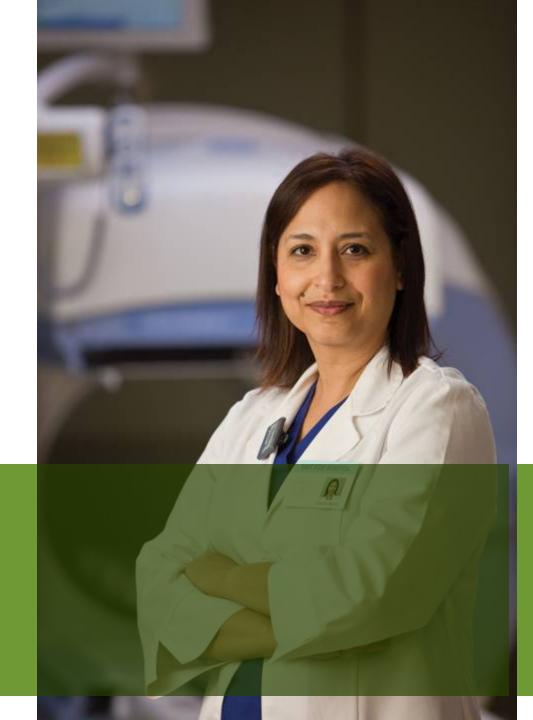


Covidien's Experience with the Conversion from Highly Enriched Uranium (HEU) to Low-Enriched Uranium (LEU)

December 6, 2011

Roy W. Brown
Director, Strategic
Alliances

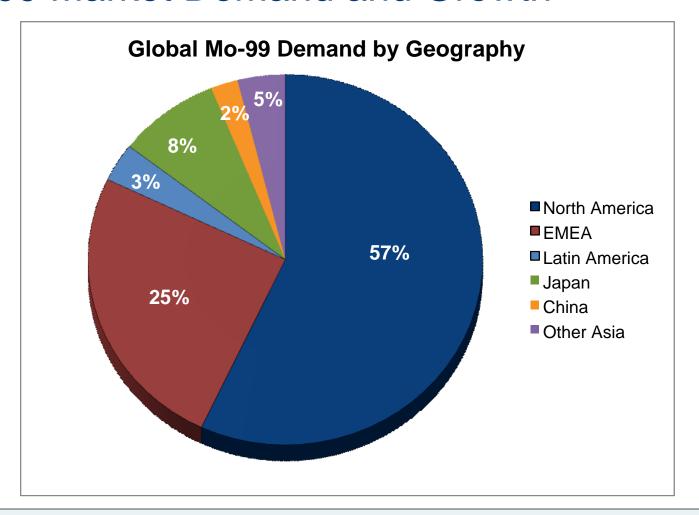


#### Covidien's Commitment to Conversion

- Committed to the conversion from HEU to LEU
- Two technology efforts underway utilizing LEU technology
  - Aqueous Homogeneous Reactor (AHR) project with Babcock & Wilcox Technical Services Group (B&W)
    - Designed to use LEU fuel to produce molybdenum-99 (Mo-99) with less waste
    - Intended for use in the U.S.
  - Conversion of Mo-99 targets from HEU to LEU at our Petten, the Netherlands, processing facility
    - •Working closely with the Nuclear Research consultancy Group (NRG) and the Company for the Study of Atomic Fuel Creation (CERCA) in the development of suitable LEU targets
- Continue to evaluate other LEU-based Mo-99 technologies being developed
- •Covidien/NRG/CERCA will require HEU until the conversion to LEU targets is complete to ensure patient access to vital diagnostic procedures



#### Mo-99 Market Demand and Growth\*



Mo-99 growth in mature markets: 2% Mo-99 growth in developing markets: 3-5%\*\*

\*Sources: Internal data. OECD report "The Supply of Medical Isotopes", June 2011.



## Technetium-99m (Tc-99m) Market Summary

- The Tc-99m market continues to remain strong
- Procedure volumes, which dipped during the Mo-99 shortage, are expected to return to pre-shortage levels within the next few years
- The installed base of SPECT and SPECT/CT\* cameras favor Tc-99m SPECT imaging vs. PET\*\*

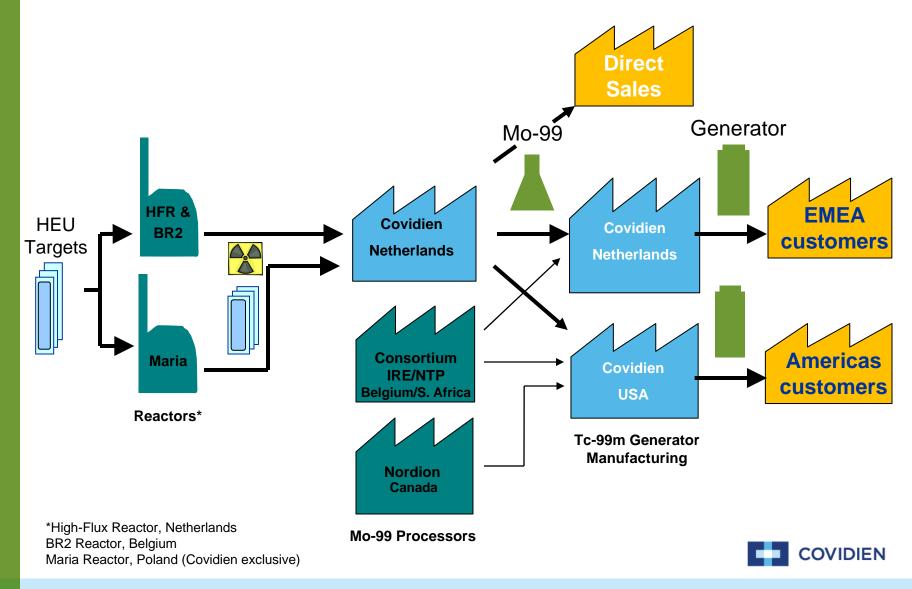


<sup>\*</sup>Single-photon emission computed tomography/computed tomography

<sup>\*\*</sup>Positron emission tomography



## Covidien's Current Mo-99 Supply Chain



## Update on B&W Project

- Development of an AHR
- LEU-based fuel, no separate target required
- Completed milestones
  - Facility & process design
  - Conceptual design
  - Reactor simulation code
  - Off-gas system design
  - Extraction column design & sorbent
- Process simulation underway
- Mo-99 successfully produced in "mini-loop" at reactor in Argentina, meeting specifications



Drawing of B&W AHR



# Conversion of Covidien Mo-99 Processing Facility Targets to LEU

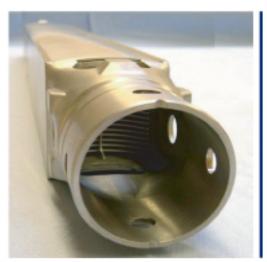
- Original goals of conversion project
  - Convert from HEU to LEU targets
  - Complete conversion as soon as technically feasible
  - Design a target to maintain a Mo-99 production efficiency of 90% of current level
  - Retain as much of the current configuration as practicable (to control costs and expedite schedule)
  - Convert with minimal transitional disruption to Mo-99 supply
  - Provide robust process and redundancies to ensure uninterrupted supply for the future
  - Minimize waste for ecological considerations



## Conversion from HEU to LEU Targets

- Current target is a plate type with the uranium (U) UAI<sub>x</sub> meat inside a laminated aluminum exterior
- Target plates are stacked inside target rig for irradiation in reactor
- Total U content will increase due to reduced enrichment
- Advanced technology has been employed to maximize the amount of U per volume without impacting current extraction/purification process
- Change in target cladding was made which required change in dissolution chemistry
- Close coordination is maintained with target manufacturer to ensure robust design







## Costs of Conversion to LEU Targets

- There are multiple cost components to the development and use of new LEU targets
  - Upfront development costs
  - Facility modification costs
  - Regulatory costs
  - Operational cost of using new targets
- These costs require upfront investment several years before LEUbased Mo-99 is produced
- Conversion to LEU targets will have inherent loss of efficiency
  - Conversion from 93% to <20% U-235 enrichment</li>
- Development of a new target creates a conflict between taking the time necessary to optimize a new LEU target versus trying to stay on a reasonable schedule



#### Detail on Costs of Conversion to LEU

- Upfront development costs
  - Target design, trial irradiations, post irradiation evaluations, new waste effluent process
- Facility modification costs
  - Modifications to existing processing lines, new transport containers for targets
- Regulatory costs
  - New drug master file (DMF), cost of validation runs, drug supplement submissions, licensing costs for amendments to reactors, processing facility and containers
- Operational cost of using new targets
  - Additional waste disposal charges



#### Regulatory Needs

- New batch records will need to be written for processing targets
- DMF will need to be written for new process
  - Must be filed with regulatory authorities
- Tc-99m generators will need to be produced from multiple LEU-based Mo-99 validation batches
- Supplements will need to be filed for U.S. Food and Drug Administration and European Medicines Agency, and in other countries where generators are sold
- Validation and licensing of new target transport container will be needed
- License upgrades will be needed at Mo-99 production facility and at all relevant reactors



## **Operational Costs**

- Fixed costs
  - Plant overhead will remain the same
  - Liquid waste disposal costs
     (fixed fee paid to waste facility
     in addition to volume fees) will
     rise with LEU use due to higher
     volume needs
  - Irradiation positions in reactor will likely remain the same
  - Contractual purchase obligations will likely remain the same



Mo-99 Process



Hotcells



#### Results of Conversion Efforts to Date

- Original target design had to be modified
  - The resulting yield was less than desired
  - Decision made to stick with modified design to keep project on track
  - The result will be a less-than-optimal target and increased cost
- The new target design chosen is not entirely compatible with all the reactors' target rigs currently in use
  - In some cases the number of targets per rig will need to be reduced
  - This will result in lower production efficiency
  - Target rig re-design is also being examined, which would require further capital investment



## Covidien Remains Committed to LEU Conversion

- Covidien will continue conversion of its Petten, the Netherlands, Mo-99 processing facility to LEU
- Covidien's conversion program is in full compliance with the recommendations of the OECD
- The current expected date of first commercial production of LEU-based Mo-99 is 2015
- We have sacrificed target yield optimization to minimize the time for conversion

