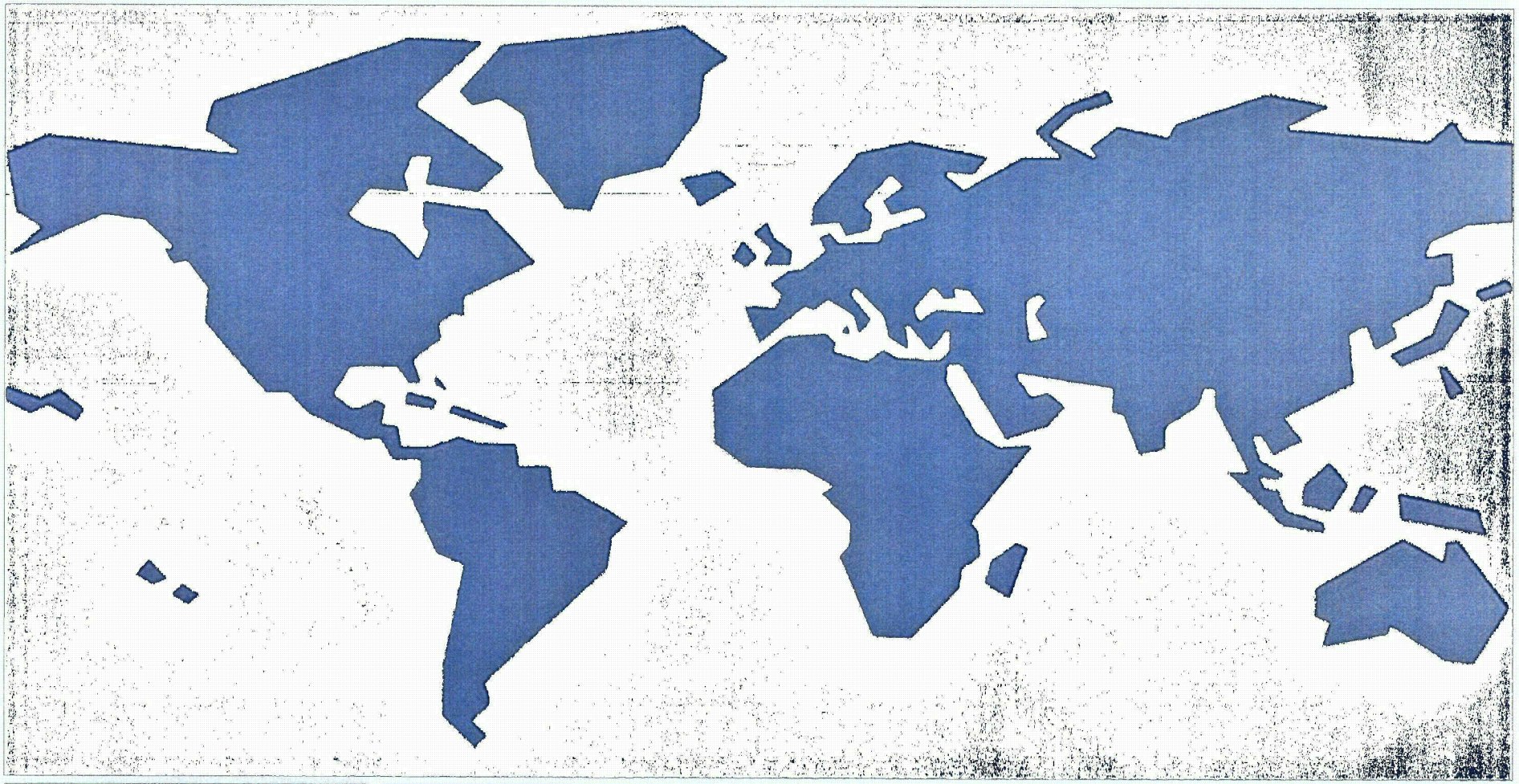
U.S. DEPARTMENT OF ENERGY

Defense Nuclear Nonproliferation

Global Threat Reduction Initiative

National Nuclear Security Administration

Defense Nuclear Nonproliferation



DOE/NNSA Efforts to Support the Domestic Production of Mo-99

May 11, 2012

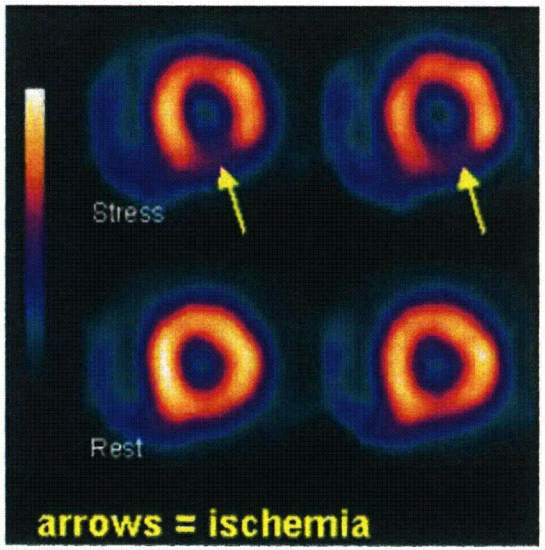
U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration
Defense Nuclear Nonproliferation

Mo-99 Policy Objectives*

Balance improving nuclear security with maintaining a reliable medical isotope supply.

- Ensure reliable supply of Mo-99 for 30 million worldwide patients annually
- Eliminate HEU use in Mo-99 production
- End subsidies and establish an economically-sound industry



* Excerpt from Office of Science and Technology Policy presentation at December 4-7, 2011 Topical Meeting in Santa Fe, NM.

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National Nuclear Security Administration
Defense Nuclear Nonproliferation

GTRI Mission & Program Goals

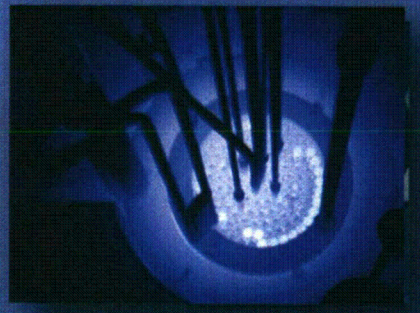
MISSION

REDUCE AND PROTECT VULNERABLE NUCLEAR AND RADIOLOGICAL MATERIAL LOCATED AT CIVILIAN SITES WORLDWIDE.

GOALS

1. CONVERT
2. REMOVE
3. PROTECT

CONVERT



CONVERT RESEARCH REACTORS AND ISOTOPE PRODUCTION FACILITIES FROM THE USE OF HIGHLY ENRICHED URANIUM (HEU) TO LOW ENRICHED URANIUM (LEU)

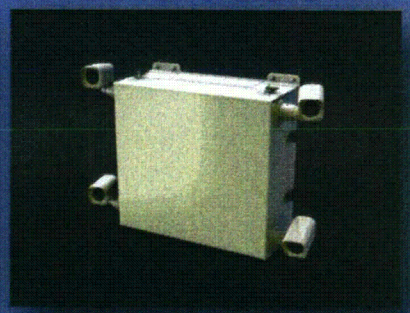
THESE EFFORTS RESULT IN PERMANENT THREAT REDUCTION BY MINIMIZING AND, TO THE EXTENT POSSIBLE, ELIMINATING THE NEED FOR HEU IN CIVILIAN APPLICATIONS – EACH REACTOR CONVERTED OR SHUT DOWN ELIMINATES A SOURCE OF BOMB MATERIAL.

REMOVE

REMOVE AND DISPOSE OF EXCESS NUCLEAR AND RADIOLOGICAL MATERIALS.

THESE EFFORTS RESULT IN PERMANENT THREAT REDUCTION BY ELIMINATING BOMB MATERIAL AT CIVILIAN SITES – EACH KILOGRAM OR CURIE OF THIS DANGEROUS MATERIAL THAT IS REMOVED REDUCES THE RISK OF A TERRORIST BOMB.

PROTECT



PROTECT HIGH PRIORITY NUCLEAR AND RADIOLOGICAL MATERIALS FROM THEFT AND SABOTAGE.

THESE EFFORTS RESULT IN THREAT REDUCTION BY IMPROVING SECURITY ON THE BOMB MATERIAL REMAINING AT CIVILIAN SITES – EACH VULNERABLE BUILDING THAT IS PROTECTED REDUCES THE RISK UNTIL A PERMANENT THREAT REDUCTION SOLUTION CAN BE IMPLEMENTED.

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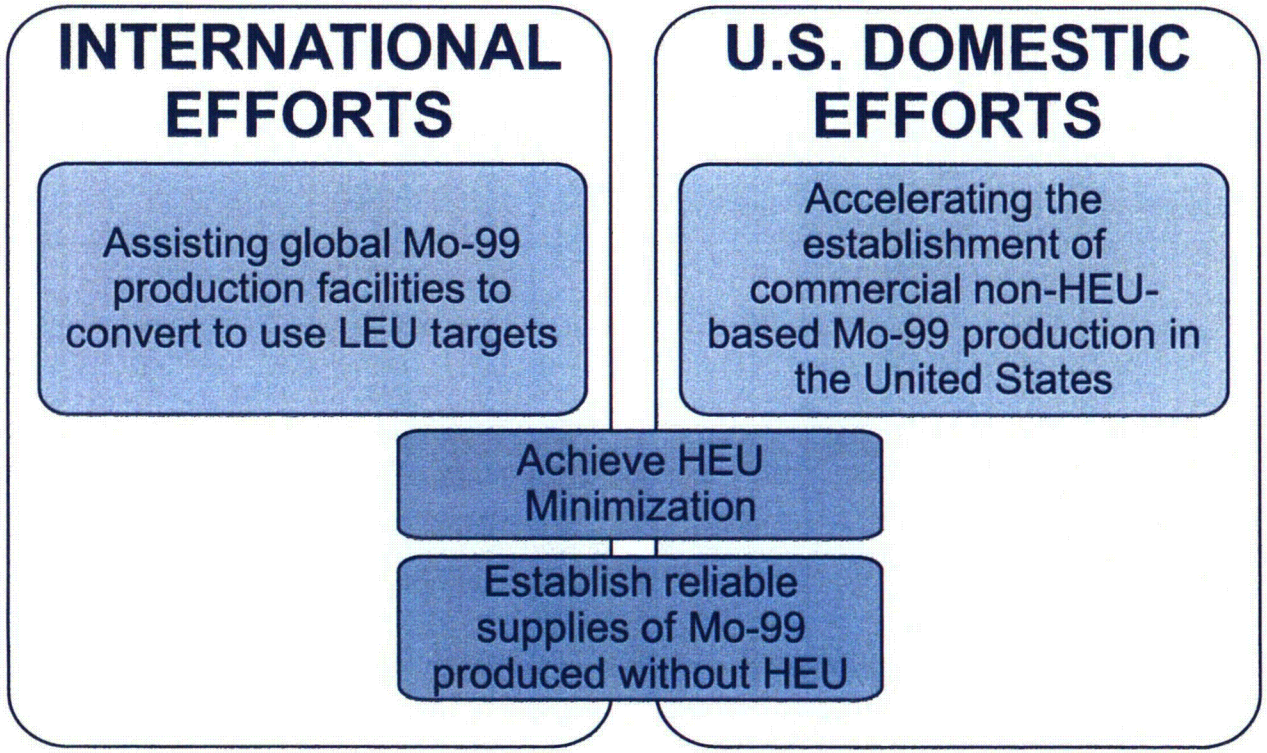
Defense Nuclear Nonproliferation

GTRI & Mo-99

International & U.S. Domestic Approaches

- Under its long-standing HEU minimization mission, GTRI provides assistance to research reactors and isotope production facilities to convert from the use of HEU to LEU.
- GTRI's mission includes accelerating the establishment of a reliable U.S. domestic supply of Mo-99 produced without the use of HEU.



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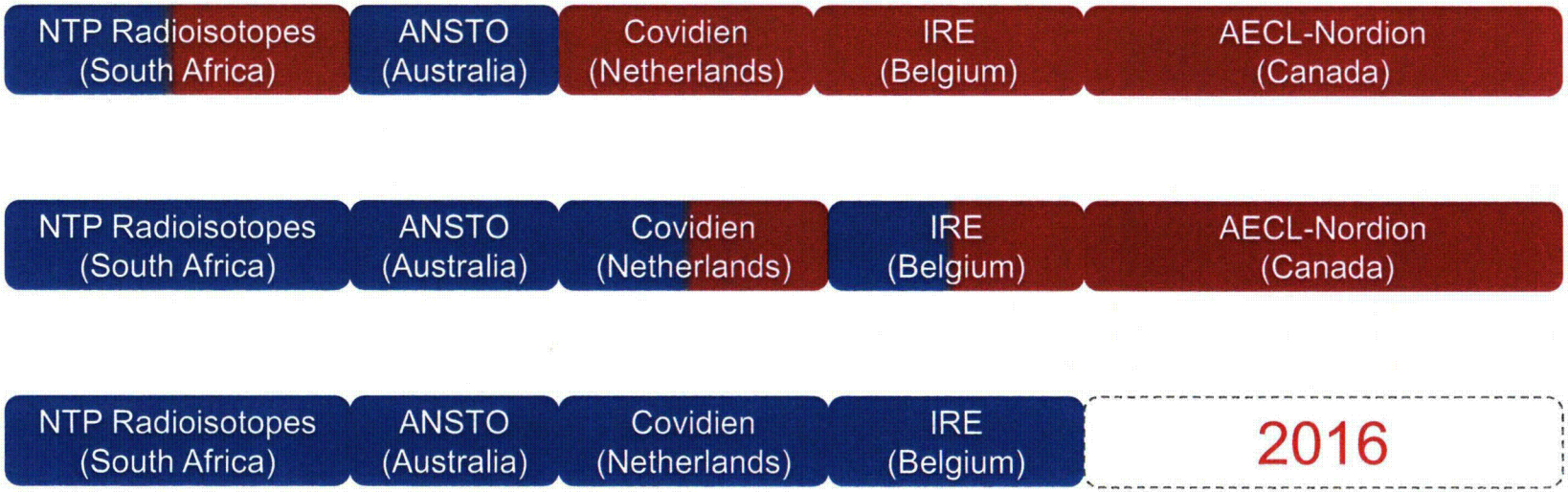
GTRI & Mo-99

National Nuclear Security Administration
Defense Nuclear Nonproliferation

Strategy for Reliable Non-HEU-Based Mo-99 Supply

Global Mo-99 Market – Major Producers

HEU | Non-HEU



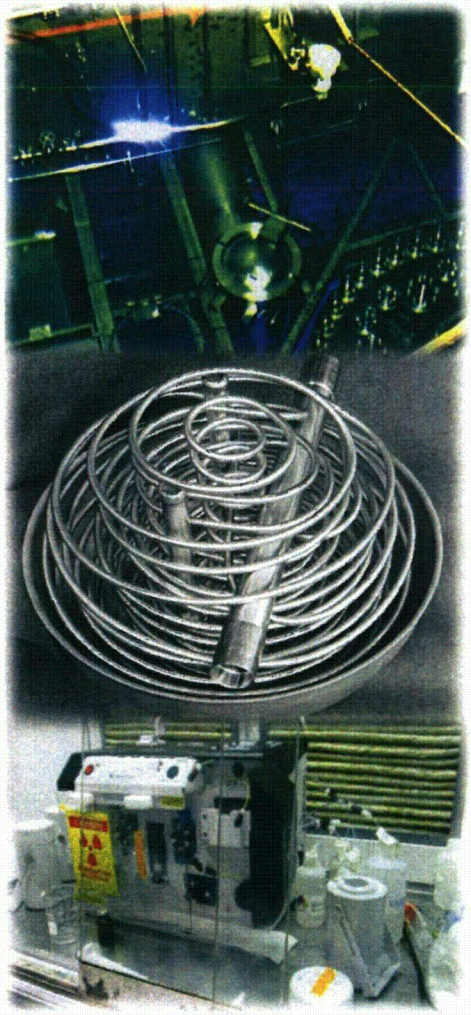
U.S. Domestic Mo-99 Projects

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration
Defense Nuclear Nonproliferation

GTRI and U.S. Domestic Mo-99:
Cooperative Agreement Partners

Objective: To accelerate existing commercial projects to meet at least 100% of the U.S. demand of Mo-99 produced without HEU.



Neutron Capture:

- On September 30, 2009, NNSA awarded a cooperative agreement to General Electric-Hitachi for $2.3M to pursue neutron capture technology. On February 7, 2012, GEH announced its business decision to suspend progress on the project indefinitely due to market conditions.

LEU Solution Reactor Technology:

- On September 30, 2009, NNSA awarded a cooperative agreement to Babcock and Wilcox (B&W) for $9.1M to pursue the LEU solution reactor technology.

Accelerator Technology:

- On September 29, 2010, NNSA awarded a limited-scope cooperative agreement to NorthStar Medical Radioisotopes, LLC for $500,000 to pursue accelerator technology. On September 19, 2011, NNSA awarded an additional cooperative agreement for $2.3M.

- On September 29, 2010, NNSA awarded a limited-scope cooperative agreement to Morgridge Institute for Research for $500,000 to pursue accelerator technology. On April 30, 2012, NNSA awarded an additional cooperative agreement for $10.2M.

Each cooperative agreement project is currently limited to $25M, under a 50% - 50% cost-share arrangement.

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration
Defense Nuclear Nonproliferation

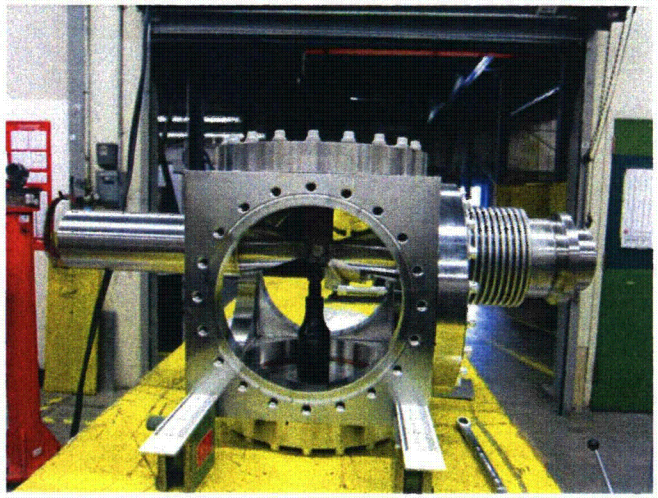
U.S. National Laboratories Support to Mo-99 Production

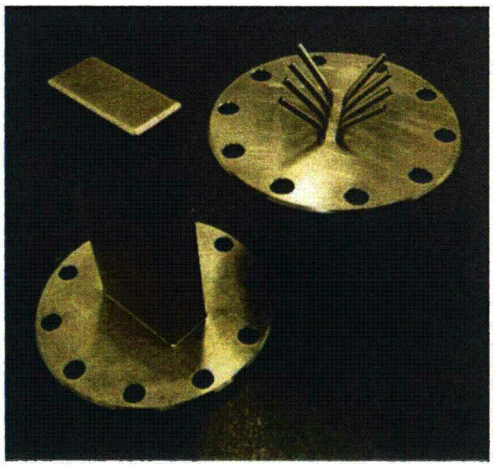
GTRI makes the expertise of the U.S. National Laboratories available to:

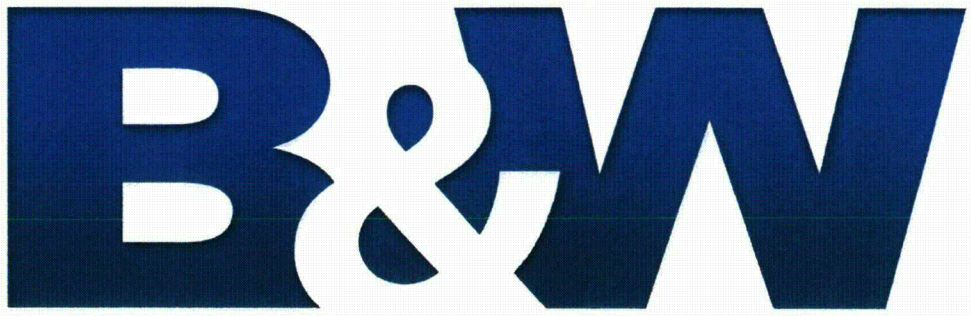
- Support technical development of each of the Mo-99 technical pathways
- Ensure the expertise at the national laboratories is available to support the acceleration of commercial projects using non-HEU technologies

All work packages funded by NNSA outside the cooperative agreement are open-sourced, non-proprietary, non-critical-path activities.

If requested, the work conducted by the laboratories outside of the cooperative agreements is available to help inform the NRC.







technical services group

B&W Medical Isotope Production System (MIPS)

May 11, 2012

R.J. (Randy) Spickard,

Vice President of Corporate Development

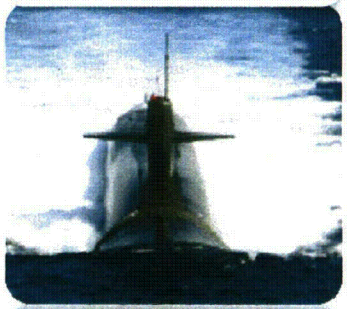
The Babcock & Wilcox Company

Government Operations

B&W Technical Services Group, Inc.

Manages and operates high-consequence facilities, provides technical services and support to government agencies and private customers

B&W Nuclear Operations Group, Inc.



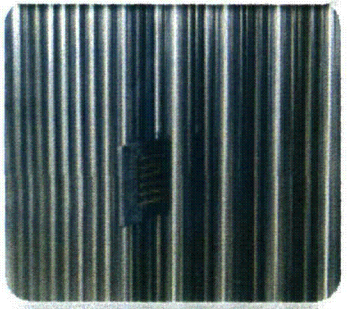
Manufactures nuclear components for U.S. Department of Energy

Power Generation Systems

B&W Power Generation Group, Inc.

Manufactures and services coal, biomass, CNG, concentrated solar power plant equipment, & Nox, Sox, mercury scrubbers

B&W Nuclear Energy , Inc.



Manufactures commercial nuclear components and provides services to commercial nuclear market

B&W mPower

Design, license & qualify B&W mPower™ SMR

High-Consequence Operations & Services

Advanced Engineering and Manufacturing

Covidien Reaches Globally and Locally

- 20,000+ U.S. employees, 41,000+ worldwide
- Diverse healthcare products used in all clinical settings
- Products manufactured in 17 states

Nuclear Medicine:

- One of two U.S. suppliers of technetium 99m (Tc 99m)
- Covidien Tc 99m-based products sold in all 50 states

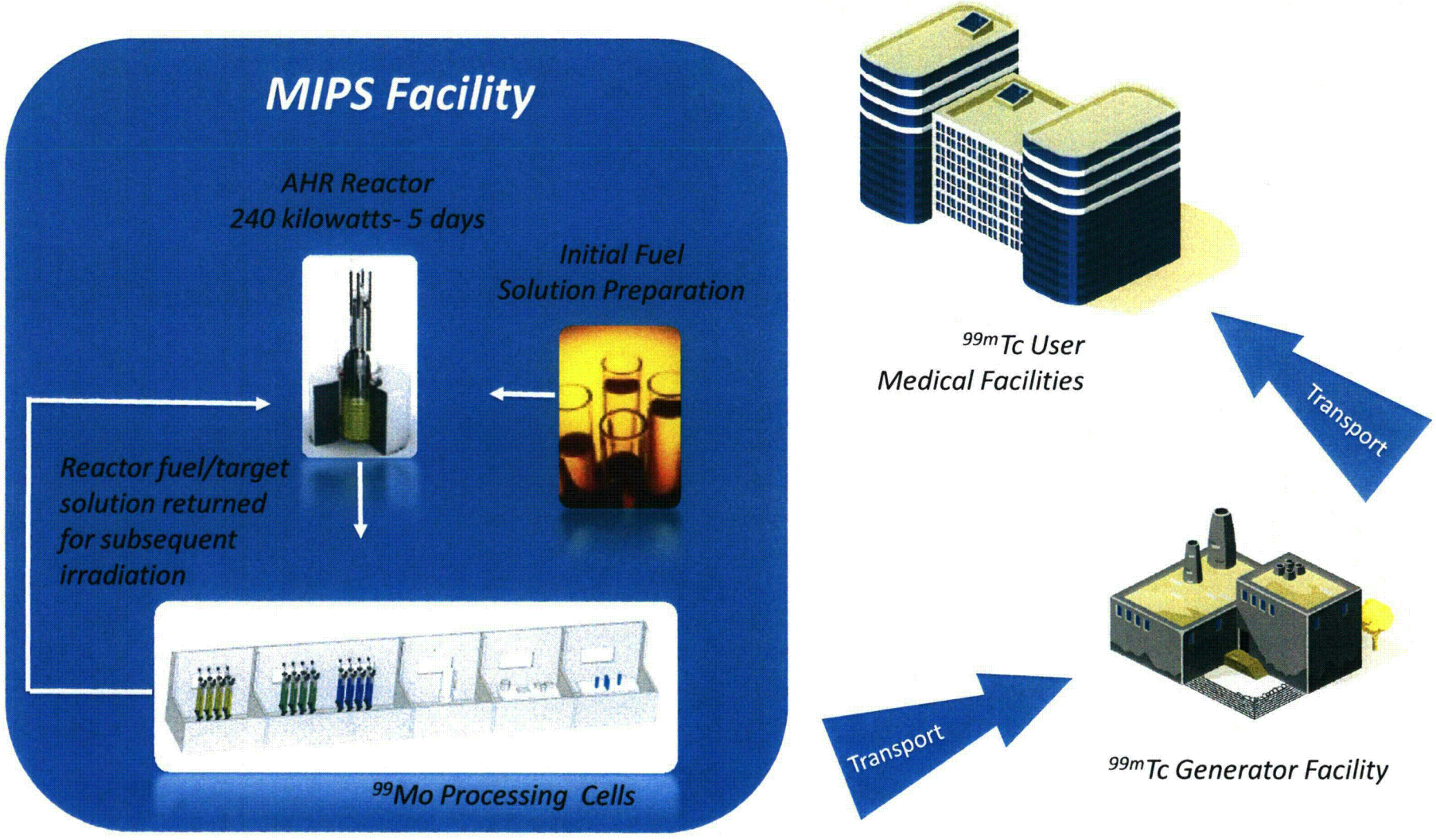
Image courtesy of Covidien

COVIDIEN

^{99}Mo Production Using Aqueous Homogeneous Reactor (AHR)

- Market studies in Late 1990s
- 2007 MIPS project re-initiated
- 2009 Agreement with Covidien
- 2009 Cooperative Agreement with NNSA
  - Non-proliferation (LEU)
  - Domestic supply

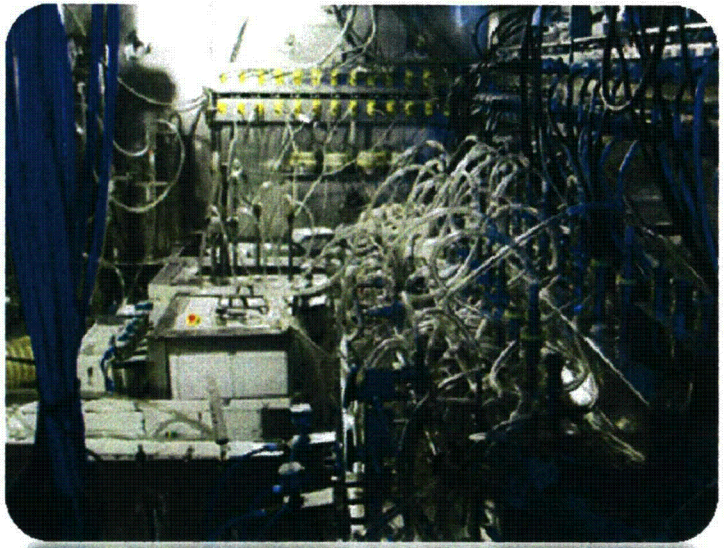
B&W MIPS Technology



Completed R&D and Conceptual Design Phase of Project

- National Laboratories
  - Argonne
  - Los Alamos
- Armed Forces Radiobiology Research Institute, MD
- Purdue University
- B&W Labs, VA
- INVAP, Argentina

Extraction and purification experimental hot cell, INVAP, S.E.



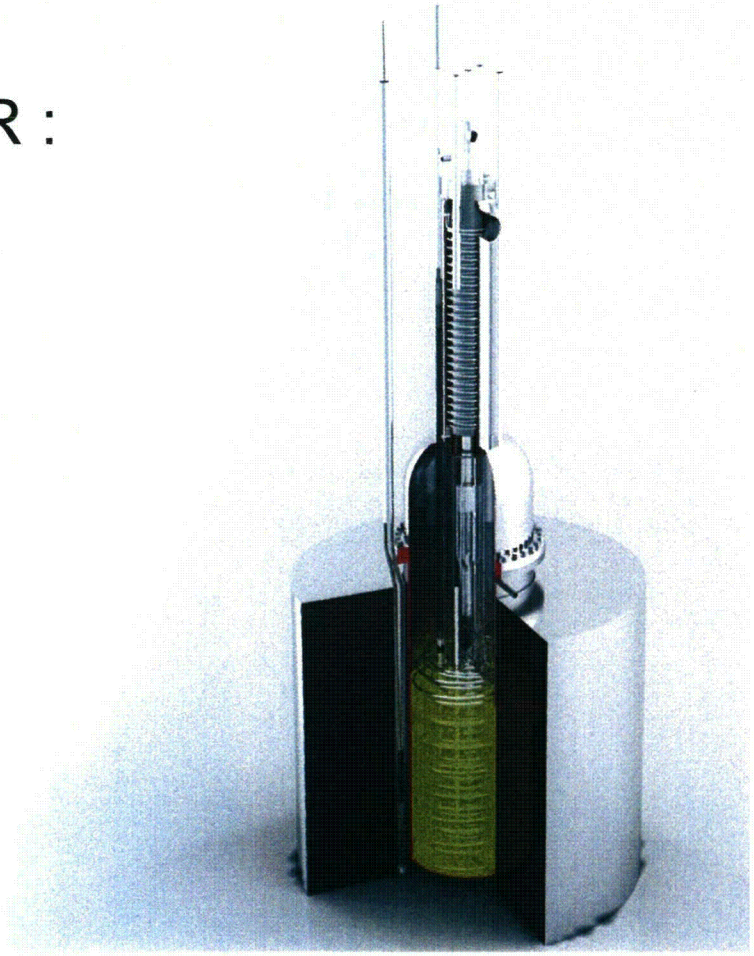
MIPS Path Forward

- Licensing Approach (SECY-09-0101 Policy)
  - Single license under 10CFR50
  - MIPS is both utilization (reactors) and production (processing) facility
  - Reactors are considered non-power reactors
  - Construction permit and operating license required
  - Waste other than Used Liquid Fuel is Low Level Radioactive Waste
- Preliminary design, environmental report and construction application
- Final design and operating application
- Construction, commissioning and FDA approval

B&W MIPS Summary

Production of ^{99}Mo using LEU AHR :

- Increased efficiency
- Reduced waste
- No proliferation concerns
- Safe operation
- Stable domestic supply of ^{99}Mo



Briefing on Potential Medical Isotope Production Licensing Actions Coquí RadioPharmaceuticals Corp.

Topic: Coqui's current status for the production of Mo-99.

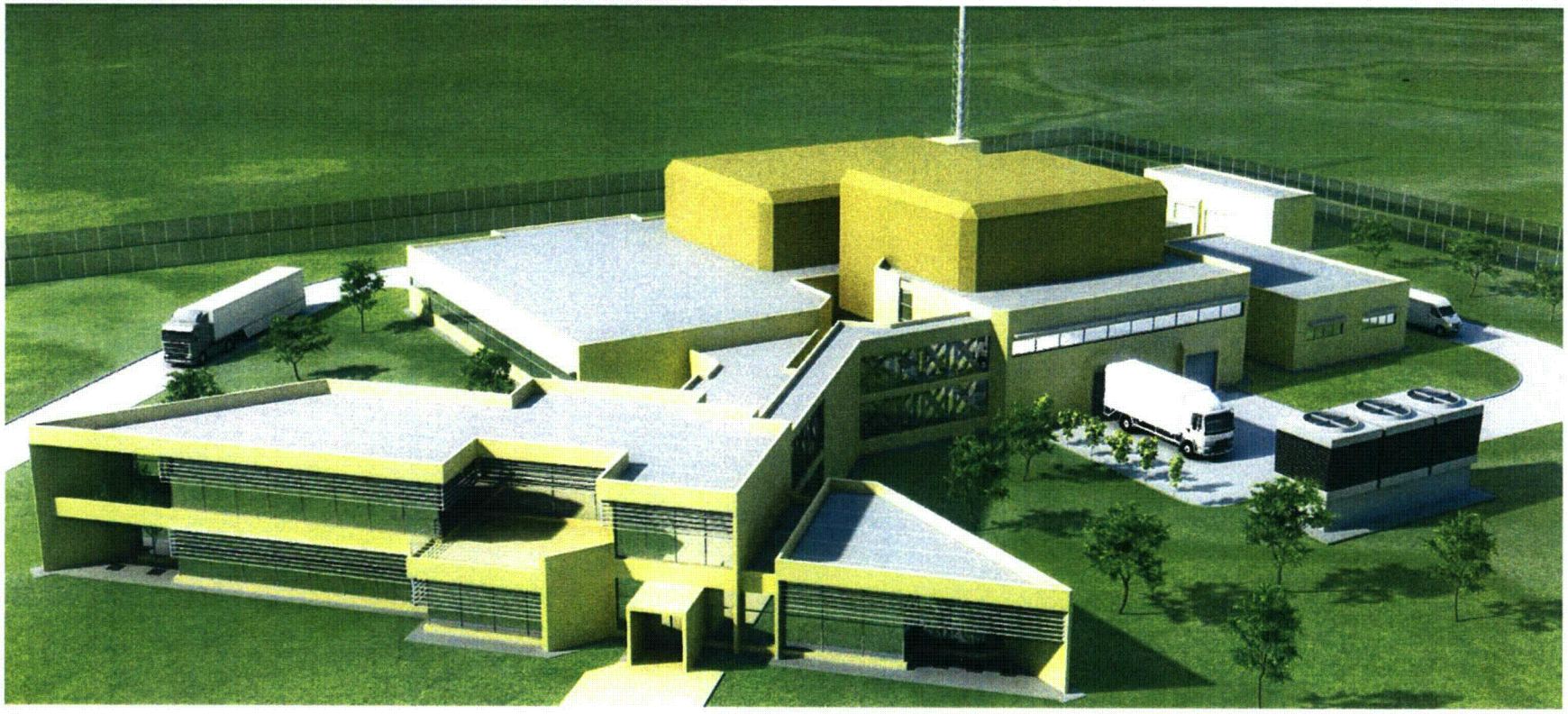
Carmen Irene Bigles, President/ CEO

May 11th Nuclear Regulatory Commission

Acronyms

- NRC – Nuclear Regulatory Commission
- Coquí - Coquí RadioPharmaceuticals Corp.
- MIPF - Medical Isotope Production Facility
- ER - Environmental Report
- Mo-99 - Molybdenum 99
- FDA – Food and Drug Administration
- GTRI – Global Threat Reduction Initiative
- LEU – Low Enriched Uranium

Coquí RadioPharmaceuticals Corp.



Coquí Commercial Domestic Producer

- **Supply Capacity**: 100% U.S. market
- **First Private Sector Producer:** Supply chain outages and decommissioning of existing reactors and the looming price increases assure transition of Mo-99 production from government to the private sector

- **<u>Timing of Transition:</u>** without proven technology, private sector commercial scale production in the U.S. could be delayed causing Mo-99 to be scarce in the U.S. together with substantial price and demand increases.

Coquí's Technology

- **<u>Supporting GTRI with Proven LEU Technologies</u>**: LEU reactor fuel and fission targets and radiochemical process, currently used in Australia, Argentina and South Africa
- **<u>INVAP:</u>** proven designs successfully executed worldwide.

- **FDA Approved Product:** Our end product is the same already approved by the FDA that is subsequently imported to the U.S. for patient use.
- **Capacity:** production design objective is 7,000 Six-Day Curies per Week and allows for maintenance and refueling downtime assuring stable supply.

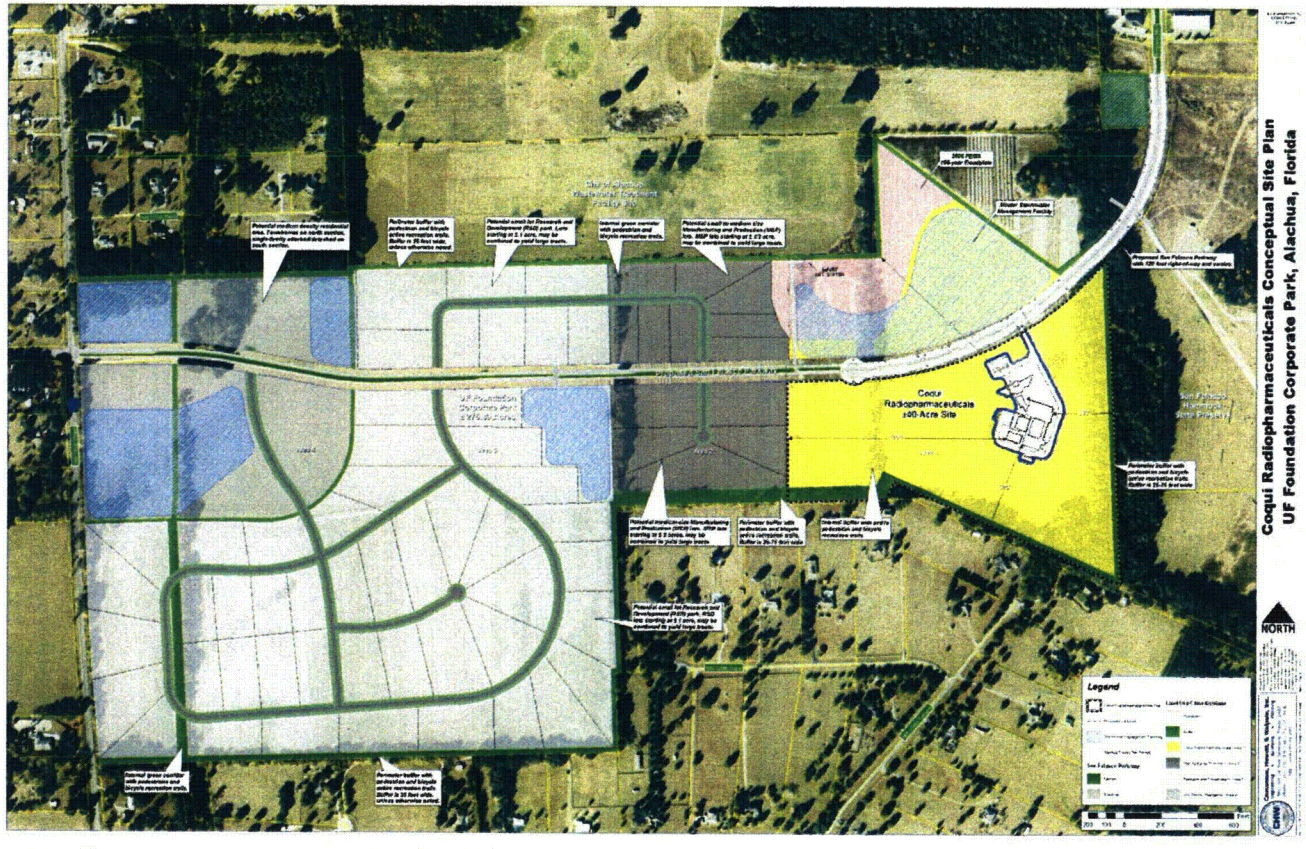
Application Status

- March 15, 2010: Coquí submitted a Letter of Intent to the NRC indicating its intention of submitting an application to License the MIPF
- May 2010: Coquí submitted its first licensing strategy document to the NRC

- June 2010: Coquí submitted its second licensing strategy document to the NRC, which provided for the NRC staff's review a Safety and Licensing Plan for the technical portions of the application
- September 2010: The NRC responded to these submittals providing Coquí with important information on preparing its application

- October 2010: Coquí held its first public hearing at the NRC
- Currently: a sufficient amount of the technical portion of the application has already been prepared

Conceptual Site Layout



Site Selection

- **Site and Location:** Thanks to the efforts of Enterprise Florida, and the University of Florida Foundation a site has been chosen, which has been offered to Coquí by the Foundation
- **NUREG 1537 Compliance**
- **Status:** Phase I ER completed.

Financing

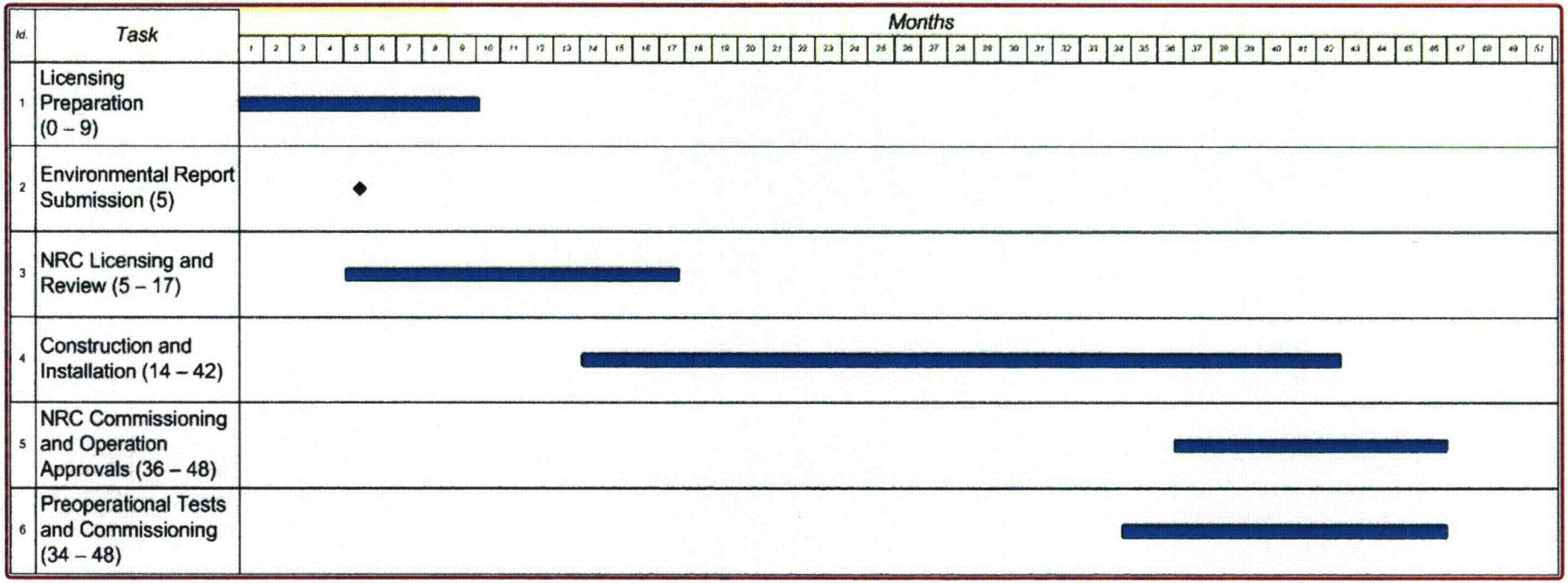
- **<u>Demand for Mo-99 = Price Increase:</u>**
  - continued increased worldwide demand
  - production shortfalls
  - scheduled decommissioning
- **<u>Investment Situation:</u>**
  - price increments will benefit the investment situation of proven Mo-99 production

Status: Coquí RadioPharmaceuticals Corp. is engaged in negotiations with investors to finance the licensing and the construction of the MIPF. Enterprise Florida also provided Coquí with a tax and workforce incentive package to establish the facility.

Moving Forward

- Coquí would like to take this opportunity to thank the NRC staff
- We are already well underway preparing our application, we have located a site and our technology is proven
- Long pole in the tent is financing. Once we have that lined up:
  - We will eagerly complete our NRC submittal

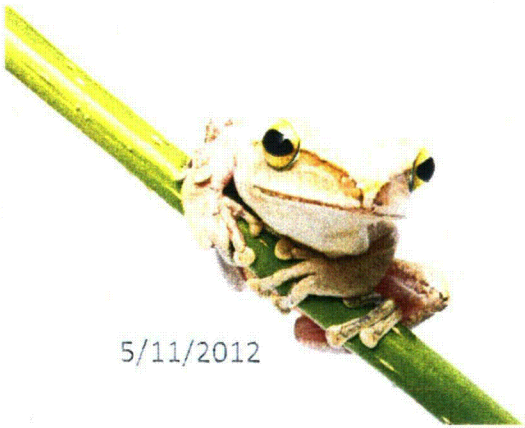
Time Line Financing in Place



Coquí RadioPharmaceuticals Corp.

Sustainable Design + Proven Technology + Finance = Saving Lives + Global Threat Reduction = A Better World

- Questions?



SHINE Medical Technologies Presentation to NRC(1): Status Update on Medical Isotope Facility

May 11, 2012

Gregory Piefer, Chief Executive Officer

SHINE Values and Culture

- **We share values with the NRC(1): Protect the health and safety of people and the environment**
- **SHINE recognizes it is impossible to operate business unless safety is paramount**
- **Will work with NRC(1) to ensure safety while achieving national priorities**

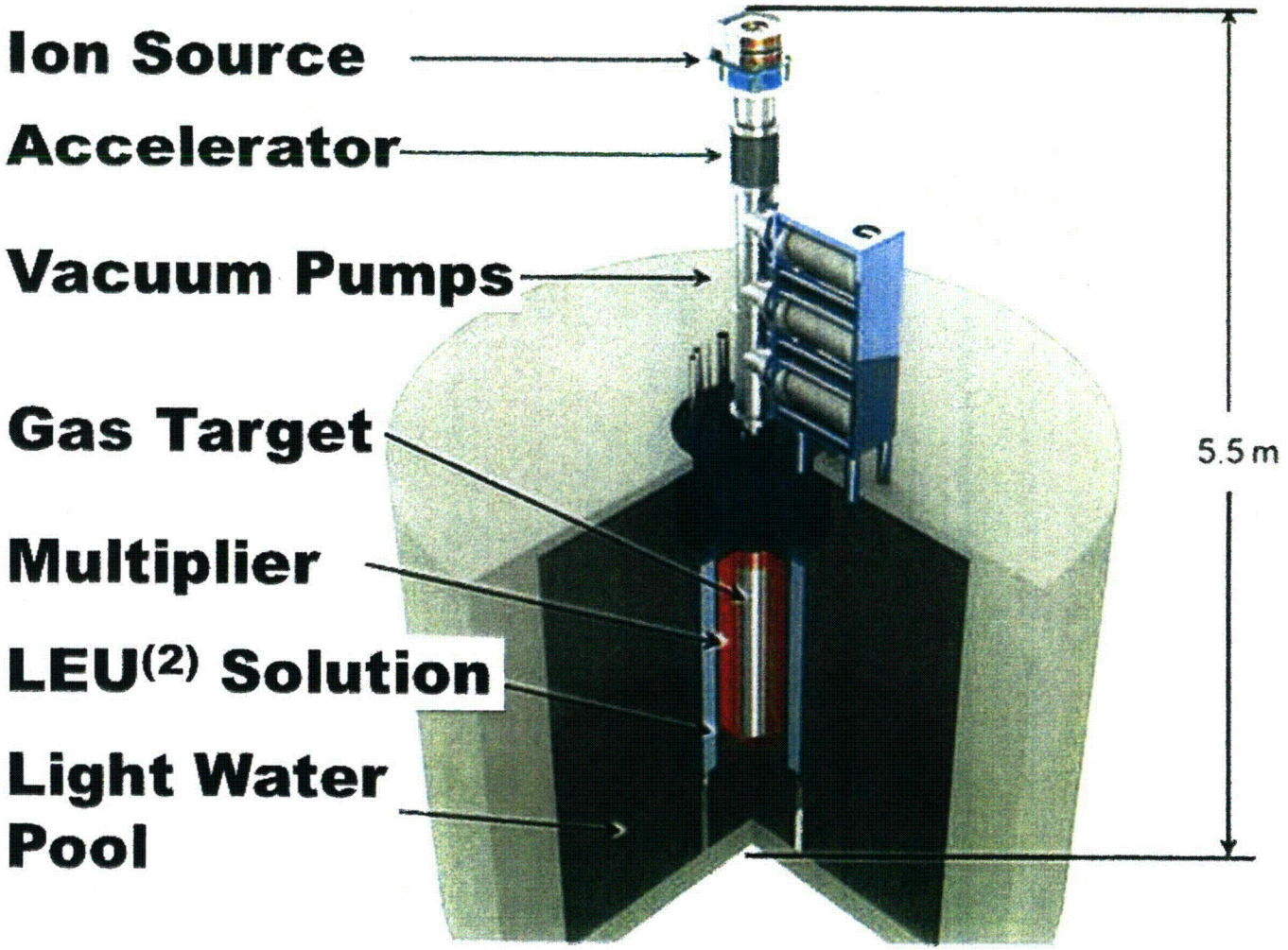
Company Background

- Created in 2010 to pursue the production of medical isotopes
- Motivated by new, eco-friendly, LEU(2) based technology and failure of existing supply chain
- Plan to be a world leader in the production of a range of medical isotopes (^{99}Mo, ^{131}I, ^{133}Xe, others)

Technology Overview

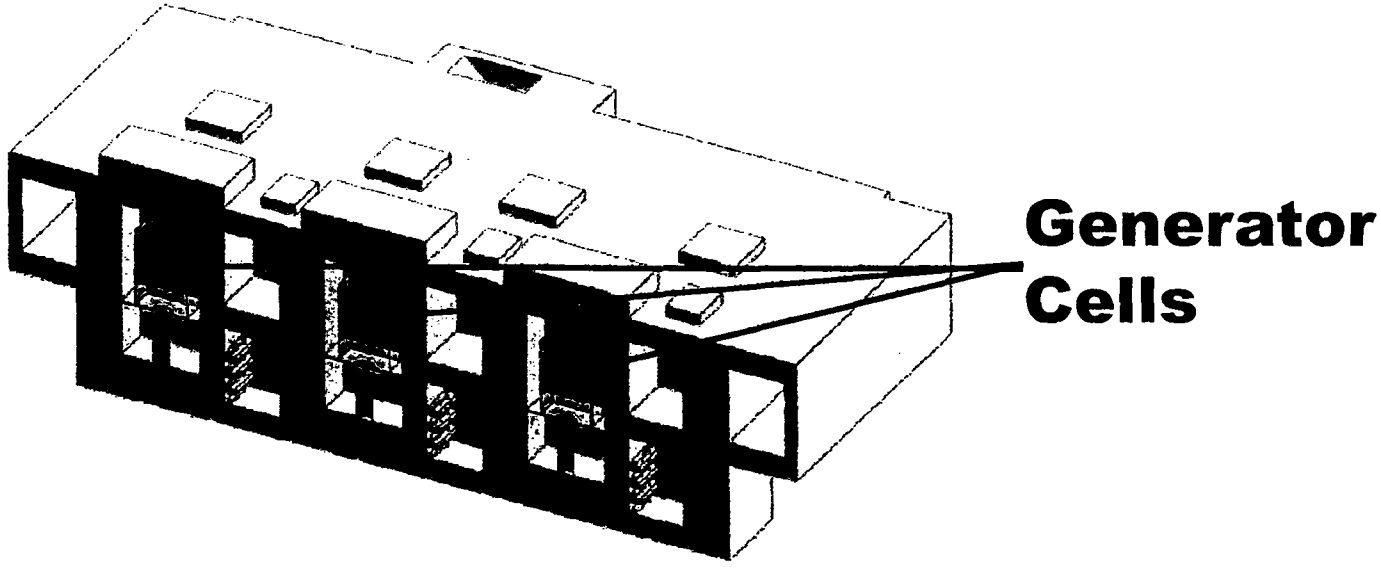
- Neutrons are produced by particle accelerator and pass into aqueous LEU[(2)] solution
- Neutrons induce subcritical fission in ^{235}U present in solution
- Fission creates medical isotopes
- After irradiation, isotopes of interest are isolated in chemical separation process

Isotope Generation System



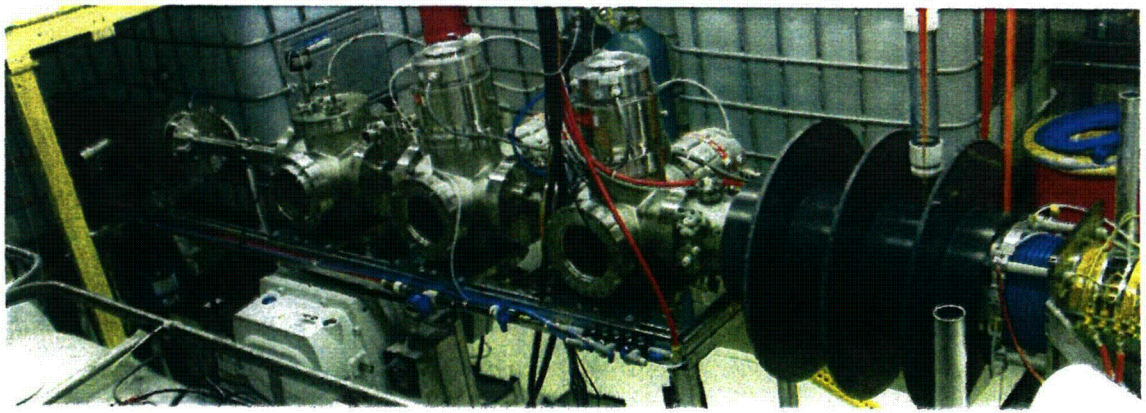
Generator Basic Specifications

- **Capacity: 10% U.S. need for ^{99}Mo**
- **Fission thermal power: ~ 100 kW each**
- **Facility will house multiple units**



Project Status

- Technology proof-of-concept done
- Team with extensive nuclear experience in place, growing
- Facility preliminary design started
- ER[4] submittal late 2012
- PSAR[3] submittal late 2012



Challenges

- **Regulatory structure for licensing is not mature, could lead to delays in approval**
- **National objectives call for rapid deployment of domestic supply**
  - **Short period of time before shortages will recur (2016 shutdown of NRU[5])**
  - **Shortages will lead to patient suffering, continued reliance on HEU[6]**

National Support Helpful So Far

- NNSA program has accelerated efforts to establish domestic supply, eliminate HEU
- NRC staff recognized need for supplemental guidance, released in draft form
- Inter-agency working groups have communicated the urgency and provided cross-agency integration

Continued Support Needed to Achieve National Priorities

- Elevate priority of medical isotope license actions in order to:
  - Prevent loss of healthcare tools which benefit millions of Americans annually
  - Support HEU[(6)] minimization
  - Establish domestic supply
- Ensure NRC staff has resources required for expeditious, complete review

Our Perspective

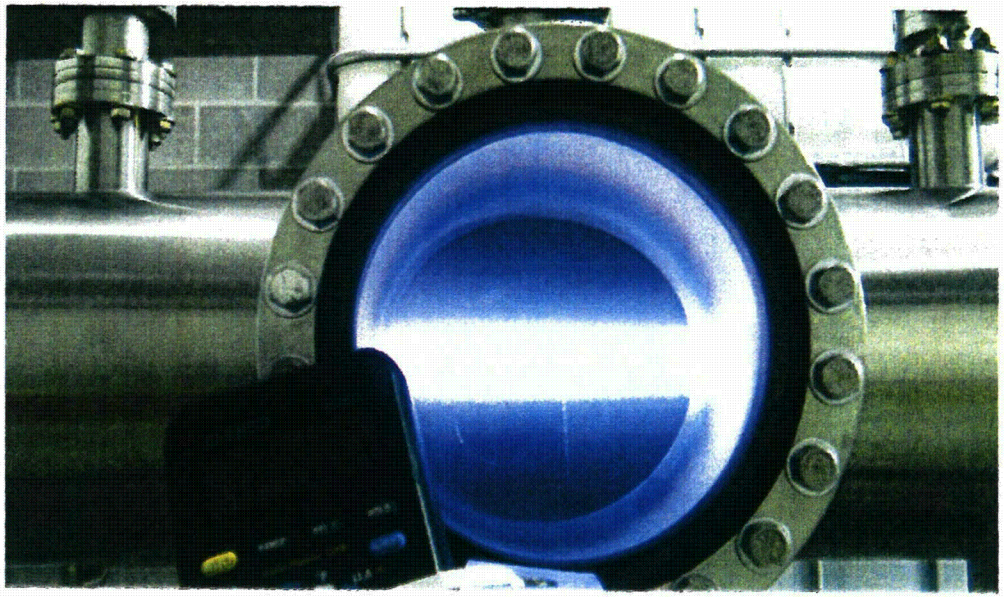
- SHINE isotope facility is of the scale of small research reactors
- Facility inventory smaller than many campus reactors
- Environmental impacts are insignificant compared to power reactors

Thank You!

Questions?

Gregory Piefer

CEO-SHINE Medical Technologies



Acronyms

1: NRC—Nuclear Regulatory Commission

2: LEU—Low Enriched Uranium

3: PSAR—Preliminary Safety Analysis Report

4: ER—Environmental Report

5: NRU—National Research Universal reactor at Chalk River, Canada

6: HEU—Highly Enriched Uranium

U.S.NRC

United States Nuclear Regulatory Commission

Protecting People and the Environment

Briefing on Potential Medical Isotope Production Licensing Actions

Office of Nuclear Reactor Regulation

May 11, 2012

Agenda

- **NRC Interactions with Potential Applicants**
- **Licensing and Technical Processes**
- **Summary**

NRC Interactions with Potential Applicants

- 5 Letters of Intent
  - B&W
  - Coqui
  - GE Hitachi/Exelon
  - MURR
  - SHINE
- Issuance of RIS 2011-06
  - Early and Frequent Communication

NRC Interactions with Potential Applicants (con't)

- **Public Meetings**
  - Regulatory Framework
  - Licensing Process
  - Technical Methodologies and Review Process
- **Letters**
  - Class of Licenses
  - Combined Licenses

Licensing and Technical Processes

- Regulatory Framework
- Moly-99 Working Group
  - Review of Regulatory Framework and Guidance
  - Inter-office Coordination

Licensing and Technical Processes (con't)

- **Guidance Development**
  - **Application Format and Content**
  - **Standard Review Plan**
- **NRC Environmental Review**
  - **EA or EIS Required Under NEPA**
  - **Coordination with DOE/NNSA**

Summary

- **Pre-application Activities**
- **Actively Developing Regulatory and Licensing Infrastructure**
- **Coordinating Inter-agency Activities**
- **Ready to Review Applications**

Acronyms

- **B&W** Babcock and Wilcox
- **DOE** Department of Energy
- **EA** Environmental Assessment
- **EIS** Environmental Impact Statement
- **GE** General Electric
- **ISG** Interim Staff Guidance

Acronyms (Cont.)

- **Moly-99** — **Molybdenum-99**
- **MURR** — **University of Missouri Research Reactor**
- **NEPA** — **National Environmental Policy Act**
- **NNSA** — **National Nuclear Security Administration**
- **RIS** — **Regulatory Issue Summary**