

OECD-NEA HIGH-LEVEL GROUP ON THE SECURITY OF SUPPLY OF MEDICAL RADIOISOTOPES:

POLICY APPROACH FOR A SECURE SUPPLY OF MOLYBDENUM-99/TECHNETIUM-99M

Ron Cameron

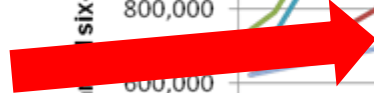
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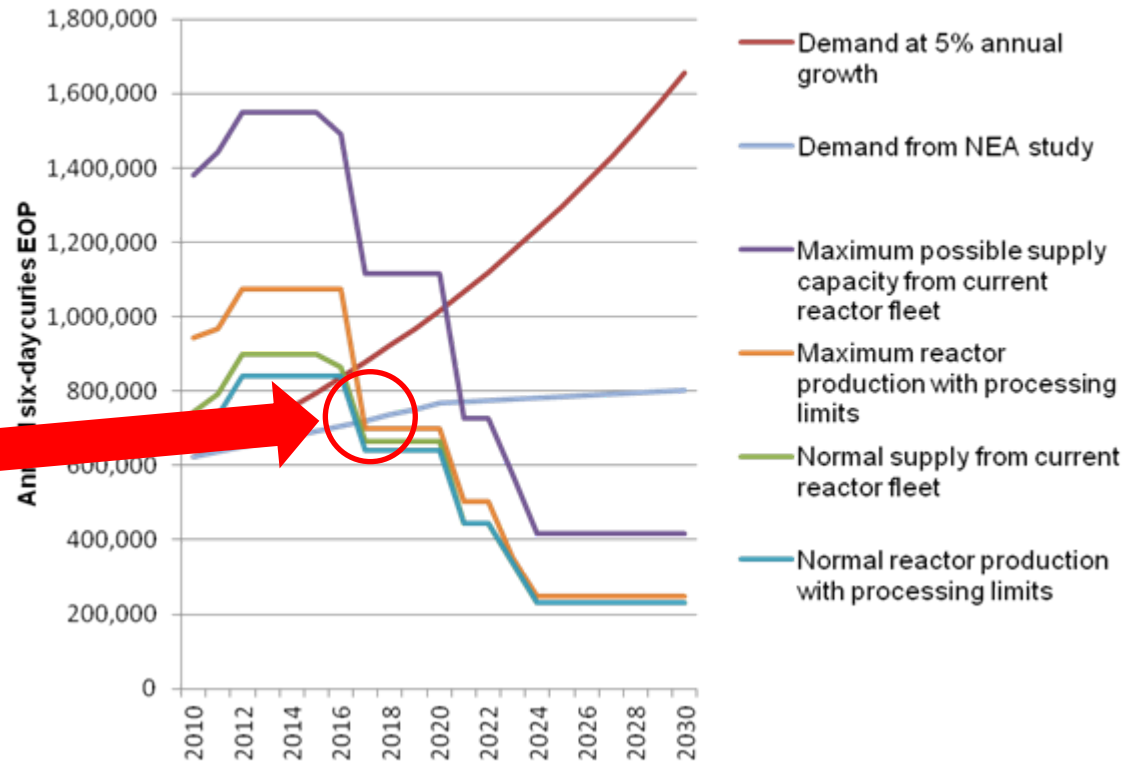
What is the physical problem?

- Historically: 5 reactors, all > 45 yrs old
- Now ~11; however all (-1 or 2) are >37 yrs old
- Demand continues to increase; Supply falling
- Supply < Demand in less than a decade

2016/
2017



Current Supply vs. Demand



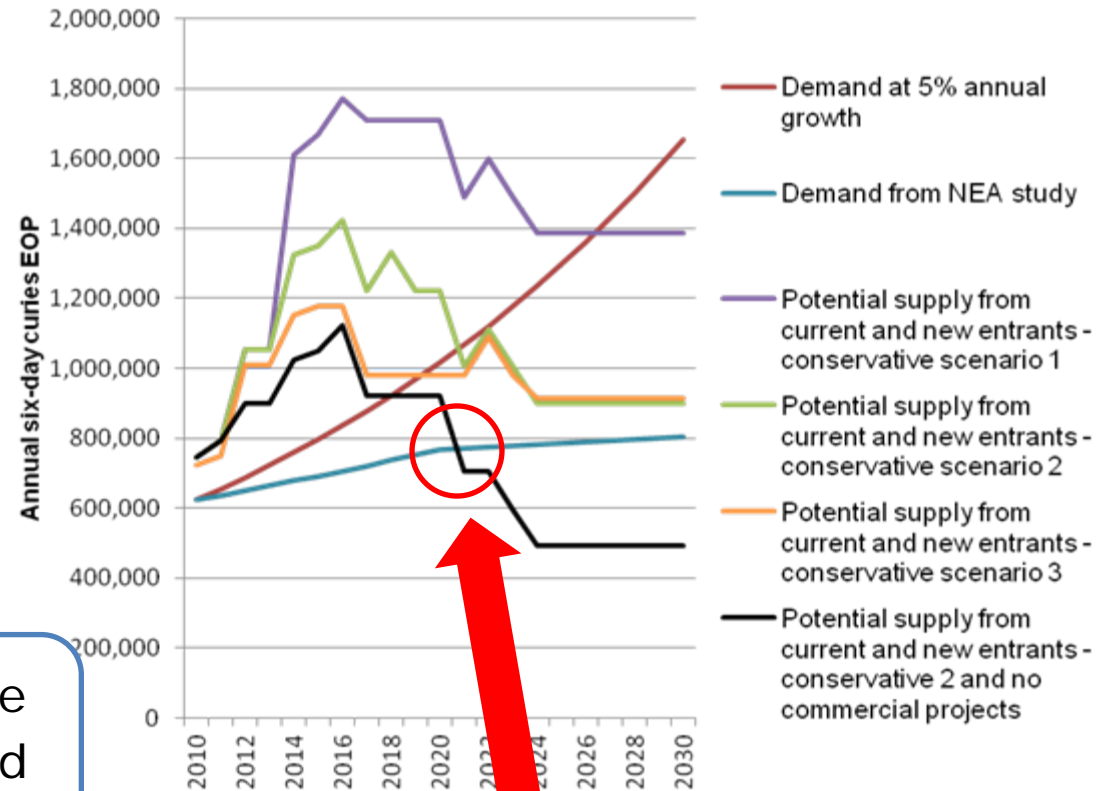
What about new projects?

New projects may not be sufficient

- New projects being discussed and some being developed
- However, not all may materialise
- Some may face processing constraints
- Conversion to using LEU targets may have impact on production capacity

Need to keep working to ensure these happen – cannot be lulled into complacency

Conservative Potential Supply vs. Demand



2021

Why are we in this situation?

Key findings of the HLG-MR: Quick Summary



- Demand for $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ will continue
- Supply of reactors/processors not sufficient to meet future demand
 - Demand side management may partially alleviate worst shortages
- Historically, developed unsustainable economic model
 - Reactor irradiation prices too low; structure perpetuated
 - Industry survived through government financial support; but meant supporting foreign health care systems
- Governments have indicated move to more commercial funding
 - Need full-cost recovery to encourage new infrastructure
- Increasing supply chain prices will have a very small impact on patient end prices – irradiation value remaining less than $<1\%$
- Transport regulatory processes and denials of shipment are impediments to reliable supply
 - IAEA and others are working to address
- Alternative production techniques are important for increasing security of supply, minimising HEU use and in some cases, waste
 - Uranium fission route is currently most efficient and market ready but alternative technologies are making progress

To achieve secure, reliable supply: HLG-MR Policy Approach



- Supply problem at its roots is a policy failure
 - Commercialisation not done on a sustainable basis: long-term contracts with too low revenues prevented full-cost recovery
 - Long-term government subsidies hid failure
 - Market practices and technology failures perpetuated inadequate revenues
- For new investment and long-term reliability, approach addresses:
 - Economic return needs to be improved, especially for reactors
 - Outage reserve capacity needs to be sourced, valued, paid for
 - All supply chain participants need to make the changes
- Should be applied by all countries that have an impact on the global market – Producers or consumers of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$

Policy Approach: Addressing economic returns

Improve reactor economic returns

Pay for ^{99}Mo related infrastructure and operating costs

P.1: Implement full-cost recovery, including costs related to capital replacements

P.3: Governments should establish the proper environment for infrastructure investment and set the rules for efficient market operations

P.4: Governments should support conversion to use LEU targets

P.3: Governments should refrain from day-to-day intervention in market operations

- Work with health care providers and insurance companies to review if sufficient for securing adequate supply
- Where required, support public-private partnerships with appropriate returns
- R&D
- Examine options for market justification to using LEU targets
- Meantime, consider financial support of price differential
- Encourage development of alternatives

Policy Approach: Ensuring outage reserve capacity

Sourcing, valuing and paying for outage reserve capacity



Removes “excess supply” of irradiation spaces, ensures reliability by rewarding providers of back-up capacity



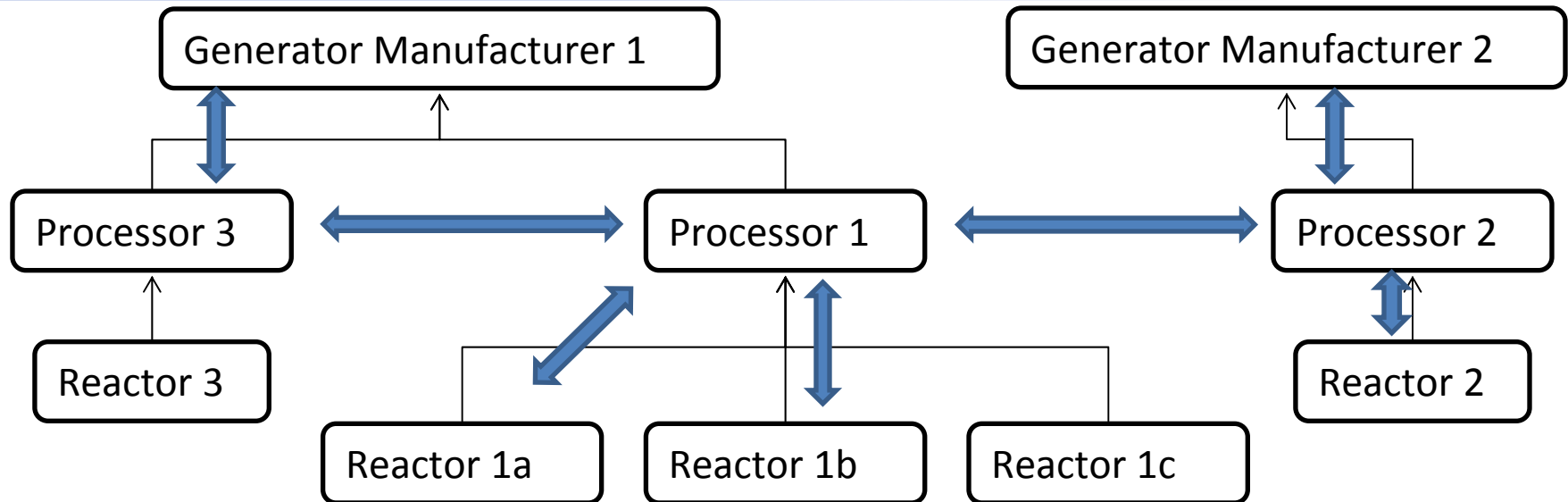
P.2: Reserve capacity should be sourced and paid for by supply chain



P.3: Governments should establish the proper environment for infrastructure investment and set the rules for efficient market operations

- Processors should hold, at every point in time, ORC equal to their largest supplier
- Can come from anywhere in supply chain, even demand side
- Must be credible, incremental and available
- Co-ordination efforts should continue to keep all informed
- Monitor ORC levels: if too low, consider regulating
- Consider ^{99}Mo production needs when planning new research reactors

Example of ORC options in action



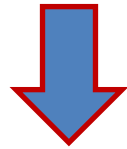
- P2, in a single source supply chain, holds ORC options contract with:
 - P1 to supply product if R2 down
 - GM 2 to implement DSM downstream to address shortage condition
- P1 holds ORC options contracts with:
 - R1a,R1b and P2 in enough quantity to address if reactor in supply chain down
 - P2 then must hold ORC within R2 at amount offered to P1
- P3 holds ORC options contracts with:
 - GM 1, who can implement DSM downstream to use supply from P1 more efficiently during shortage period
 - P1 to provide supply if R3 goes down
 - P1 then must hold additional ORC from R1a, R1b to amount offered to P3

Policy Approach: All players must make changes

All supply chain participants need act in accordance with principles



If one player does not, there will not be supply security, global consistency is necessary



P.5: International collaboration should be continued through policy forum



P.6: Need for periodic review of supply chain to verify implementing the HLG-MR policy approach, especially full cost recovery

- Domestic/regional action must be consistent with proper functioning of global market
- IAEA and partners continue international dialogues
- International collaboration should be used for other goals
- NEA will continue HLG-MR through second mandate

- NEA will undertake review of supply chain progress

Applying the policy approach: Small cost impacts on patient



- The end user will have to pay for increases in costs from full-cost recovery and outage reserve capacity
- Requires significant increases upstream, but only small amount of ^{99}Mo is actually used for each $^{99\text{m}}\text{Tc}$ procedure

	Irradiation value/ORC within final radiopharmaceutical price	Irradiation value/ORC as % of reimbursement rate	Radiopharmacy price of $^{99\text{m}}\text{Tc}$ as % of reimbursement rate
Current Situation (pre-shortage)	0.36 \$	0.11%	4.42%
20% MPR with full-cost recovery and ORC	1.73 – 2.18 \$ ¹	0.51 – 0.63%	4.82 – 4.95%
50% MPR with full-cost recovery and ORC	4.34 – 5.43 \$	1.26 – 1.58%	5.58 – 5.9%

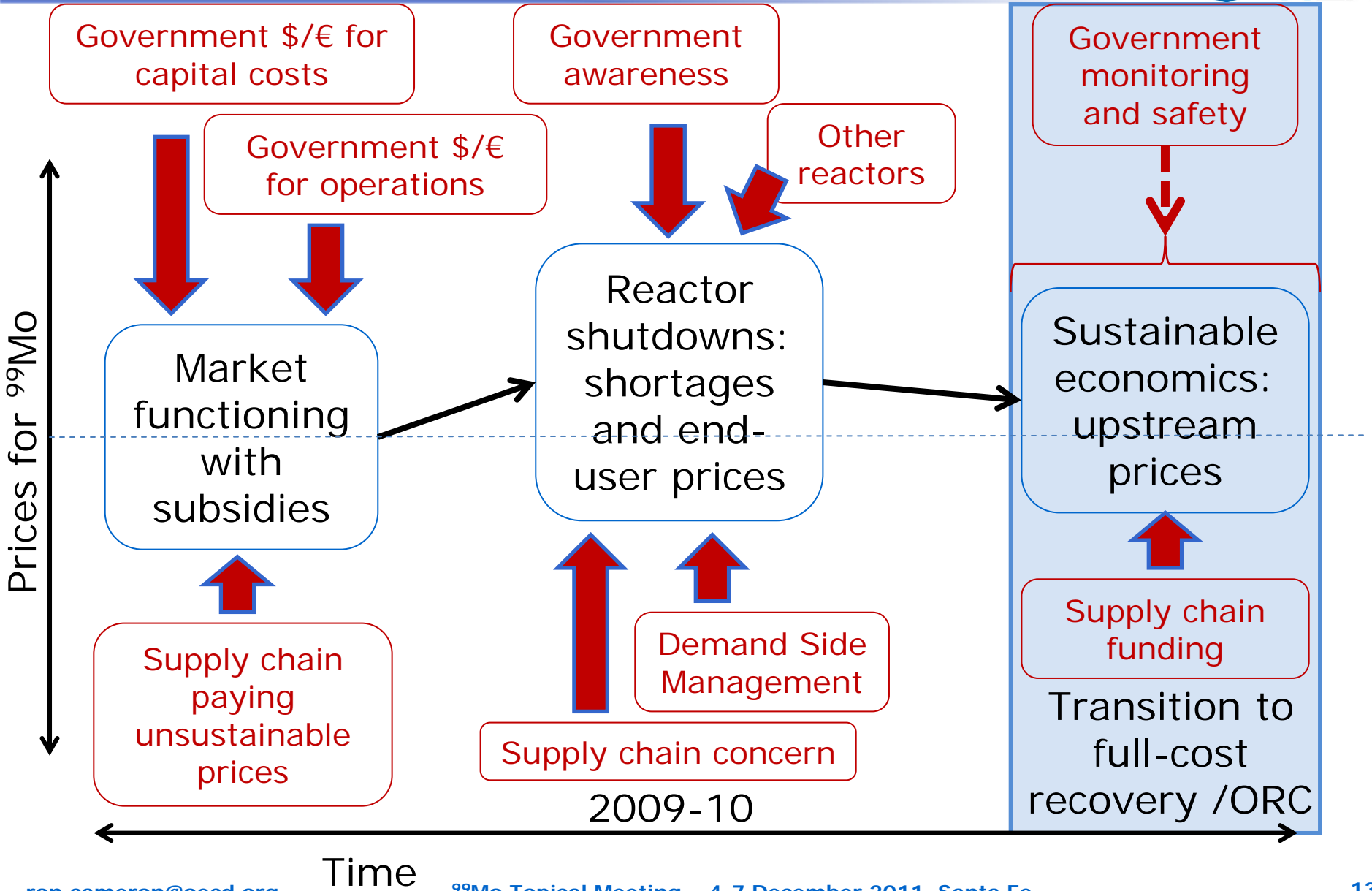
¹ Range is 33% ORC to 47% ORC

- ...remains small portion of patient price with full-cost recovery and ORC (<2%)
- Should not be too much to pay for reliability
- Efficient generator elution can more than offset price increases

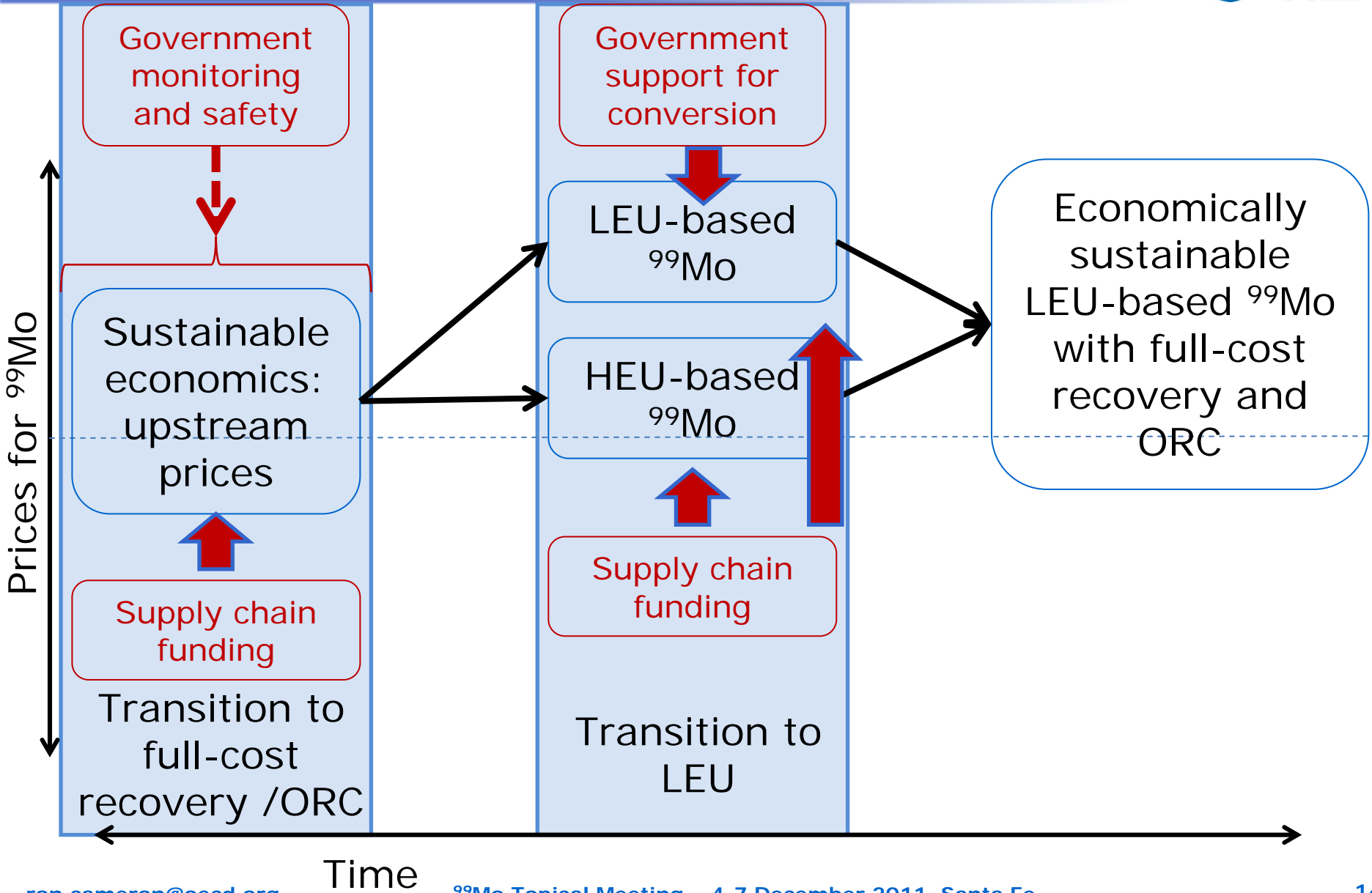
- Governments to require reactor operators to apply the full-cost identification methodology and then fully recover costs within pricing
 - Should apply to other production technologies as well
 - Does not mean price setting – operators would now provide ^{99}Mo irradiation services as any other commercial company, with prices that cover costs; purchasers decide if they can pay needed prices
 - Mechanism up to government (e.g., regulations, policy direction or removal of subsidies for ^{99}Mo production)
- Processors should start, if they aren't already, sourcing and paying for ORC as recommended
- Health care systems should review payment rates to determine if sufficient to ensure adequate supplies: impact should be small
- Supply chain participants undertake self-assessments and participate in NEA review of progress towards supply security

- Governments to require reactor operators to apply the full-cost identification methodology and then fully recover costs within pricing
 - Should apply to other production technologies as well
 - Does not mean price setting – operators would now provide the same irradiation services as any other commercial company, with prices that cover costs; purchasers decide if they can pay needed prices
- **Has to happen within 3 years from June 2011**
- **Otherwise, commercial players may have difficulty remaining in supply chain – greatly reducing reliability**
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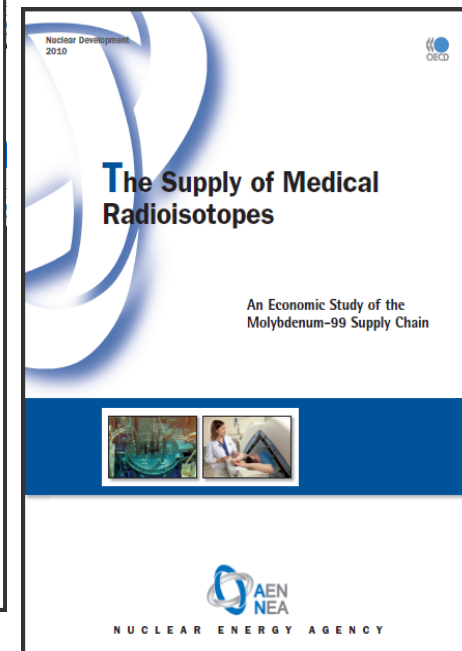
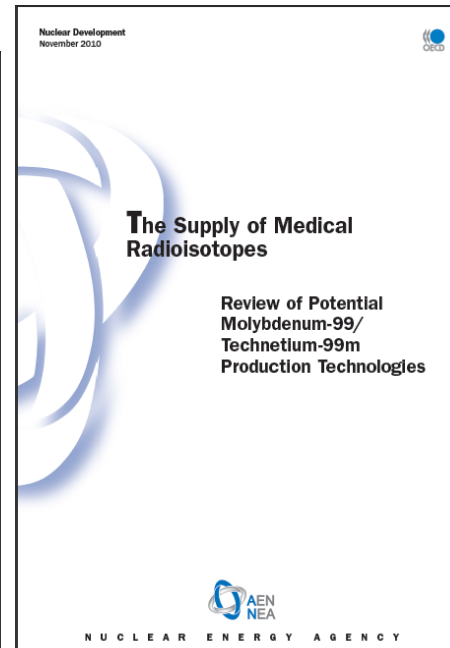
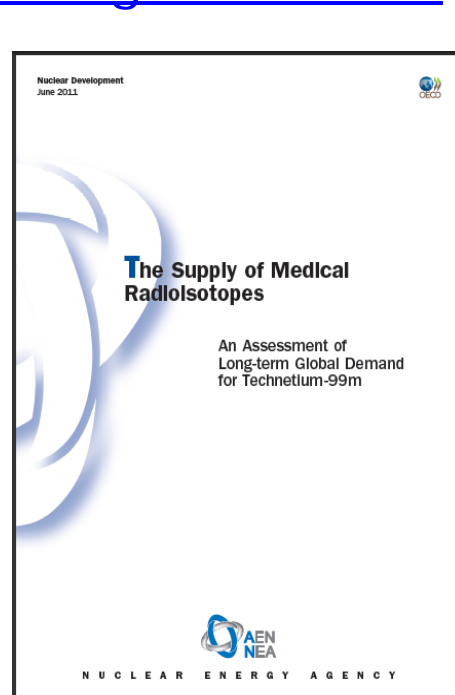
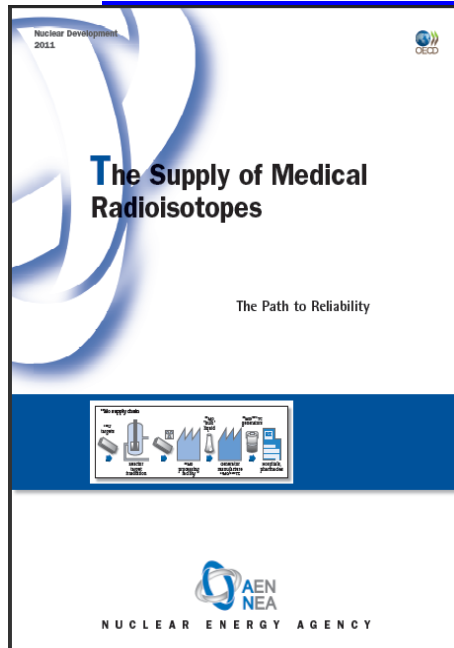
The transition to an economically sustainable future



The transition to an economically sustainable future



- If economic structure does not change, some proposed new projects likely not proceed – supply concerns within the decade
- Additional detail on HLG-MR policy approach in *The Supply of Medical Isotopes: The Path to Reliability*
- HLG-MR will continue work with second mandate
- www.oecd-nea.org/med-radio



The second mandate of the HLG-MR



- Sharing information for transparency
- Communicating final policy approach
- Providing guidance reports on implementation issues
 - Defining full-cost recovery methodology
- Supporting implementation of approach through further analysis or encouraging action, where appropriate and feasible
 - Proposal to study impacts of consistent ^{99m}Tc shortages
 - E.g.: Analysis of impacts of health care costs (different funding models, specific procedure costs, price elasticity of demand)
 - E.g.: Analysis of cost-saving actions at radiopharmacies/hospitals to facilitate economic sustainability
- Carrying our related studies
 - Market and economic impacts of converting to LEU targets
- Evaluating progress towards implementation
- Evaluating policy approach once experience obtained
- Regular reports to governments and major stakeholders