Implementation of the HLG-MR Policy Approach for a Secure Supply of Medical Radioisotopes

Ron Cameron

Head, Nuclear Development Division

OECD Nuclear Energy Agency

The High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

- Decision to establish the HLG-MR – at the request of OECD Nuclear Energy Agency member countries in April 2009.
  - At present, approximately 30 experts representing the governments of 17 countries, the European Commission, the International Atomic Energy Agency, and the Euratom Supply Agency
- HLG-MR Terms of Reference
  - Review the total ^{99}Mo supply chain from uranium procurement for targets to patient delivery
  - Identify weak points and issues in the supply chain in the short, medium and long term
  - Recommend options to address the vulnerabilities to help ensure stable and secure supply of radioisotopes
- Two mandates to date (2009-11 and 2011-13), with a recent agreement for a third mandate (2013-15)

The HLG-MR Policy Approach

- 6 policy principles:
  - All ^{99m}Tc supply chain participants should implement full-cost recovery.
  - Reserve production capacity should be sourced and paid for by the supply chain.
  - Governments should establish proper environment for efficient and safe market operations, ensure all market-ready technologies implement full-cost recovery, and refrain from direct intervention.
  - Government should facilitate the conversion to low-enriched uranium by reactors and processors.
  - International collaboration should continue through a policy and information-sharing forum, recognizing the importance of a globally consistent approach to addressing the security of supply of ^{99}Mo/^{99m}Tc.
  - Periodically review the supply chain to determine whether participants are implementing full-cost recovery and other approaches agreed to by the HLG-MR.

HEU-LEU Conversion Project

- HEU-LEU conversion – capacity and cost impacts analyzed, policy options presented
  - LEU-target conversion is important for long-term security of supply of $^{99}Mo/^{99m}Tc$.
  - Reduces the available irradiation and processing capacity, but does not cause potential long-term supply shortages.
  - Long-term supply shortages could occur if the unsustainable economic situation in the $^{99}Mo/^{99m}Tc$ supply chain does not improve. However, under an "economic challenges" situation, LEU conversion could accelerate expected long-term shortages.
  - Converted LEU-based ^{99}Mo is more expensive than HEU-based ^{99}Mo.
  - Negative price impacts (i.e., price increases) from LEU conversion along the entire supply chain, however, less pronounced at the radiopharmacy level compared to upstream.
  - Potential role for governments to encourage LEU-target conversion and consumer uptake of non-HEU-based $^{99}Mo/^{99m}Tc$ to help ensure long-term supply security.

Implementation of the HLG-MR Policy Approach

- Periodic review of the $^{99}Mo/^{99m}Tc$ supply chain: Self-assessment
  - Analyse and report on the functioning of the $^{99}Mo/^{99m}Tc$ supply chain
  - Provide a "monitoring mechanism" for the HLG-MR on the progress of the supply chain in implementing the HLG-MR policy approach
    - Highlight supply chain participants who have implemented or are making good progress, and those who have not
  - Increase awareness of actions taken by the supply chain
  - Provide basic information on the status of the supply chain
  - Focus on Principles 1-3: full-cost recovery, outage reserve capacity, and governments' role in the market
- Questionnaires sent to: governments, reactor operators, processors, generator manufacturers, and end-user/industry associations (NANP, EANM, SNMMI, AIPES)

Figure 3.1. Full-cost recovery implementation, producing reactors

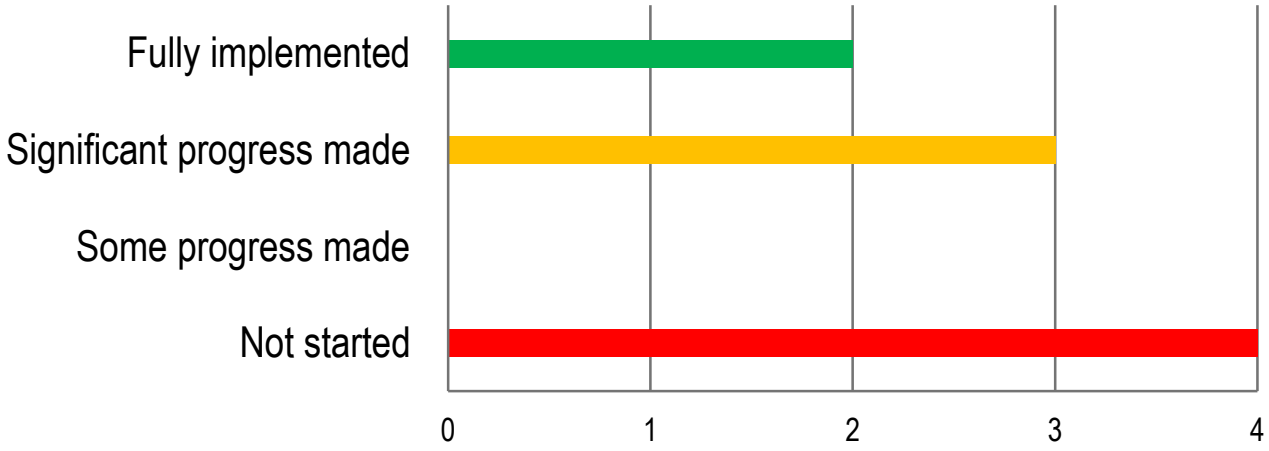
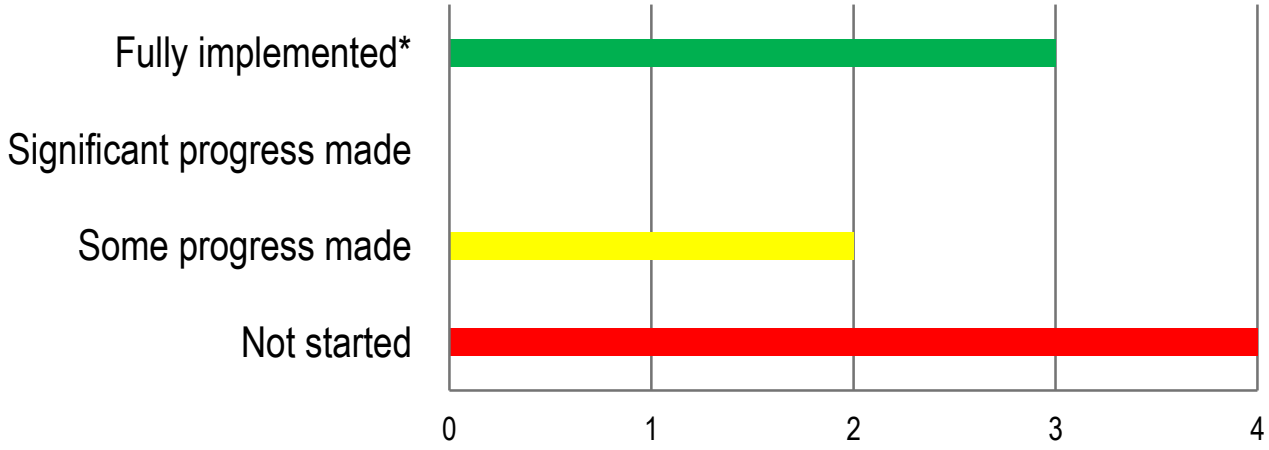


Figure 3.2. Outage reserve capacity implementation, producing reactors



* "Fully implemented" means that these reactors maintain outage reserve capacity and have indicated that they receive an adequate payment for it.

Figure 3.3. Full-cost recovery implementation, processors

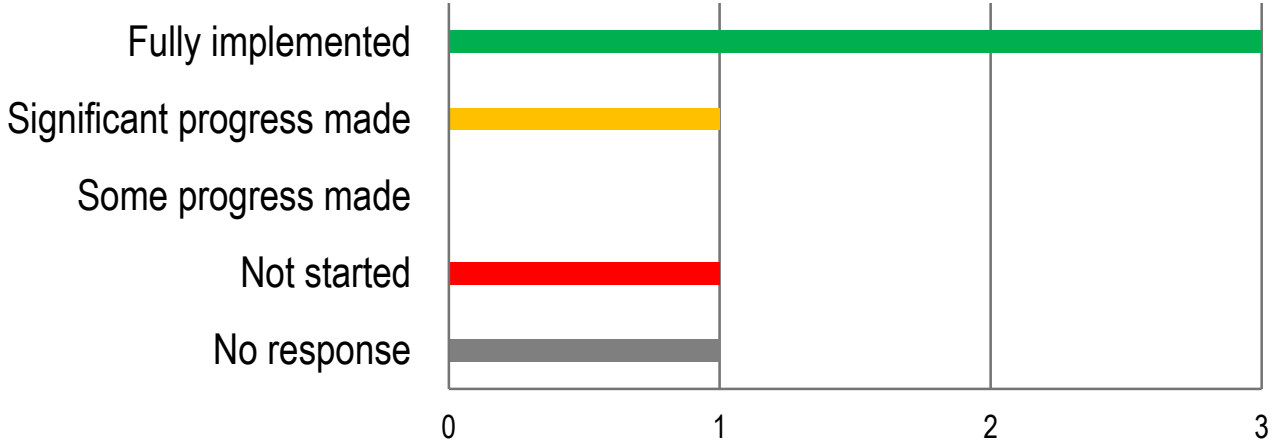
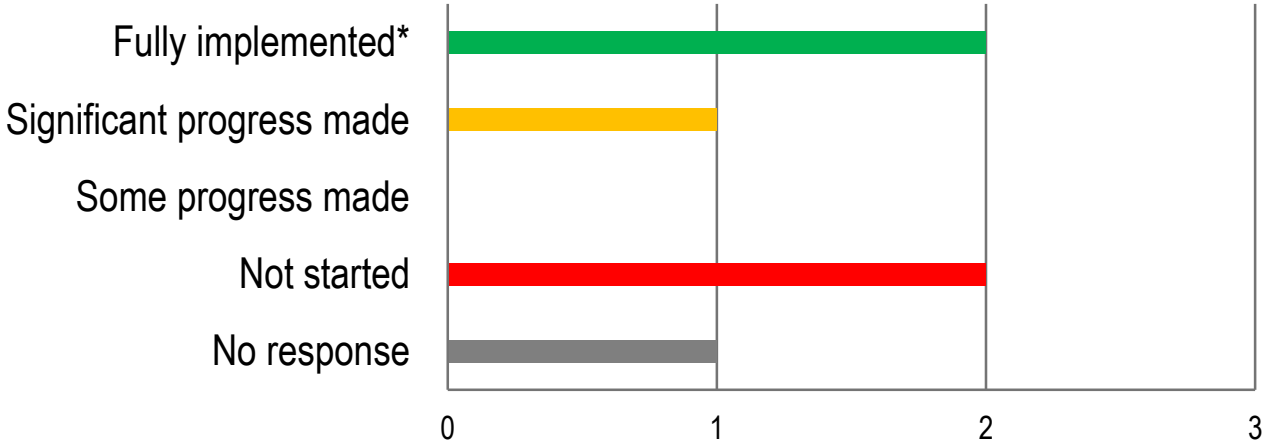


Figure 3.4. Outage reserve capacity implementation, processors



* "Fully implemented" means that these processors maintain outage reserve capacity and have indicated that they make and/or receive an adequate payment for it.

Figure 3.5. Government support for Mo-99 production, producing reactors

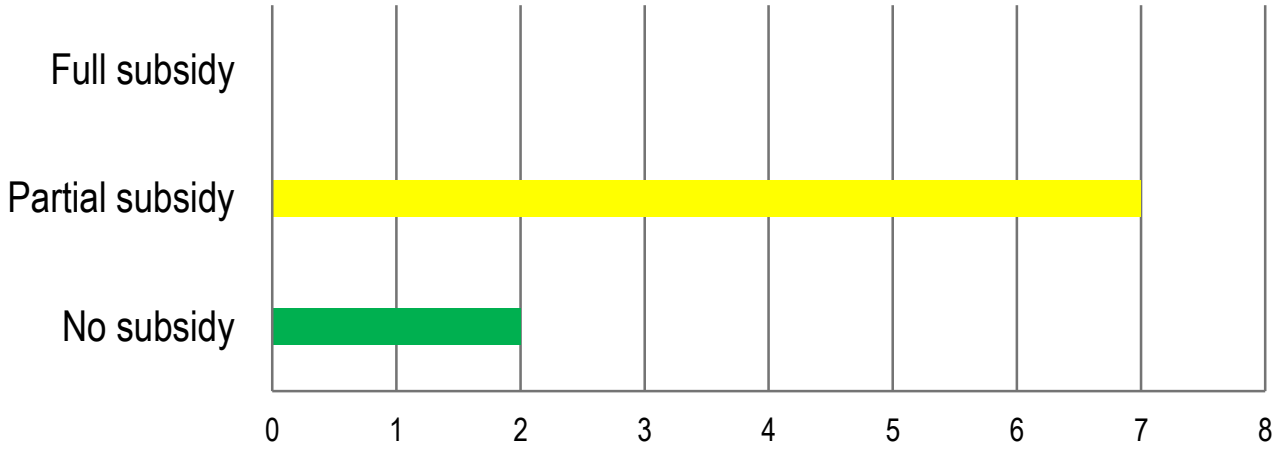
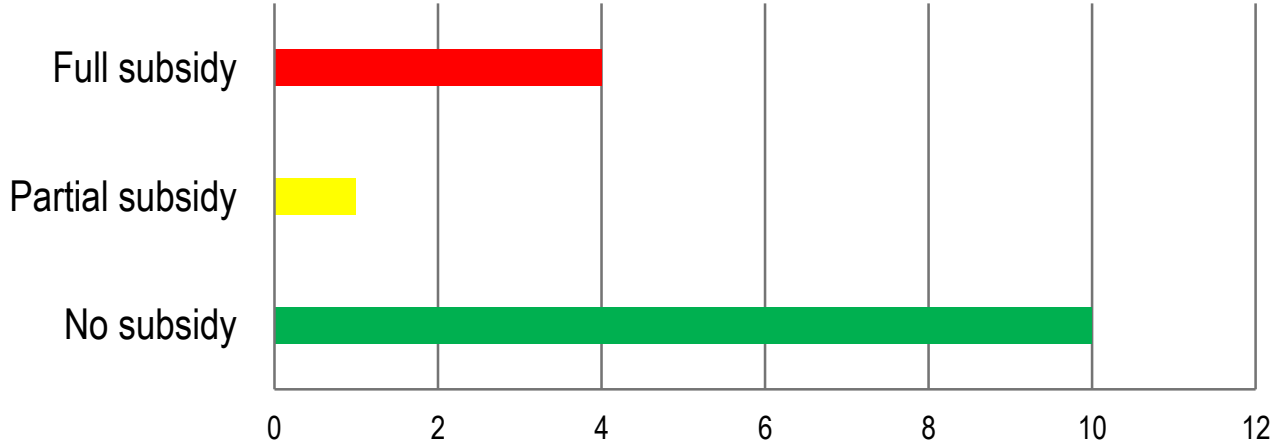


Figure 3.6. Government support for ^{99}Mo production at new/replacement reactors and reactor-based projects*



* Based on current understanding of the announcements by those countries

Progress Reported in the Self-Assessment

- Most supply chain participants have begun to implement full-cost recovery
- This process is occurring at different speeds in different regions and not everywhere
- Some countries have completed implementation[π] (Australia, South Africa), others will not implement in the short term or at all
- Significant improvement in coordination of reactor operating schedules and communication within the supply chain – reduced risk of supply shortages
- Most processors[π] and generator manufacturers have implemented full-cost recovery as expected for-profit entities
- However, despite positive steps, <u>some parts of the economic fundamentals remain unsustainable for the long term</u>

[π] Except for waste management

Major Issues Highlighted in the Self-Assessment

- Continued government subsidisation of ^{99}Mo production at reactors and some processors
- Long-term contracts at below-FCR prices
- Short-term exploitation of subsidised production and the practice of international reverse auctions, where suppliers compete on price ⟹ "Price warring"
- Non-payment or partial payment for outage reserve capacity
- In the absence of adequate provision for outage reserve capacity, apparent over-capacity when all existing reactors and processors are available
- Simultaneous transition to full-cost recovery and LEU conversion, creating technical and economic challenges for some processors
- Insufficient reimbursement for the medical isotope at the end-user level

Next Steps to Implement the HLG-MR Policy Approach

- Collect and analyse information on waste management practices and costs - currently a joint study with IAEA, the results of which will be published in a report later in 2013
- Conduct a second self-assessment of the global $^{99}Mo/^{99m}Tc$ supply chain (perhaps, a focus on LEU conversion?)
- Engage more closely with governments on:
  - the need to reduce and eliminate subsidies for ^{99}Mo production; and
  - providing appropriate reimbursement for the isotope in nuclear medicine procedures
- Engage more closely with ^{99m}Tc generator manufacturers and the medical community on the need to implement the HLG-MR policy approach for long-term security of supply

Documents and Reports

- The Supply of Medical Radioisotopes Series
  - *Implementation of the HLG-MR Policy Approach: Results from a Self-assessment by the Global $^{99}Mo/^{99m}Tc$ Supply Chain*
  - *Market Impacts from Converting to Low-Enriched Uranium Targets for Medical Isotope Production*
  - *The Path to Reliability*
  - *An Assessment of Long-term Global Demand for Technetium-99*
  - *An Economic Study of the Molybdenum-99 Supply Chain*
  - *Review of Potential Molybdenum-99/Technetium-99m Production Technologies*

Documents and Reports

- Guidance documents
  - *Provision of Outage Reserve Capacity for Molybdenum-99 Irradiation Services*
  - *Full-cost Recovery for Molybdenum-99 Irradiation Services*
  - *Full-cost Recovery Identification Workbook*
- Discussion documents
  - *Policy options for ensuring long-term supply security of molybdenum-99 and/or technetium-99m produced without highly enriched uranium targets*
  - *Unbundling payments for radioisotopes from radiopharmaceuticals and from diagnostic procedures: A tool to support the implementation of full-cost recovery*
- All documents are reports are available at: http://oecd-nea.org/med-radio/docs/

Thank You!

http://www.oecd-nea.org/

Update on ^{99}Mo Demand and Supply

- Web-published 2012 update on global supply and demand for ^{99}Mo

Demand

- Lower demand at 10 000 six-day Ci/week and projected to increase only slightly by 2030.

Supply

- Expected significant reduction in irradiation capacity from the exit of NRU (2016) and OSIRIS (around the same time) and commitment to LEU conversion (most of existing irradiators by 2015-16)
- Difficult to estimate the likelihood of new irradiation/processing capacity coming online despite some projects being at advanced stages of development

Conclusions

- Continuing unsustainable economic situation - disincentive for new infrastructure investment (already two project cancellations)
- Projected supply shortages (as early as 2016 from insufficient irradiation capacity) due to unfavourable economics
- Need to implement the HLG-MR policy approach