

Stakeholder Outreach

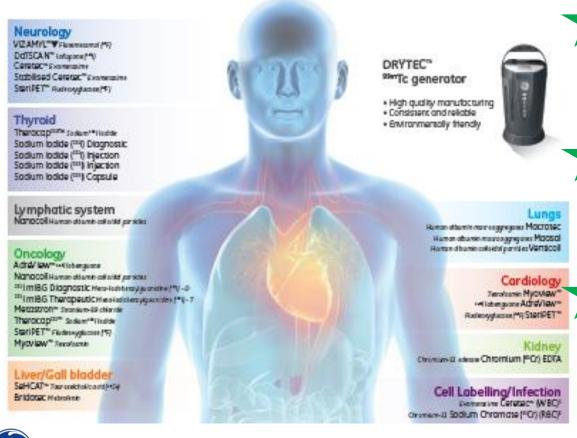
Reliable Supply of Mo-99 and LEU Conversion

Jessica Hinkle September 2, 2015

Imagination at work.

GE SPECT Supply Chain

A Comprehensive Molecular Imaging Portfolio



31 US radiopharmacies

Manufacturer of Tc-99 generators

 Tc-99 Cold Kit Development / Manufacturer



Critical Need to Ensure Product Quality and Patient

Sa



NECC triggers tsunami of activity (FDA, Boards of Pharmacy)

Drug Quality and Security Act, November 2013

Obama signs Drug Quality and Security Act into law

President Obama has signed H.R. 3204 into law, setting the wheels in motion for the FDA to develop a national track-and-trace system to secure the pharmaceutical supply chain



The aim of the Drug Quality and Security Act (DQSA) is to

"minimise opportunities for

contamination, adulteration, diversion, or counterfeiting," whilst also clarifying the FDA's authority to regulate compounding pharmacies, according to the White House.

Senator Tom Harkin (D-IA), who introduced the DQSA into the Senate, and the legislation "will dramatically improve the safety of compounded drugs and will also establish an unprecedented tracing system that will track prescription drugs from manufacturing to distribution."



DQSA and USP<797> just the start...

The Joint Commission's Gold Seal of Approval®



GE Healthcare's national network of nuclear pharmacies are accredited as part of The Joint Commission's Home Care Accreditation program

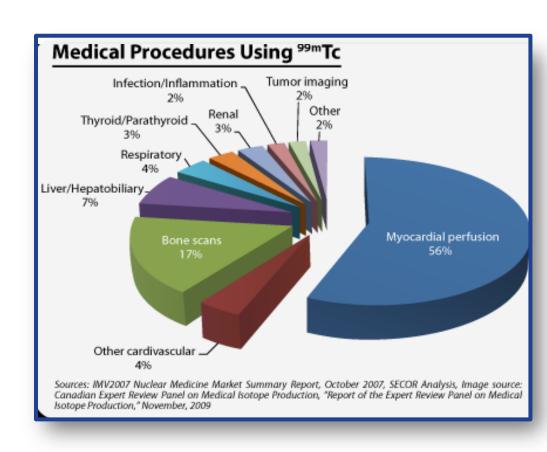
- Programs and processes equal to what is required for your healthcare organizations
- A commitment to ongoing improvements

Independent confirmation of GE Healthcare's high-quality standards



Mo-99/ Tc-99 Applications

- Essential in >30 diagnostic procedures
- Worldwide >40M scans per year (~80% nuclear medicine procedures)
- Used to diagnose various types of disease
- Provides predictive data about success of therapy, therapy options and/ or surgical intervention





Mo-99 Supply Today

Key Challenges with current Supply Chain

- 1. Historical supply dynamics
- 2. Reactor age and reliability
- 3. Use of highly enriched uranium (HEU)
- 4. Financial model

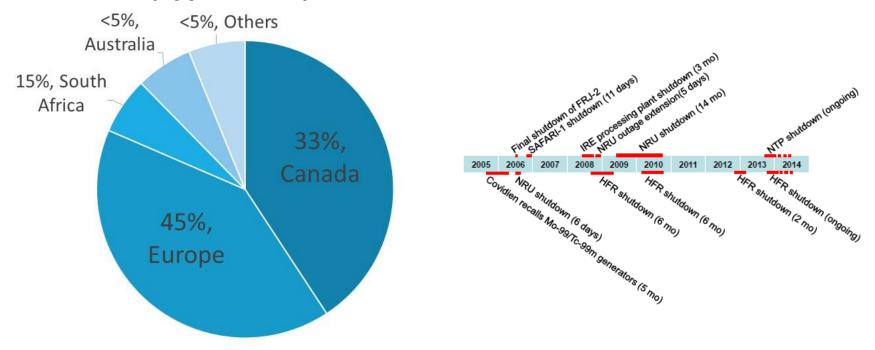




Mo-99 Supply vs. Demand

Global Producers of Mo-99 Today (Approximate)

magination at work



- 2/3 of world's supply comes from two research reactors, NRU in Canada and HFR in the Netherlands
- No currently approved isotope production in the US, despite the US being the world's largest consumer

Future Mo-99 Pricing

Many forces currently working to increase Mo-99 pricing

- International (OECD) push toward unsubsidized market rates (FCR)
- HEU to LEU conversion
- Supply vs. Demand when reactor schedules not aligned

Meanwhile, countries are pushing to lower healthcare costs





Current challenges with FCR/ORC End customer **Target** price increase challenge for generator manufacturers **Fuel** RX **Processor 1 HEU** to Multi reactors Reactors Generator Customers manufacturers (Radio-pharma & hospitals) Processor 2 Reimbursement Governments Uni reactors it work

Effect of HEU to LEU conversion

Mo-99 produced from fission of U-235, must be enriched from natural state to increase Mo-99 yield

Most current production uses highly enriched uranium (HEU) targets

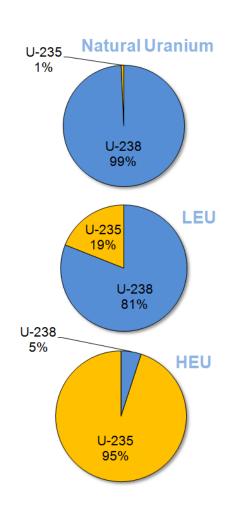
U.S. begrudgingly ships HEU abroad for this purpose

HEU = "bomb grade"; proliferation threat

Global effort to convert Mo-99 production from HEU to low-enriched uranium (LEU)

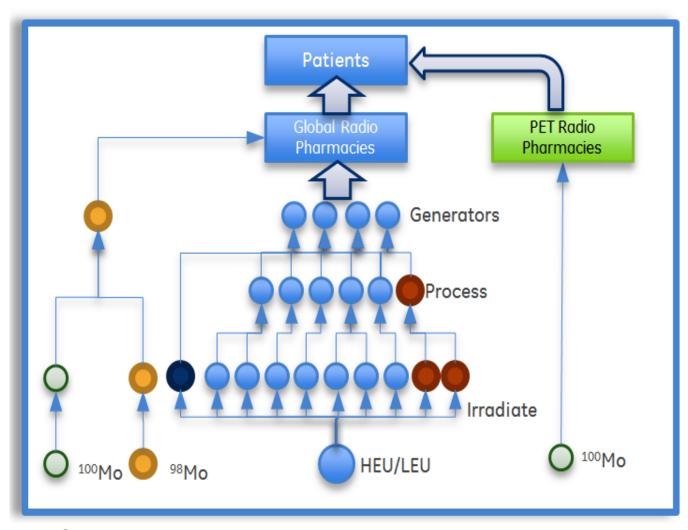
Move from highly enriched targets to low-enriched targets further hurts global production capacity

- As high as 20% efficiency loss
- Increase in waste disposal costs
- U.S. to stop exporting HEU in 2019





Tomorrow's Mo-99/Tc-99 supply?



Accelerator of particles

Neutron Capture

Reactors and processors

Cyclotron

GE: Investing in our Nuclear Medicine

External Stakeholder Programs

- ✓ Educate, inform and support
- ✓ Customers and payers
- ✓ Local governments
- Nuclear Medicine Societies and committees
 - AIPES and NEA HLG-MR
 - SNMII
 - **O EANM**

FCR Program

- ✓ Communication program
- ✓ Customer ppt; Mo-99 Environment, challenges and opportunities...
- ✓ Pricing strategy implementation
 - Sustainable price re-evaluation
- ✓ LEU conversion readiness
 - Validation, System Upgrades and Regulatory approvals

Mo-99

- ✓ Support both existing and future production options for Mo-99
- ✓ Active participation in Mo-99 coalition
- ✓ Lobbying efforts with regulators to create a sustainable Supply Chain

Added value services

- ✓ Customer Efficiency program
 - Product use optimisation
- ✓ Lean program Manufacturing site improvements

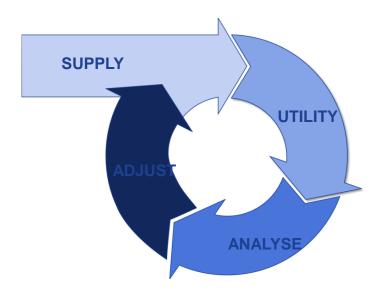




GE Healthcare: Strengthening our Mo-99 supply

- · Chain nuous investment in resources and manufacturing
 - Dedicated and knowledgeable cross-functional team
- Secure and diverse supply arrangements with processors and reactors
 - Strong relationships, Examples
 - Backup supply
- Global LEU conversion registration program
 - Versatility of supply options
 - Meeting market requirements
- Support for alternative technologies
 - In US market supply
 - Increased volume
 - Pricing stability
 - Strengthening reliability of supply





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