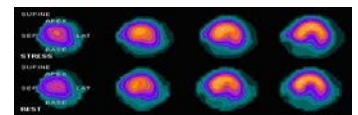


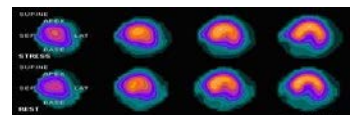
# Outlook for Future Mo-99 Supply

2016 Molybdenum-99 (Mo-99) Topical Meeting  
St. Louis, Missouri  
September 2016



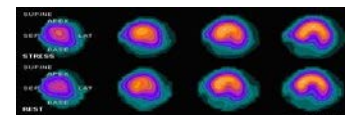
# CORAR

The Council on Radionuclides and Radiopharmaceuticals (CORAR) is an association comprised of companies in the United States and Canada who manufacture and distribute radiopharmaceuticals, sealed sources, radionuclides, and contrast agents primarily used in medicine and life science research. CORAR is tasked with advocating for regulations and legislation that facilitate the growth and viability of its member companies.



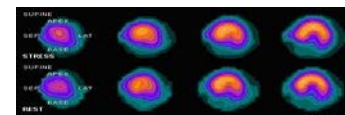
# Overview

- Mo-99 Background
- Current Mo-99 Supply Chain
  - International scope
  - OECD NEA HLG-MR publicly reported capacity demand
- Delivering Reliable Mo-99 Supply
- Delivering Reliable Future Mo-99 Supply
  - Domestic Mo-99 production programs
  - Non-domestic Mo-99 production programs
- Key Points - Looking Forward



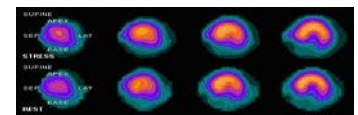
# Mo-99 Background

- Mo-99 is the parent isotope of Tc-99m
- Mo-99 provided through international supply chain
  - Currently, no Mo-99 production in United States
- Severe Mo-99 shortages in 2009 and 2010
- Nuclear pharmacies have increased efficiencies since 2009 and 2010
- Reduction and elimination of Highly Enriched Uranium (HEU) based Mo-99 production
- American Medical Isotope Production Act (AMIPA)
  - The Act was incorporated in the National Defense Authorization Act for Fiscal Year 2013 and enacted on January 2, 2013.
  - Intended to help establish a reliable domestic supply of non- HEU Mo-99

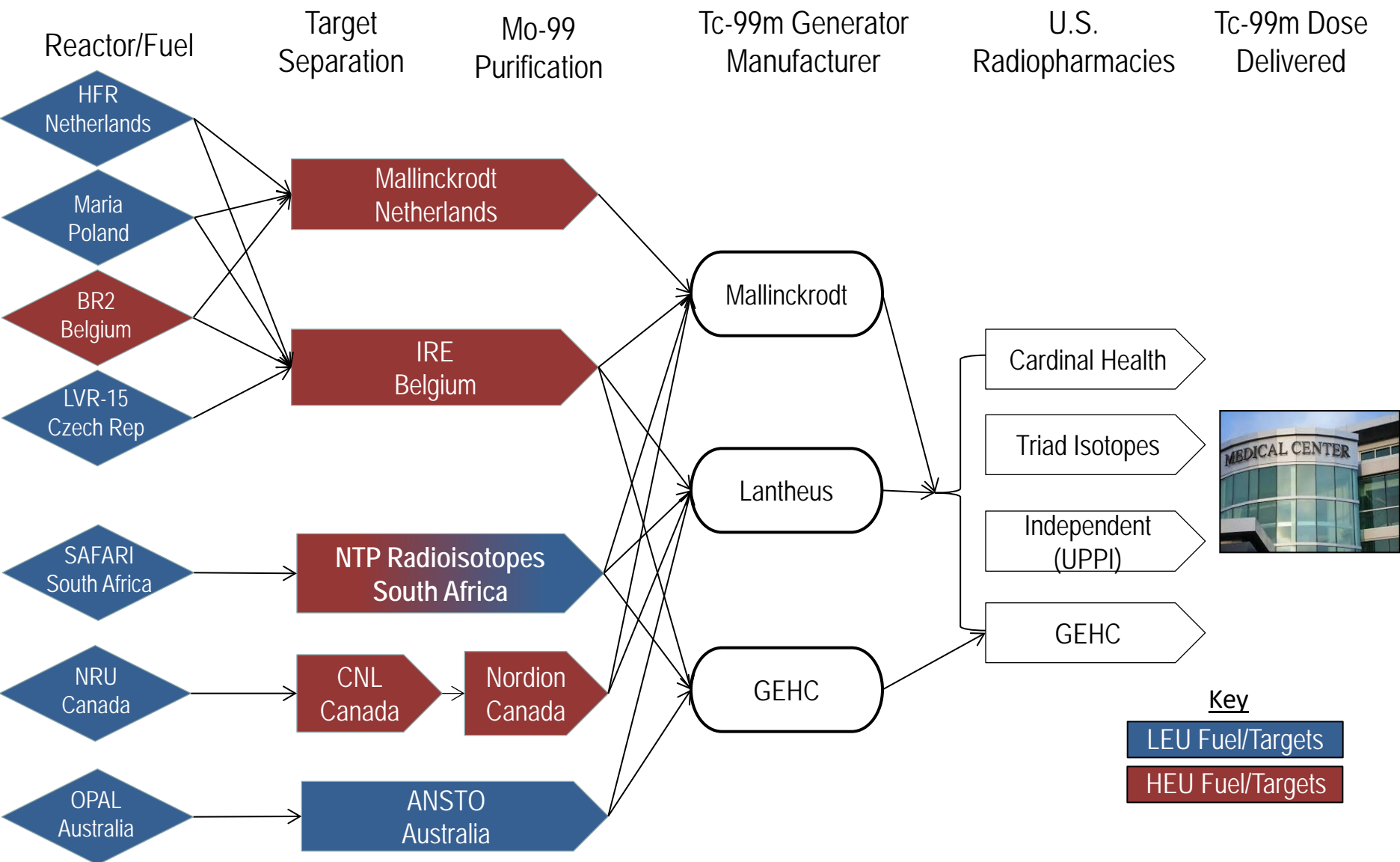


# AMIPA

- Provisions of the Act:
  - Requires DOE to establish a technology-neutral program to provide assistance to commercial entities to accelerate production of Mo-99 in the United States without the use of HEU
  - Requires annual public participation and review
  - Requires development assistance for fuels, targets, and manufacturing processes
  - Establishes a Uranium Lease and Take Back program
  - Requires DOE and NRC to coordinate environmental reviews where practicable
  - Provides a cutoff in exports of HEU for isotope production in 7 years, with possibility for extension in the event of a supply shortage
  - Requires a number of reports to be submitted to Congress



# Current U.S. Mo-99 Supply Matrix



# Current Global Mo-99 Sources

Reactor	Location	Commissioning Date	Fuel Type	Target Type	Global Mo-99 Processor
NRU	Chalk River, Canada	1957	LEU	HEU	Nordion
HFR	Petten, Netherlands	1961	LEU	HEU*	Mallinckrodt/IRE
BR2	Mol, Belgium	1961	HEU	HEU*	Mallinckrodt/IRE
SAFARI	Pelindaba, South Africa	1965	LEU	HEU/LEU	NTP
MARIA	Otwock-Swierk, Poland	1974 1993 (rebuilt)	LEU	HEU*	Mallinckrodt
LVR-15	Rez, Czech Republic	Mid 1950's	LEU	HEU*	IRE
OPAL	Lucas Heights, Australia	2007	LEU	LEU	ANSTO

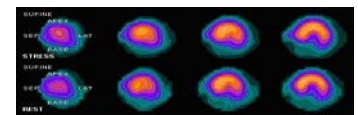
\*In the process of converting to LEU targets

Mean age ~ 47 years

Exclude Opal – Mean Age of Remaining Reactors ~ 54 years

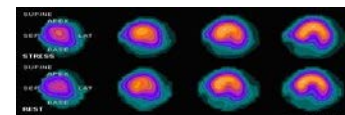
LEU - Low Enriched Uranium

HEU - Highly Enriched Uranium



# Delivering Reliable Supply

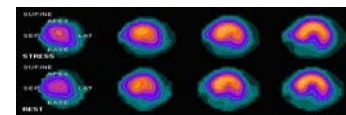
- Current Mo-99 Production
  - Extra targets added at current reactors
  - Additional reactors were added to the fleet (Maria and LVR-15)
  - Use of higher neutron flux positions in reactors
  - AIPES R&I Workgroup planning to ensure reliable supply
- Mo-99 Generator Manufacturers
  - Supply chain diversification; multi-sourcing Mo-99 (requiring mutual back-up arrangements)
  - Advance planning for scheduled outages
- Nuclear Pharmacies
  - Improving Tc-99m efficiency (e.g. reduce bulk Tc-99m, optimize delivery, new information technology)
- Hospitals and Physician Offices
  - Coordinate patient scheduling with Tc-99m availability
  - Using new technology to improve efficiencies and reduce Tc-99m activity





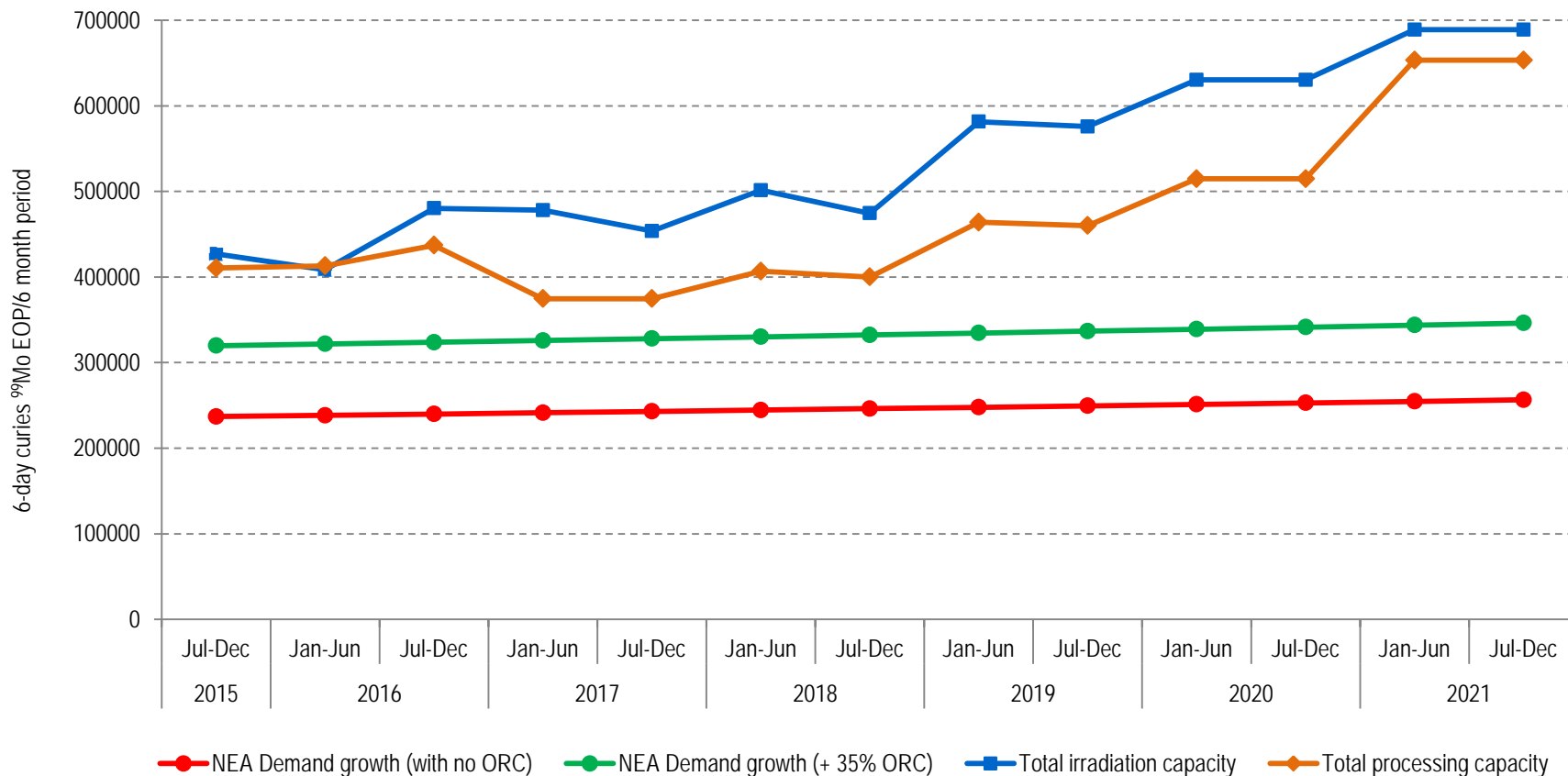
# Delivering Reliable Future Supply

- New North American Mo-99 Production Options – CORAR Members:
  - Northwest Medical Isotopes, LLC:
    - Traditional fission (reactor) based approach irradiating LEU targets
    - Process irradiates targets/recover Mo-99 and recycle Uranium
  - Nordion, Inc.:
    - In conjunction with General Atomics and MURR - LEU targets with SGE Technology
  - NorthStar Medical Technologies, LLC:
    - Traditional reactor irradiation of stable molybdenum targets; either natural Mo-98 or enriched Mo-98 and
    - Accelerator irradiation utilizing stable enriched Mo-100 targets
  - SHINE Medical Technologies
    - Accelerator based technology utilizing LEU solution
- Ongoing Efforts:
  - Mallinckrodt Pharmaceuticals
    - Increasing target irradiation capacity at all reactors
    - Increasing from four to six Mo-99 productions per week
    - Converting to LEU targets
    - LEU Generators
  - Lantheus Medical Imaging
    - Diversifying Mo-99 and Xe-133 supply chain
    - LEU Generators

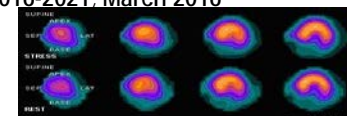


# OECD HLG-MR Capacity 2016-2021

HLG-MR reports current Mo-99 demand (9,000 6-day Ci 99Mo/week EOP) and demand +35% ORC v total irradiation capacity and total processing capacity – projects delayed: Scenario C

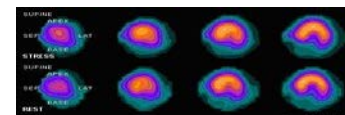


Source: OECD-NEA Report "2016 Medical Isotope Supply Review: 99Mo/99mTc Market Demand and Production Capacity Projection 2016-2021: March 2016



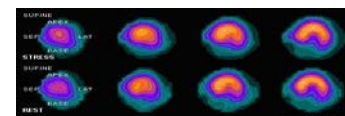
# Reliable Supply - NRU Post 2016

- Natural Resources Canada announcement (Feb. 6, 2015)
  - NRU operations extended to March 31, 2018; thereafter will be decommissioned
  - Support global Mo-99 demand between 2016 and 2018 in the unexpected circumstances of shortages
  - Reactor will have a routine operating schedule
  - Subject to licensing approvals, propose to operate the NRU reactor
  - Associated facilities required for Mo-99 processing would be kept in a “hot standby” mode for the same period
- CORAR Appreciates Canadian Government decision to support continuing operations of NRU reactor as a back-up Mo-99 producer from November 2016 - March 2018
  - Ensure that patients have continued access to important nuclear medicine products and procedures during a critical time



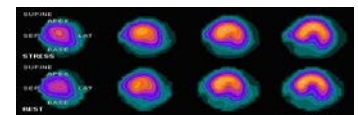
# Non-Domestic Mo-99 Projects

- NTP; South Africa
  - 20 MW Research Reactor called SAFARI-1; Currently manufacturing LEU Mo-99
  - Sustainable and reliable supply projected through 2030
- ANSTO Nuclear Medicine, Australia
  - Existing Mo-99 processing facility upgrade on track
    - Additional 1,000 6 day Ci's available August 2016
  - Managing transition program between existing facility and ANM
  - Full transition to new Mo-99 processing facility anticipated by mid 2017
    - Capacity for 3,500 6 day Ci's
- IRE, Belgium
  - Currently processing Mo-99 from HEU
  - Conversion to LEU projected for late 2017



# Key Points

- Increased Mo-99 efficiencies have been realized in the supply chain
- Fission production of Mo-99 will convert to LEU
- Current Mo-99 manufacturers have publicly reported increases in Mo-99 production capacity by current producers
  - Captured in latest HLG-MR report
- Canadian government plans for NRU as supplier of last resort
- Potential domestic Mo-99 producers are working on several technology tracks – none require HEU targets
  - Augment international Mo-99 production activities
  - Domestic Mo-99 supply for patients in the United States
- Reduced risk for short and mid-term global Mo-99 shortages



# Thank You

