The Final Push

Ensuring LEU Use for Medical Isotope Production

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Outline

- The current situation
- Recent Positive Developments
- Technical, Political, and Economic Obstacles
- New strategies to ensure move to LEU
Medical Isotopes: Current U.S. Mo\(^{99}\) / TC\(^{99m}\) Supply Matrix

**Reactors:**
- Maria
  - Poland
- HFR
  - Netherlands
- BR2
  - Belgium
- LVR-15
  - Czech Republic
- OSIRIS
  - France
- SAFARI *
  - South Africa
- NRU
  - Canada
- RIAR
  - Russia
- OPAL
  - Australia

**Mo\(^{99}\) Extraction & Purification:**
- Covidien
  - Netherlands
- IRE
  - Belgium
- NTP
  - South Africa
- AECL
  - Canada
- NTP
  - Canada
- ANSTO
  - Australia

**Tc\(^{99m}\) Manufacturer:**
- Covidien
- Lantheus

**Key:**
- HEU Fuel & HEU Target
- LEU Fuel & HEU Target
- LEU Target & LEU Fuel
- HEU Processing
- LEU Processing
- * Fully converting to LEU targets
Medical isotope production: Switching from HEU to LEU or not?

- Positive developments:
  - Greater Political Support—UNSC 1887 and NS Summit
  - U.S now receiving regular commercial shipments of medical isotopes produced using LEU fuel and targets, from South Africa and Australia
  - 2016 closure of NRU
  - New production capability moving forward in S Korea, S America, E Europe, US
  - Conversion of Polish (2012), Czech reactors to LEU fuel

- Not so positive developments:
  - Delays in European licensing of Tc-99m
  - Russia plans to export Mo-99 isotopes to fill in shortages in production but using HEU
Potential New Projects for Mo-99 Production

<table>
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<tr>
<th>REACTOR</th>
<th>Six-day ci EOP/yr</th>
<th>Six day ci EOP/wk</th>
<th>Weeks/yr</th>
<th>Potential first year</th>
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*  Project includes three reactors, two of which would be used to produce Mo-99 in a continuous fashion, with the third being a back up.
** Research reactor already exists, but is not yet irradiating targets for Mo-99 production.
*** Under active construction.
**** Projects in Europe would face a processing capacity limitation.

SOURCE: OECD Nuclear Energy Agency
Mo-99 producer NECSA has committed to operate solely on LEU
- $25 million from NNSA to produce fully LEU-based isotopes
- 2009: reactor fueled only with LEU
- Current: Anticipates using only LEU targets for Mo-99 production-2013
2 X density of LEU targets
More waste, problems with Mo-yield, NECSA wants to develop higher-density targets
Costs 10% more than HEU process— but little cost impact on patients
Tc-99m licensed quickly by FDA, but not by EU states
- Expensive, cumbersome process of country-by country validation tests necessary
Conversion: Not Mainly Technical Challenge

- 2009 National Academies of Science study:
  - “…no technical reasons that adequate quantities [of medical isotopes] cannot be produced from LEU targets in the future.”

- Fuel at major production reactors has been converted to LEU
  - BR2 only exception, but seeking to convert

- Need to develop LEU targets
  - LEU substitution would require reactor and Mo-99 processors to process about five times as many targets and an equivalent increase in waste.
    —or—
  - Make targets larger, or with greater uranium density, or with more uranium and less cladding
Conversion: Not Mainly Technical Challenge (2)

- Production costs would likely rise marginally compared to the existing HEU targets and processes, but without significantly increasing the cost of diagnostic imaging.

- To minimize disruption, seek to ensure LEU targets are compatible with existing processes for target dissolution and Mo-99 recovery and minimize waste
  - Advantage of reactor irradiation vs. neutron capture etc (different specific activity levels)
Conversion: An Economic Problem

- Instability in Mo-99 market
  - Exemplified by the shut down of aging NRU Chalk River reactor 2009-2010
  - No incentive for creation of new irradiation facilities due to operating subsidies
  - Government reimbursements rates for isotopes do not reflect the full costs of processing and other production
  - Lack of adequate geographic distribution hampers supply
  - Concerns that conversion could lead to shortages
Conversion:
An Economic Problem (2)

- **Processors resist additional $ of conversion**
  - Changes to processing may be needed to accommodate higher throughput levels
  - Limited access to needed addl. reactor irradiation time
  - LEU isotopes need to be licensed

- **Russia**
  - Kiriyenko: LEU production the goal but need to ensure market supply
  - There are some indications Russia in the short term may switch to LEU fuel, but not targets
  - Better to convert now to LEU than gear up HEU production
  - **Are incentives needed to ensure move?**
    - Letter from NNSA Administrator D’Agostino to Congress positive move—Calls for Congress to consider measures to counter subsidized HEU-based production
      - Possibilities include labeling, addl export constraints, preferential gov procurement
Recent Responses to Instability

- Governments sought ways to ensure sufficient supply
  - Asked the OECD Nuclear Energy Agency and the IAEA for recommendations for altering the market structure
  - Better sharing of information about proposed reactor shutdowns and conversion

- Reduced demand:
  - Physicians and other participants chose alternatives or were conservative in using their supply of isotopes

- Increased production: New entrants or local reactors reaching the global market (all HEU)
  - Poland—converting to LEU fuel (2012)
  - Czech Republic—converted to LEU fuel
  - Russia—?
Policy Prescriptions Offered

- **US Congressional Action**
  - First introduced in 2009, passed House
  - Revised version has passed Senate recently
    - Would ban US exports of HEU for targets to Western Europe and Canada
    - Authorizes efforts to promote Mo-99 production through LEU fuels and targets, including the construction of domestic facilities
    - Would establish government responsibility for waste disposition

- **OECD Nuclear Energy Agency**
  - Governments should terminate subsidies
Commitment by leaders at the 2012 NSS
- phase out deadline for HEU use for medical isotope
- USG has sought this
- May need to push date back some— 2018-2020?

Further restrictions on US HEU exports
- Informal

Subsidy cutoffs
- Governments should more quickly raise prices of irradiated Mo-99 produced using HEU fuel or targets to market levels as suggested by the HLG-MR
- US could consider countervailing duties for those who continue to use subsidized production (subsidized production will also tend to be HEU)
New Strategies

- **Preferential procurement**
  - By National governments and the WHO
  - Need clear studies by US and NEA of alternative strategies of preferential procurement strategies and costs and benefits
  - Should consider supporting or requiring government purchases of LEU-based isotopes
  - Natl governments should agree to take steps to move quickly to license LEU-based isotopes
  - Taxing HEU or ensuring full cost of HEU (enrichment)

- **US Market power**
  - World’s largest importer of Mo-99
  - The US could impose tariffs or a ban on the import of HEU-based isotopes
  - Once sufficient LEU supplies available