Stakeholder Outreach

Reliable Supply of Mo-99 and LEU Conversion

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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 Safety

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

- 45%, Europe
- 33%, Canada
- 15%, South Africa
- <5%, Australia
- <5%, Others

- 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

Target

Fuel

HEU to LEU

Governments

Reactors

Processor 1
Multi reactors

Generator manufacturers

Processor 2
Uni reactors

Customers
(Radio-pharma & hospitals)

End customer price increase challenge for generator manufacturers

Reimbursement

it work

End customer price increase challenge for generator manufacturers
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 ?

Diagram showing the process of obtaining Mo-99/Tc-99 using accelerators, neutron capture, reactors, and cyclotrons.
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
  - 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

- Continuous 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