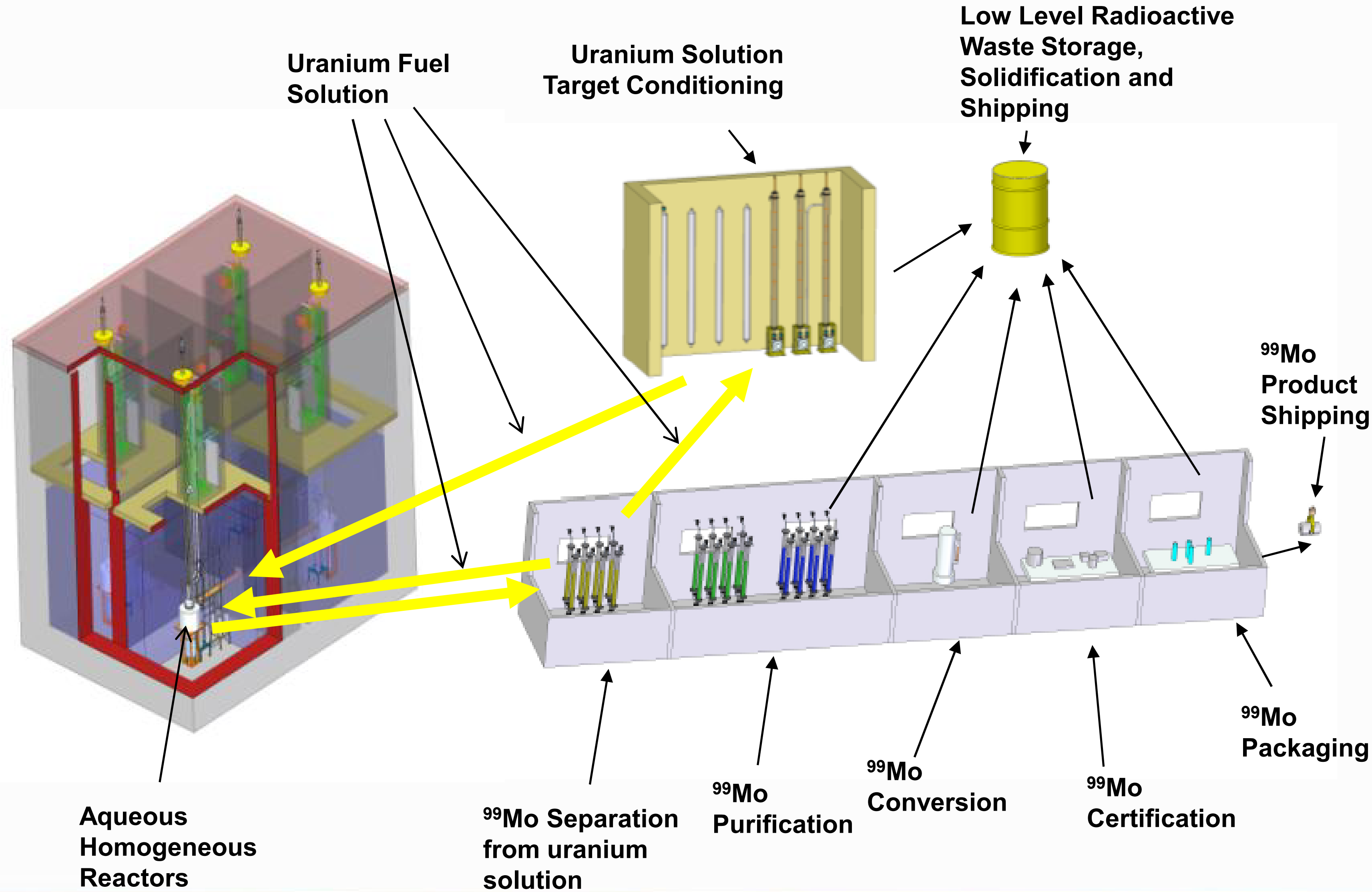
- Simple, no separate target, much less waste
- Non-proliferation attributes
- Low power, small footprint
- Passive safety factor for reactor

MIPS Reactor Module

200 kW Reactor Module



Process Flow For MIPS

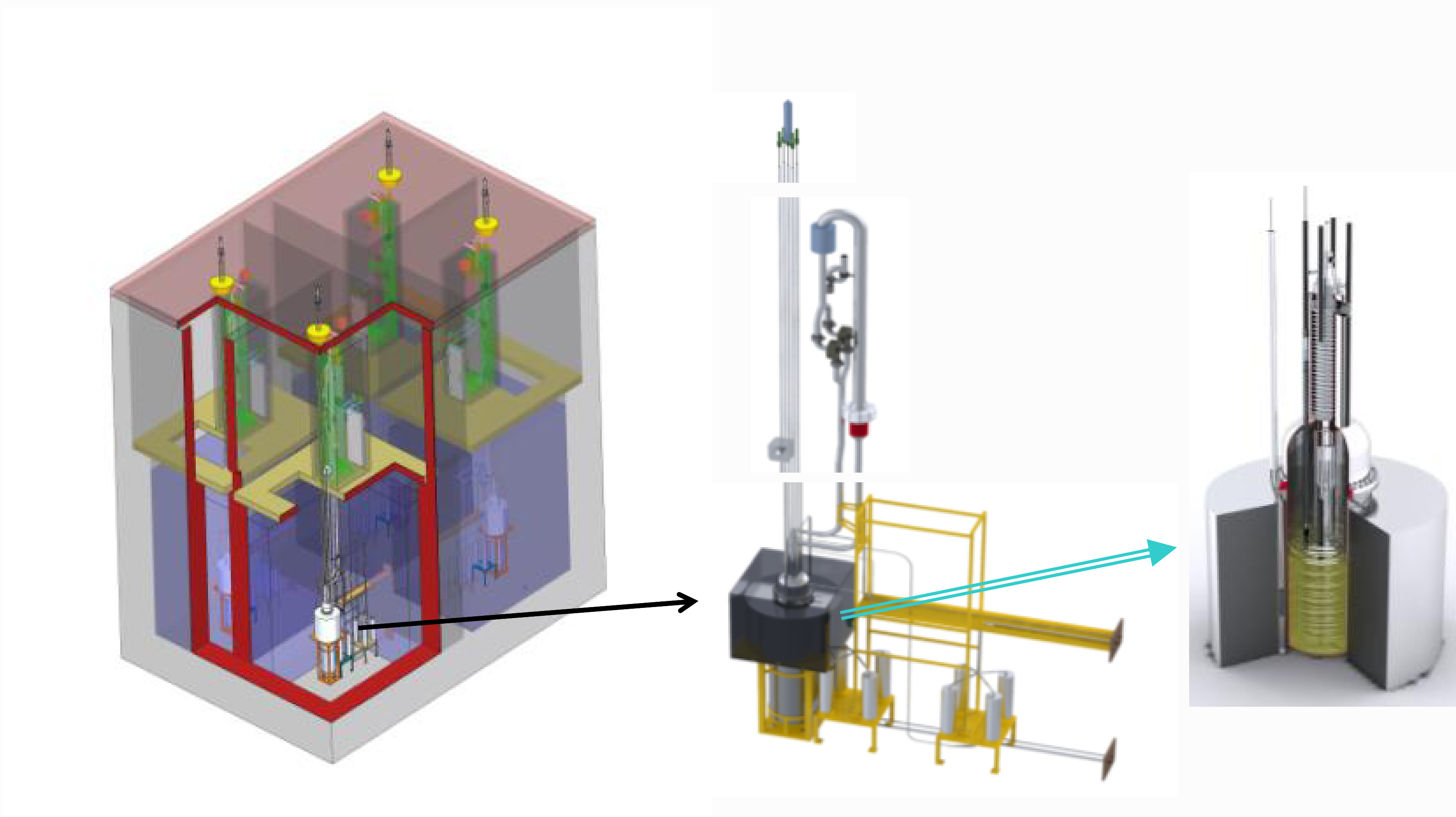


Comparison to Traditional Target Production

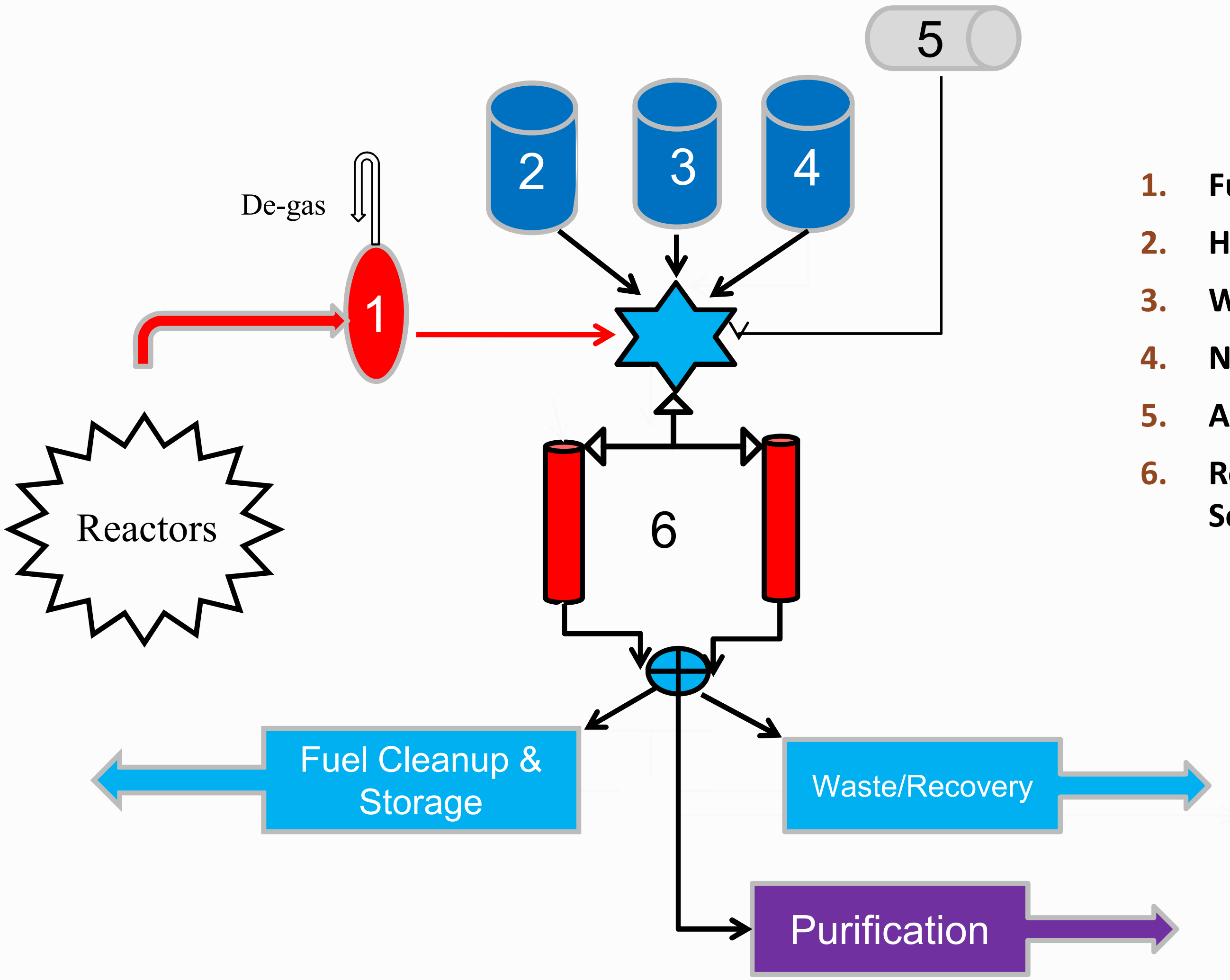
	MIPS	Traditional Target System
Reactor Power Level	200kW modules less than 1 MW total	10+ MW Reactor
Fuel Type	Uranyl nitrate LEU solution	Clad HEU or LEU uranium
Typical Reactor Flux	$1x10^{12}$ n/cm^2-s	$6x10^{14}$ n/cm^2-sec
Target Description/ ^{99}Mo Production	LEU reactor solution fuel serves as target. ^{99}Mo produced in entire reactor solution. Volume is available for separation after removal from reactor	Manufactured LEU clad target. ^{99}Mo produced in target irradiated in the reactor available for separation after dissolution in separate facility
Target Power Level (fissions in the target)	Same as MIPS reactor (fuel is target)	Equal to MIPS for equal ^{99}Mo production
Reactor Fuel/Target Consumption	Initial LEU fuel load is reused with minimal periodic additions over life	Frequent refueling with new reactor driver fuel and new targets for each ^{99}Mo production cycle
Operating Temperature	80° C	
Operating Pressure	Atmospheric	Atmospheric or Pressurized
Reactor Licensing	Part 50, Class 103 non-power	Part 50, Class 104 non-power if existing R&D reactor utilized
Separation Facility Licensing	Included in Part 50 reactor license	Separate part 70 license
Waste Generation	Fuel cleanup waste End-of-Life used fuel Miscellaneous low level waste	Dissolved target waste Periodic reactor spent fuel (DOE) Miscellaneous low level waste

MIPS Reactor Module

200 kW Conceptual Module Arrangement



Extraction System Functional Design



1. Fuel Hold & Vent Tank
2. HNO_3 Wash
3. Water Wash
4. NaOH Elution
5. Air
6. Regenerative & Replaceable Sorbent Columns

Research and Development

Sorbent Performance
(INVAP and ANL)

Acid resilience
Radiation resilience
K_d performance
Recycle effects

Column Design
(Purdue)

Particle size
Column shape
Sorbent volume

Chemistry Control
(INVAP, ANL, B&W)

pH effects & control
Precipitant prevention
REDOX behavior
Fuel recycle effects

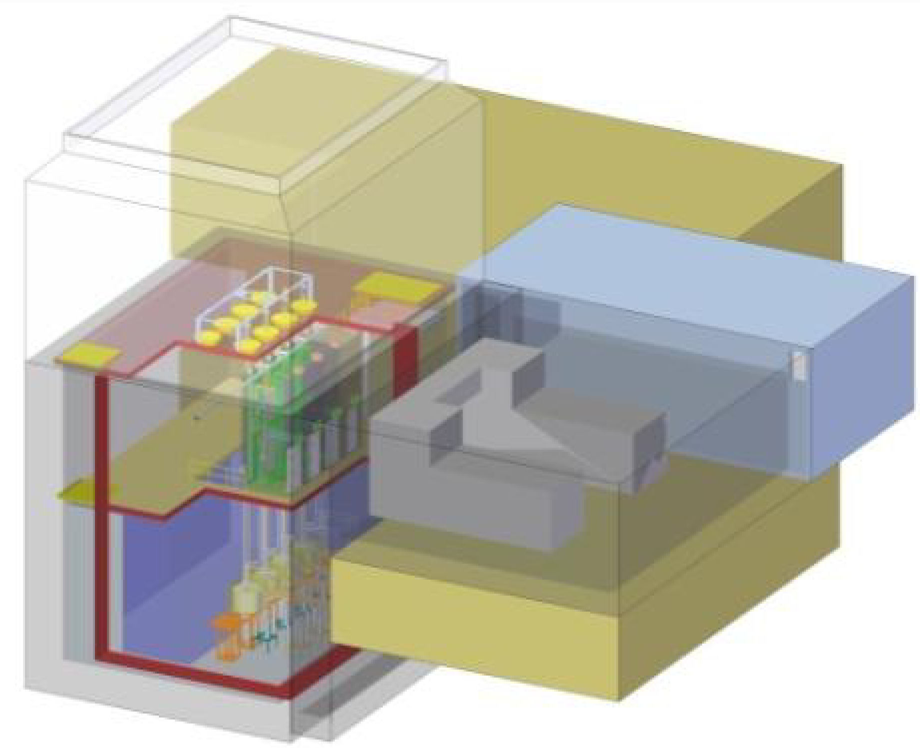
Integrated small-scale system performance
Designed to yield confidence in conceptual design and process success

R&D Assets

- **INVAP** (Argentina) – Subcontractor for MIPs R&D for separation and purification systems
- **ANL** – R&D input for Fission Product effects and Redox & pH behavior (AFRRI Experiments)
- **Purdue University** – Subcontractor for sorbent column design
- **Covidien** – Consulting Partner for purification, certification, P&T and FDA & pharmaceutical requirements
- **B&W TSG** – Mt. Athos Laboratories

MIPS Systems

- Reactor core system
- Reactor gas management system
- Reactor core cooling system
- Reactor protection system
- Reactor control & instrumentation system
- Safeguards features actuation system
- ^{99}Mo processing system
- Reactor fuel solution management system
- Confinement system
- Radioactive waste management system
- Facilities & services
- Material control and accounting systems
- Security systems



MIPS Licensing Approach

Proposed Approach Currently under NRC Consideration

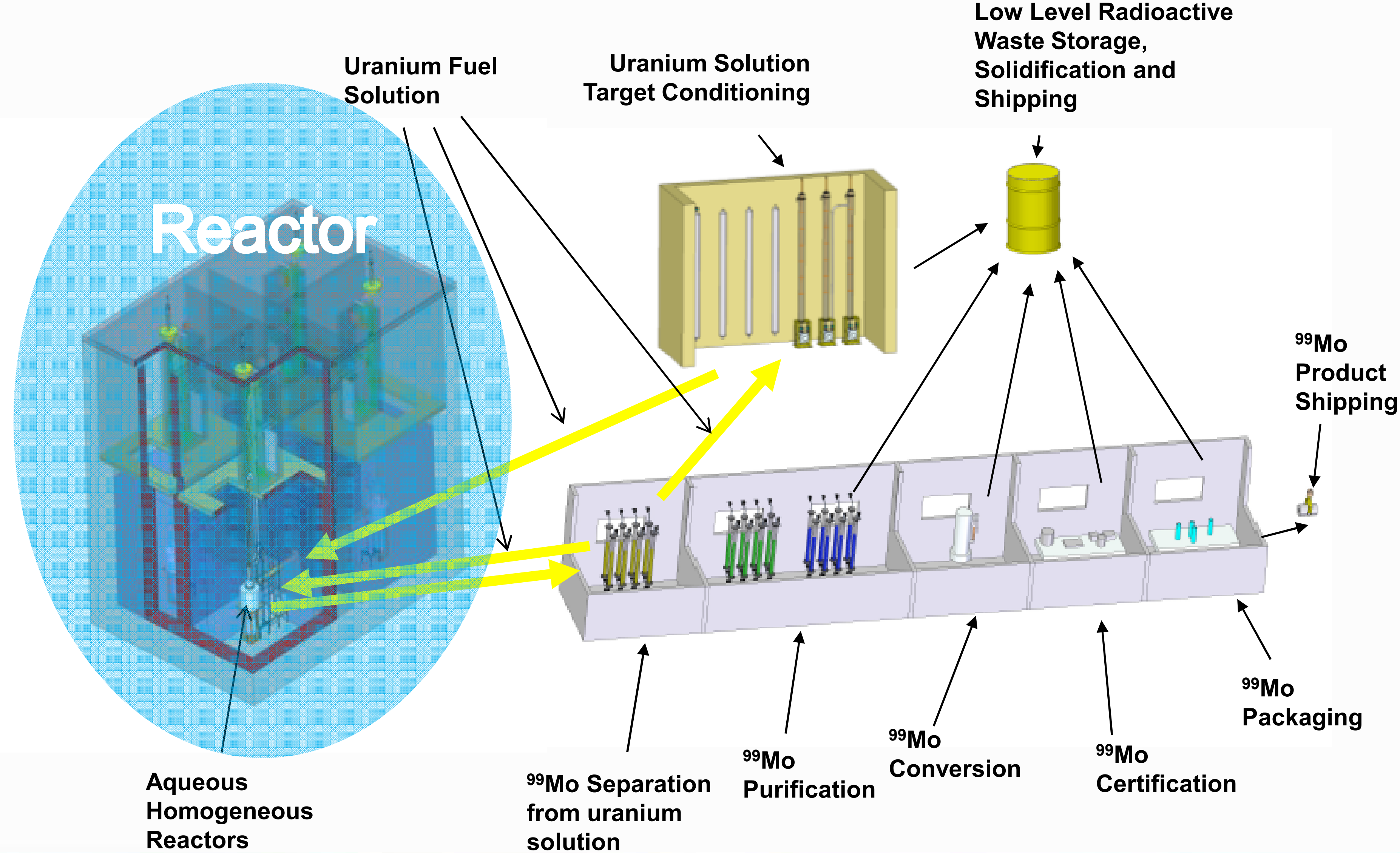
- Single license under 10CFR50
  - One-step process
- Determination MIPS is not production facility
- Licensing as non-power reactor under NUREG 1537
- Reactor license classification (103 Non-power)
- Waste classification

MIPS Site Selection Considerations

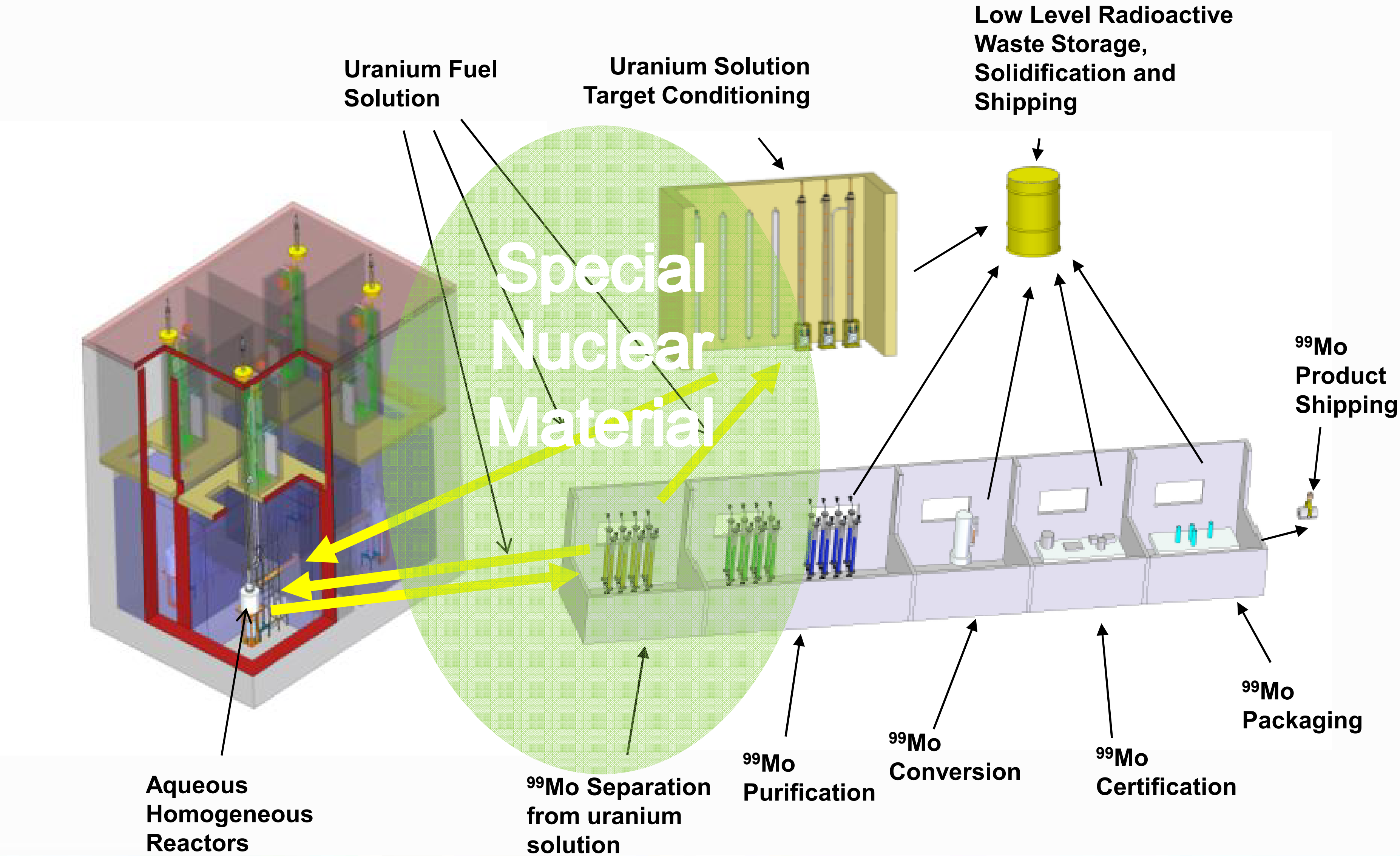
- Lynchburg VA – Mt. Athos
- DOE
- Other industrial

- Siting study - decision Fall of 2009
- Selection is key to moving forward with licensing and environmental report

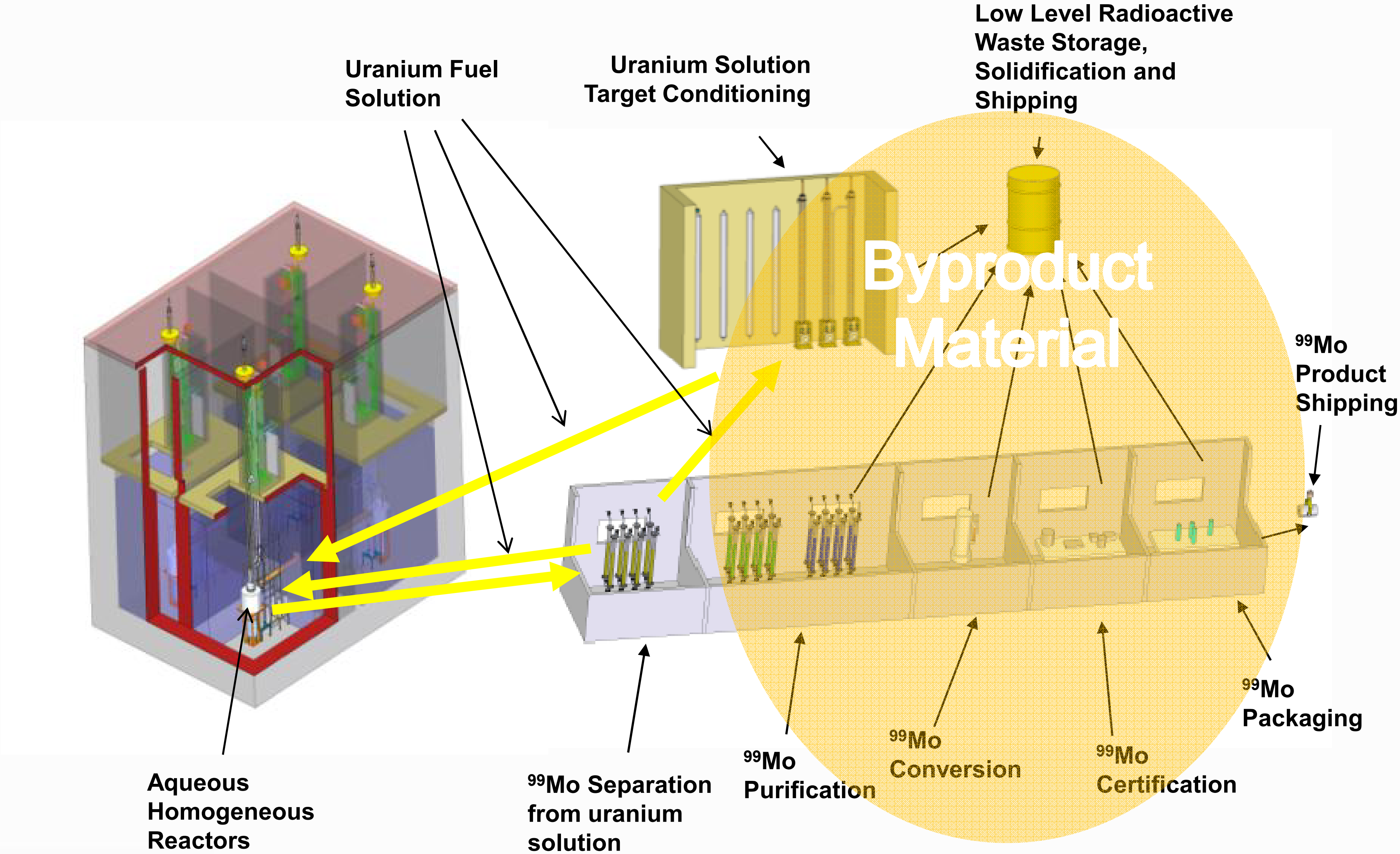
Process Flow For MIPS



Process Flow For MIPS



Process Flow For MIPS



Single Integrated License Application to Address All Aspects of the MIPS Facility

- Reactor: 10CFR 50
  - NUREG 1537 guidance for non-power reactor
- SNM Possession and Processing: 10CFR70
  - NUREG 1520 guidance for SNM facilities
- Byproduct Material: 10CFR30 (agreement state)

Contents of Application

- Environmental Report
  - NUREG 1555 (tailored for non-power reactor)
- Safety Analysis Report
  - Content from NUREG 1537 and 1520 (next slide)
- Other Licensing Documents
  - Emergency Plan
  - Material Control and Accounting Plan(s)
  - Security Plan(s)

License Application Content Matrix

Chapter 1 Example of Safety Analysis Report

1	Facility	1	Facility
1.1	Introduction	1.1	Introduction
		1.00	GENERAL INFORMATION
1.2	Summary and conclusions on principal safety considerations	1.2	Summary and conclusions on principal safety considerations
1.3	General description of facility	1.3	General description of facility
		1.1	FACILITY AND PROCESS DESCRIPTION
		1.2	INSTITUTIONAL INFORMATION
1.4	Shared facilities and equipment	1.4	Shared facilities and equipment
1.5	Comparison with similar facilities	1.5	Comparison with similar facilities
1.6	Summary of operations	1.6	Summary of operations
1.7	Compliance with 1982 NWPA	1.7	Compliance with 1982 NWPA
		1.8	Renewal only

(green)	Rx Licensing Content per NUREG 1537
(blue)	Fuel Facility Licensing per NUREG 1520

Example of License Application Content Matrix

Chapter 12 Example of Safety Analysis Report

12	Conduct of Operations	12	Conduct of Operations
12.1	Organization	12.1	Organization
		2	ORGANIZATION AND ADMINISTRATION
		12.1.1	Structure
		12.1.2	Responsibility
		12.1.3	Staffing
		12.1.5	Radiation safety
12.2	Review and audit activities	12.2	Review and audit activities
		11.3.5	AUDITS AND ASSESSMENTS
		12.2.1	Composition and qualification
		12.2.2	Charter and rules
		12.2.3	Review function
		12.2.4	Audit function
		11.3.6	INCIDENT INVESTIGATIONS
12.3	Procedures	12.3	Procedures
		12.31	CHECKLIST FOR PROCEDURES
		11.3.4	PROCEDURES
12.4	Required actions	12.4	Required actions
12.5	Reports	12.5	Reports
12.6	Records	12.6	Records
			RECORDS
			EXAMPLES OF RECORDS
		11.3.7	RECORDS MANAGEMENT
12.7	Configuration Management & Change Control(CM)	11.3.1	CONFIGURATION MANAGEMENT (CM)
12.8	Maintenance	11.3.2	MAINTENANCE
12.9	Selection and training of personnel	12.1.4	Selection and training of personnel
		11.3.3	TRAINING AND QUALIFICATIONS
12.10	Quality Assurance	12.9	Quality Assurance
		11.3.8	OTHER QA ELEMENTS
12.11	Operator training and qualification	12.10	Operator training and qualification
12.13	Startup plan	12.11	Startup plan

(green)	Rx Licensing Content per NUREG 1537
(blue)	Fuel Facility Licensing per NUREG 1520

Proposed Safety Analysis Report Content

Chapter Number	SAR Chapter Title
1	Facility
2	Site Characteristics
3	Design of Structures Systems and Components
4	Reactor Description
5	Reactor Coolant Systems
6	Engineered Safety Features
7	Instrumentation and Control Systems
8	Electrical Power Systems
9	Auxiliary Systems
10	Experimental Facilities and Utilization
11	Radiation Protection Program and Waste Management
12	Conduct of Operations
13	Reactor Accident Analysis
14	Technical Specifications
15	Financial Qualifications
16	Other License Considerations
17	Decommissioning
18	HEU to LEU Conversion
19	Nuclear Criticality Safety
20	ISA Summary

MIPS Project Schedule

What We Have Learned About Timeline

- World ^{99}Mo situation is pressing schedule
- Design and construction drive schedule
- Two-step licensing process better aligned with engineering timeline
  - Environmental Report and Construction Permit Application can be done sooner
  - Operating Application will be more complete and detailed when submitted later, resulting in fewer questions during the review

Potential for Project Acceleration

- DOE Cooperative Agreement Program
  - Accelerated production
  - B&W submitted application to DOE 7/7/09
  - NRC alignment necessary
- Corporate desire to accelerate
  - Global shortage of ^{99}Mo draws focus

Acceleration Assumptions
Construction Permit Application

- Submit Environmental Report (ER) early to allow for appropriate review and stakeholder engagement
  - Assumes a “characterized” site with existing environmental documents to build upon
- Submit Construction Permit Application (PSAR and Preliminary Plans) 6 months after ER
  - Level of detail “adequate and sufficient” to authorize construction
- Assuming quality submittals, Construction Permit issued 18 months after ER submittal (12 months after PSAR)

Acceleration Assumptions
Operating License Application

- Submit Operating Application (FSAR and Final Plans)
  - Detailed for complete NRC review to authorize operation
- Submit Updated Environmental Report
- Operating License issued 18 months after application submittal

Acceleration Milestones

- Submit Environmental Report – Jan 2010
- Submit Construction Permit Application – Sep 2010
  - Current planned application in late 2010
- NRC to issue Construction License – Sep 2011
- Submit Operating License Application – Oct 2011
- NRC to issue Operating License – Mar 2013

Actions and Path Forward

For Discussion During Meeting

Application and Schedule

- NRC disposition of licensing questions currently being reviewed key to this approach
- NRC feedback on accelerated schedule
- Discuss process for alignment on application content and level of detail in construction and operating application
- Waste Disposition – alignment with DOE

For Discussion During Meeting
Technical Information

- Early information that would facilitate the process
  - Maximum hypothetical accident analysis
  - Early submittal of QA plan (ANSI 15.8)
  - AHR learning curve (DOE Information and data)
  - Others ?

Conclusion

Opportunity

- Fill vital need for ^{99}Mo while reducing the proliferation risks associated with HEU
- Project acceleration driven by Congressional, DOE and corporate motivations addressing national priority
- Continue long history of B&W and NRC working together to assure high quality licensing submittals and reviews
- Simplicity and safety offer high success probability

Challenge

- Expedite engineering design, accelerate construction, transition to safe operations
- Resources to assure timely and efficient licensing
- Effective communications
- Full operation December 2013
- Get it right the first time

Thank You

Questions?

Backup Slides

MIPS is Not a Production Facility

- Although MIPS meets criteria 3 of 10CFR50, it is clear that it is not designed nor could it be modified to produce a significant amount of SNM. Therefore, MIPS should only be classified as a utilization facility with a single 10CFR Part 50 license
- There will be no difference in the licensing requirements under single 10CFR50 license if it is not classified as a production facility, but it will eliminate any confusion for members of the public or Congressional oversight committees

Licensing as Non-power Reactor

- Definitions
  - 10CFR50: Non-power Reactor defined as R&D (MIPS not R&D)
  - 10CFR100: Power Reactor defined to produce electrical or heat energy (MIPS not Power Reactor)
  - 10CFR50 Testing Facility defined as R&D if less than certain power levels (MIPS not Testing facility, however it is below power thresholds)
  - While MIPS fits no existing **defined** reactor type, it is a non-power reactor
- Requested Action
  - NRC conclude that MIPS will be handled as a non-power and NUREG 1537 will be used by the NRC staff for license reviews

Licensing as Non-power Reactor

- Technical Basis and Merit
  - MIPS is clearly a low power facility that is below the power level criteria of a reactor that is a testing facility
  - NUREG 1537 recognizes non-power reactor might not be for R&D
  - MIPS does not pose risks of a power reactor
  - NUREG 1537 provides a framework to apply risk-informed decisions to assure appropriate safety and safeguards to protect public health and safety

Reactor License Classification

- Class 104 License
  - Medical Therapy (MIPS not used directly in medical therapy although it directly supports medical diagnostic procedures that support medical therapy)
  - Research and Development (MIPS does not meet the 50% cost of owning and operating facility criteria for R&D)
- Class 103 License
  - Commercial and industrial facilities not meeting R&D financial criteria

Reactor License Classification

- Class 103 License
  - Commercial and industrial facilities not meeting R&D financial criteria
- Recommendation/Request
  - NRC conclude that MIPS will have a Class 103 license but use the non-power reactor licensing guidance in NUREG 1537 for the licensing reviews

Waste Considerations

- Used Liquid Fuel Waste (ULFW)
  - This will be generated at end of useful liquid fuel “load” life after many cycles of ^{99}Mo extraction. A fuel “load” is expected to last years.
- Fuel Cleanup Liquid Waste (FCLW)
  - This waste will be generated periodically as the liquid fuel “load” needs to be cleaned to remove fission products that, if allowed to build in over many cycles, could create quality or efficiency problems with ^{99}Mo extraction. Frequency of cleanup is being determined through development.

MIPS Reactor Module Test Required

Fluid-fueled reactor operating experience spans 62 years, involving over 35 reactors operating at powers from a few kW to 100 kW thermal:

- Good data available on stability limits, radiolytic gas production, corrosion behavior at a wide range of operating temperatures, fuel solution chemistry as a function of burn-up, response (power, pressure, temperature) to severe accident conditions, etc.
  - These reactors have proven inherently safe to large reactivity insertions as a result of large negative void and temperature coefficients and operation at over-moderated conditions.
  - Data is available to V & V, to NRC standards, a modern, coupled radiation transport– multi-phase computational fluid dynamics (CFD) code as required to accurately analyze normal, upset and accident conditions in a reactor such as MIPS.

MIPS Reactor Module Test Required

Work is nearing completion to acquire The FETCH code from the Applied Modeling and Computation Group, Imperial College, UK., customized and V&V'd for MIPS reactor analysis:

- FETCH has been applied to a wide-variety of complex, multi-phase fluid systems with good results and excellent acceptance world-wide.
- The code is being modified to permit accurate treatment of radiolytic gas generation, localized boiling, explicit modeling of cooling coils, etc.
- It will be benchmarked to steady-state and transient fluid-reactor operating data and to NRC-approved Monte-Carlo transport code results.

The NRC will be asked to approve an approach to first module operation in which an incremental ascension to power plan is executed during reactor commissioning to verify predicted performance:

- First-module "prototype" plan to be presented to the NRC early in the licensing process.
- The first module will be heavily instrumented to acquire appropriate data and assure safe approach to power, including instrumentation to monitor reactor stability employing random noise techniques.