Unclassified **NEA/SEN/HLGMR(2013)7**

Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development **04-Sep-2013**

English - Or. English

NUCLEAR ENERGY AGENCY
STEERING COMMITTEE FOR NUCLEAR ENERGY

NEA/SEN/HLGMR(2013)7
Unclassified

High-Level Group on the Security of Supply of Medical Radioisotopes

The Supply of Medical Radioisotopes

Progress and Future Challenges in Implementing the HLG-MR Policy Principles: Final Report of the Second Mandate (2011-2013) of the HLG-MR

Contact: Pavel.Peykov@oecd.org

JT03343950

Complete document available on OLIS in its original format

English - Or. English

Acknowledgements

This report would not have been possible without input from a significant number of supply chain participants and stakeholders including all major reactor operators, all major processors, generator manufacturers, representatives from radiopharmacies and nuclear medicine practitioners.

The Nuclear Energy Agency (NEA) acknowledges the input and participation of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) members and other supply chain participants, which was essential for successfully completing the mandate of the HLG-MR. The NEA greatly appreciates the participation of these stakeholders.

This report was written by Pavel Peykov and Ron Cameron of the NEA Nuclear Development Division. Detailed review and comments were provided by the HLG-MR.

Table of contents

List of figures

List of tables

Executive summary

At the request of its member countries, the Organisation of Economic Co-operation and Development (OECD) Nuclear Energy Agency (NEA) became involved in global efforts to ensure a secure supply of molybdenum-99 (^{99}Mo)/technetium-99m (^{99m}Tc). In April 2009, the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) was created and received an initial, two-year mandate from the NEA Steering Committee for Nuclear Energy to examine the causes of supply shortages of ^{99}Mo/^{99m}Tc and develop a policy approach to address those causes.

In its first mandate, the HLG-MR conducted a comprehensive economic study of the ^{99}Mo/^{99m}Tc supply chain, which identified the key areas of vulnerability and major issues to be addressed. It was clearly demonstrated that the fundamental issue in the market was an unsustainable economic model behind the provision of ^{99}Mo/^{99m}Tc. The pricing structure at nuclear research reactors prior to the 2009-2010 supply shortage was based on government subsidisation that led to below-market prices. With moves by governments to gradually withdraw subsidies for ^{99}Mo production, which often benefits foreign countries or foreign companies, pricing must recover the full cost of production to ensure economic sustainability and a long-term secure supply of medical radioisotopes. In its first mandate, the HLG-MR also examined the global supply and demand for ^{99m}Tc and assessed potential alternative ^{99}Mo/^{99m}Tc production technologies.

In conclusion of the first mandate, the HLG-MR released a policy approach, including six principles (see Appendix 1) and supporting recommendations, to help resolve the issues in the ^{99}Mo/^{99m}Tc market and improve the reliability of supply. The HLG-MR should target to implement the six principles within three years of adopting the policy approach (June 2014). To ensure that supply chain participants implement the policy approach and continue to provide an international forum for discussion and collaboration, the HLG-MR renewed its mandate for a further two years, until 2013.

In its second mandate (2011-2013), the HLG-MR has worked to encourage the implementation of the six policy principles and address issues related to this implementation. The HLG-MR has also promoted and encouraged an industry transition from highly enriched uranium (HEU) targets to low-enriched uranium (LEU) targets for ^{99}Mo production. To meet the objectives of its second mandate, the HLG-MR has undertaken a number of projects that resulted in the publication of documents and reports to assist the ^{99}Mo/^{99m}Tc market in implementing the HLG-MR policy approach.

As government subsidisation of ^{99}Mo production continues to be a major issue in the market, in the second mandate, the HLG-MR has focused its efforts towards encouraging the implementation of full-cost recovery and outage reserve capacity by supply chain participants. Full-cost recovery helps the market achieve long-term sustainability, which increases supply reliability. Outage reserve capacity is important in ensuring adequate production capacity in the event that a large producer has an unexpected and/or extended shutdown, as was the case with the HFR reactor in the Netherlands between November 2012 and June 2013. The NEA, with the participation of key stakeholders, has devised a methodology for calculating the full costs of ^{99}Mo production and a methodology for valuing and paying for outage reserve capacity. On the basis of these methodologies, the NEA then evaluated supply chain participants (through a self-assessment) on their progress towards implementing the HLG-MR principles related to full-cost recovery and outage reserve capacity, along with the governments' role in the ^{99}Mo/^{99m}Tc market.

The NEA also carried out a comprehensive study of the potential impacts of converting from HEU to LEU targets for ^{99}Mo production. Although this process is occurring for important non-proliferation reasons, it is expected to affect the ^{99}Mo/^{99m}Tc industry in economic and technical terms, hence the interest by the HLG-MR in estimating the impacts. The study concluded that these impacts would be mostly felt in the upstream segment of the industry, by reactor operators and processors, with a much smaller impact downstream. Reactors would be affected by a reduced irradiation capacity and a corresponding reduction in available outage reserve capacity. For processors, one of the major challenges is technical – a change to a different and, in most cases, more time-consuming processing method, which also results in producing less bulk ^{99}Mo. During the conversion period, outage reserve capacity will be negatively affected at the processor stage too, as processors are expected to use both HEU and LEU targets until consumer demand for LEU-based ^{99m}Tc enables 100% LEU-based production. The NEA study also shows that conversion to LEU targets leads to an increase in the price of ^{99}Mo, which is larger upstream than at the radiopharmacy stage. Results from the study reveal the need for governments to encourage LEU-target conversion through incentives to producers and/or consumers, given that this process is occurring for non-economic reasons. Such incentives would help supply chain participants recover their extra costs from conversion.

A second report by the NEA, related to the LEU conversion project, presents a number of policy options for government decision-makers to encourage supply chain participants to convert to LEU targets. The policy options are divided into three broad categories depending on the type of action used to change behaviour (positive versus negative):

- making the production/purchase of non-HEU ^{99}Mo/^{99m}Tc more attractive (e.g. through financial incentives);
- making the production of HEU less attractive (e.g. through taxes); and
- restricting access to HEU (e.g. through regulations).

To evaluate the progress made on the implementation of the HLG-MR policy approach, the NEA undertook a review (through a self-assessment) of the supply chain. The review found that most reactor operators and processors are gradually implementing full-cost recovery for ^{99}Mo production, although this process is happening at different speeds and not everywhere. On the other hand, government subsidies continue to present a significant barrier to full implementation, which is particularly evident at the reactor level. Furthermore, some planned new, multipurpose reactors for ^{99}Mo production may be built with public funds, further exacerbating the current unsustainable situation in the market. In the downstream segment of the supply chain, it is unclear to what degree generator manufacturers and end-users are implementing full-cost recovery, given the shortage of responses provided to the self-assessment survey. Almost all generator manufacturers are private, for-profit companies, while end-users are typically reimbursed by governments for the radiopharmaceuticals or diagnostic procedures using radioisotopes.

The self-assessment also revealed that outage reserve capacity is still not widely accepted and used by the market, although it contributes significantly to the security of supply. Outage reserve capacity is appropriately valued and paid for only in a few cases globally at present. In other cases, reactor operators are in the process of negotiating contracts with their processors for the provision and payment for outage reserve capacity. There are also instances where outage reserve capacity is used but not paid for.

Although governments have historically subsidised research reactors (the current dominant global source of ^{99}Mo and for the foreseeable future), many of them are beginning to withdraw their support and encourage reactors to commercialise ^{99}Mo production. Other governments, however, continue to provide subsidies. Where ^{99}Mo production is for the global market, governments should refrain from subsidising ^{99}Mo-related infrastructure of existing or new/replacement reactors, processors or other supply chain participants, to comply with the principle of full-cost recovery and avoid distorting the global market. Further downstream, nuclear medicine has been affected by pressure to contain costs by governments. According to the self-assessment results, few governments have taken concrete actions on reimbursement rates for medical radioisotopes. The Belgian government is planning to implement a separate reimbursement for ^{99m}Tc, while the United States government has added a supplementary payment to reimburse hospitals for the higher cost of LEU-produced ^{99m}Tc, in an attempt to encourage LEU conversion, an action that is also intended to cover the costs of moving to full-cost recovery. In addition, most hospitals in Canada already account for the isotope separately from the medical procedure, which achieves transparency in valuing the isotope. To increase awareness among governments of the importance of appropriate reimbursement for ^{99m}Tc and to assist in any potential action they take, the NEA has issued a discussion document on the separation of reimbursement for the radioisotope from the radiopharmaceutical and the diagnostic procedure. This document serves as a tool to help achieve greater transparency in determining the value of the radioisotope and enable full-cost recovery.

In this second mandate of the HLG-MR, the NEA also published an update on ^{99}Mo supply and demand to 2030. The update confirms the current unsustainable economic situation in the supply chain and provides an indication of potential future supply shortages. In the recently approved third mandate of the HLG-MR (2013-2015), the NEA will refine its supply and demand projection by focusing more intensively on a shorter time period (2016-2020), a period that appears to be critical, given the impending end of ^{99}Mo production at the NRU reactor in 2016 and the OSIRIS reactor around the same time.

The HLG-MR work during its second mandate shows that, while commendable progress has occurred in many areas, there are still major issues in the ^{99}Mo/^{99m}Tc market: continued government subsidisation of ^{99}Mo production, insufficient outage reserve capacity, inadequate reimbursement for ^{99m}Tc, and a potential supply shortage with the loss of significant irradiator capacity in and around 2016. In the third mandate of the HLG-MR, the NEA intends to address these issues by:

- conducting a second review of the supply chain to provide an update on progress with the implementation of all six HLG-MR policy principles;
- continuing to work with key stakeholders to pursue effective ways of engaging with downstream supply chain participants (generator manufacturers and government health officials) more closely in the process of implementing full-cost recovery;
- refining the supply and demand projection for 2016-2020; and
- undertaking other topic-specific projects (e.g. refining the methodology for calculating full costs), as requested by the HLG-MR.

1. Introduction

In mid-2009, following the shortages of the key medical radioisotopes molybdenum-99 (^{99}Mo) and its decay product technetium-99m (^{99m}Tc), the OECD Nuclear Energy Agency (NEA) created the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). Since its initiation, the group's main objective has been to strengthen the reliability of ^{99}Mo/^{99m}Tc supply globally in the short, medium and long term.

During its first mandate (2009-2011), the HLG-MR examined the major issues that affect the ^{99}Mo/^{99m}Tc supply chain. The HLG-MR, working with medical isotope stakeholders, completed a comprehensive assessment of the key areas of vulnerability in the supply chain and identified the issues that needed to be addressed. It also examined the supply and demand for ^{99m}Tc, undertook a full economic analysis of the supply chain, and reviewed potential alternative ^{99}Mo/^{99m}Tc production technologies. This work resulted in the release of several reports that have been issued under *The Supply of Medical Radioisotopes* series. In conclusion of the mandate, the HLG-MR released a policy approach to move the ^{99}Mo/^{99m}Tc supply chain to a sustainable economic basis. The policy approach includes six principles (see Appendix 1), which the HLG-MR should target to implement within three years of their release (June 2014), and consistent with the supporting recommendations.

In April 2011, the NEA Steering Committee approved a second, two-year mandate (2011-2013) for the HLG-MR, in which the main objective was to implement the agreed policy approach in a timely manner. To achieve that, the HLG-MR would maintain communication with stakeholders and transparency on global ^{99}Mo/^{99m}Tc market developments, evaluate progress towards the implementation of the policy approach, and provide additional information and analysis, where necessary. The broad deliverables for the second mandate of the HLG-MR include:

- Sharing of information on the status on the ^{99}Mo/^{99m}Tc market and regular reports on technical developments within the market, to increase transparency and encourage consistency in approaches.
- Communicating the HLG-MR policy approach to governments and other supply chain participants, including working more closely with the health community.
- Providing guidance on specific aspects of implementing the HLG-MR policy approach. Suggested guidance could include developing a guidance document that defines the methodology for apportioning common costs within the full-cost recovery methodology, including further study on waste disposal processes and waste costs for ^{99}Mo production along the full supply chain, how to establish a level-playing field between old and new reactors and the issues related to implementation of full-cost recovery in the supply chain.
- Supporting the implementation of all aspects of the HLG-MR policy approach, where appropriate and feasible. Suggestions would be to: work with the health community to study the potential impacts of consistent ^{99m}Tc supply shortages; explore standardised approaches to separate reimbursement of ^{99m}Tc from the radiopharmaceutical and the diagnostic procedure; undertake further analysis of the impacts on health costs looking at different health care funding models, diagnostic procedures, and price elasticity of demand; further analysis on cost-

saving actions at the radiopharmacies/hospitals to facilitate economic sustainability, such as better elution patterns, examining the role of centralised radiopharmacies, etc.

- Carrying out studies related to security of supply, e.g. analysing the market and economic impacts of converting to using low-enriched uranium (LEU) targets for ^{99}Mo production.
- Evaluating the progress towards the implementation of the HLG-MR policy approach, including the periodic review of the supply chain. This periodic review could also provide an update of the supply chain and its evolution, and an assessment of key issues affecting the supply chain, e.g. the growth of use of alternative technologies or examining changes in reimbursement rates.
- Re-evaluating the appropriateness of the policy principles once experience has been obtained.
- Regular reports to governments and other major stakeholders.

In the second mandate, the HLG-MR has given priority to the implementation by supply chain participants of the first two policy principles – on full-cost recovery and outage reserve capacity for ^{99}Mo production, in a timely and globally consistent manner. To that end, the NEA, in co-operation with key stakeholders, has created methodologies for calculating full costs and valuing and paying for outage reserve capacity. It issued reports on these methodologies and their implementation, which are particularly useful to the upstream segment of the industry (reactor operators and processors), where the most changes need to occur for long-term market sustainability (see Sections 2 and 3 of this report). The NEA has also worked with key stakeholders to ensure that the methodologies are applied in a consistent manner. Additionally, in its second mandate, the HLG-MR has focused on working with governments to accelerate the withdrawal of public funds to support reactors and processors, thus helping drive the process towards full-cost recovery and the provision of outage reserve capacity.

To better understand the transition from highly enriched uranium (HEU) to LEU targets for ^{99}Mo production, the HLG-MR requested that the NEA undertake a project to study the impacts on the ^{99}Mo/^{99m}Tc supply chain and propose actions to support this transition. This work resulted in the release of two reports – one on the market impacts of conversion and one on potential policy options to encourage the conversion process (see Section 4).

A key project during the second HLG-MR mandate was a review of the ^{99}Mo/^{99m}Tc supply chain, based on input from key supply chain participants, provided through self-assessment questionnaires, the results of which were presented and analysed in a report (see Section 5).

The NEA also produced an update on ^{99}Mo/^{99m}Tc demand and supply (see Section 6) and is currently working on a joint study with the International Atomic Energy Agency (IAEA) on the back end of ^{99}Mo production, with a report expected later in 2013, which would enable a refinement of the full-cost recovery methodology by including waste management costs.

This report concludes the second mandate of the HLG-MR.

2. Full-cost recovery methodology and implementation

The first principle of the HLG-MR policy approach states the need for $^{99}Mo/^{99m}Tc$ supply chain participants to implement full-cost recovery to ensure a long-term reliable supply of these important medical isotopes. This will provide the economic incentives to develop sufficient ^{99}Mo-related infrastructure and fully recover costs. It will also provide a more equitable field for competition among producers.

For a consistent approach on how ^{99}Mo production costs are identified, the NEA issued a guidance document that provides a full-cost recovery methodology for irradiation services. The methodology includes the high-level cost components to be used in calculations and a discussion of how these components should be allocated between various missions in the case of multipurpose facilities. The guidance document, *Full-cost Recovery for Molybdenum-99 Irradiation Services: Methodology and Implementation* (OECD/NEA, 2012b) is accompanied by an Excel workbook to enable reactor operators to calculate their full costs more readily.

Full-cost identification

Any multipurpose facility that irradiates targets for ^{99}Mo production (all of the currently irradiating research reactors) needs to attribute a certain portion of its general or shared costs to ^{99}Mo production, with the remaining portion of the costs being attributed to the other missions within the facility. In addition, the facility has some specific costs that can be clearly and directly attributed to ^{99}Mo irradiation services.

The identified high-level cost components in the irradiation facility are:

A. Capital costs:

- refurbishment costs that would be depreciated (to distinguish from maintenance): amortised over the life of the refurbished components;
- new infrastructure amortised over its lifetime, which was decided to be 40 years for a research reactor to ensure consistency, including any financing costs.

B. General overhead costs:

- general or shared administration, including: human resource management, financial and accounting services, legal services, information technology (IT), government relations, etc.;
- site infrastructure support: roads and grounds, site and facilities maintenance.

C. General operational costs:

- reactor operation and maintenance staff, safety staff, centralised engineering, design and manufacturing services, etc.;
- reactor fuel (or equivalent with alternative technologies) and other generic consumables;
- utilities: energy, water, etc.;
- licensing and regulatory requirements, quality control;

- security, including staff;
- waste management: management of full waste streams from the reactor (or other production technology), not including legacy waste;
- final waste disposal provisions (not including legacy waste).

D. Decommissioning costs:

- annual provisions for the decommissioning (and related final waste disposal) of the research reactor or alternative production technology.

E. Specific ^{99}Mo irradiation costs:

- irradiation device (e.g. rigs): design, construction, operation, maintenance, dismantling; specific costs associated with the device to be recouped if they were not already paid by the processor;
- handling of irradiation targets:
  - reception, storage, loading/unloading, conditioning;
  - "ex-works truck loaded" services, where provided (e.g. shipping, providing shipping containers, provision of targets); specific costs associated with these services to be recouped if they are not already provided by processor;
  - administration: specific staff, insurance, security.
- processing waste management: if the reactor operator manages waste from the processing procedure or facility;
- processing waste final disposal: if the reactor operator is responsible for the final disposal provisions for waste from the processing procedure or facility.

The overall methodology for determining the costs of ^{99}Mo irradiation services is given by the following equation:

$$\textit{Full Cost of } {}^{99}Mo = wA + y_m (x_r B + C) + zD + E$$

Where:

A = Capital costs

B = General overhead costs of the entire site

C = General operational costs of the reactor

D = Decommissioning

E = Specific ^{99}Mo irradiation costs

And w, y_m, x_r, and z are the respective fractions of these components.

Even though the NEA full-cost recovery methodology documents (guidance document and Excel workbook) are primarily for use by reactor operators, full-cost recovery should be implemented by all producers that supply the global market. Otherwise, there will be inconsistencies leading to market distortions that could jeopardise the long-term economic sustainability of the irradiation providers and thus, the long-term supply security of ^{99}Mo/^{99m}Tc. In addition, it should be recognised by all consumers within the global market that the price increases expected by the application of full-cost recovery should flow through the supply chain and should be reflected in the costs of the final medical procedure, to be reimbursed appropriately by the health care system. As shown in the NEA Economic Study (OECD/NEA, 2010), the final impact on end-users should be reasonably small; however, the increases are necessary to ensure reliable supply.

3. Outage reserve capacity methodology and implementation

The second principle of the HLG-MR policy approach states that outage reserve capacity (ORC) should be sourced and paid for by the ^{99}Mo/^{99m}Tc supply chain. This is the capacity set aside at reactors to provide a contingency against unplanned or extended outages. To help supply chain participants implement this principle, the NEA has produced a guidance document explaining the methodology for valuing and paying for ORC, and the economic effects from it. The document is titled *Provision of Outage Reserve Capacity for Molybdenum-99 Irradiation Services* (OECD/NEA, 2013a).

In order to recognise the need for fair distribution of operating capacity in times of shortage and still create the incentive for the supply chain to pay for the reserve capacity, it is necessary to set a minimum amount of ORC that needs to be maintained by the supply chain and increase end-users' prices accordingly. This would require transparency and verification of the amount of reserve capacity being held within the supply chain to ensure that the payments received were used to increase reliability.

After examining a number of possible approaches, the HLG-MR agreed that ORC should be provided through incremental capacity options. For ease of implementation, and recognising the pivotal role of processors in the supply chain, processors should be responsible for holding ORC options equal to at least the largest source in their supply chain at all times. This is referred to as the "n-1" criterion, where the supply chain should be able to absorb the loss of the largest unit in the chain. Different levels of ORC were considered, but it was determined that a level greater than n-1 would be too onerous and not necessary for the supply chain to maintain. It was recognised, however, that the n-1 level should be evaluated after some experience to determine if there was a need to change it.

Valuing and paying for ORC

In relation to full-cost recovery, the price paid for options contracts should cover the transaction costs and fixed costs (capital and operating) of ORC providers. When the option is exercised, the processor would have to pay additional variable costs based on the actual production capacity used. Governments should clearly indicate that they will not subsidise ORC at reactors and therefore, costs will have to be fully recovered through ORC contracts. How that pricing is designed should be up to the supplier of the ORC options contract (e.g. whether bundled with irradiation services or priced as a separate product from irradiation services).

However, it should be noted that options contract prices, even if determined by market forces, may not capture the actual full costs to the supply chain in the event of ORC use. If a reactor fails, hence activating ORC elsewhere in the supply chain, the processor(s) that is(are) using this reactor as their main (or only) source of ^{99}Mo irradiation services will attempt to source capacity from another reactor/processor or further downstream. This alternative source is likely to be less efficient for the processor (e.g. located farther from their production facilities or irradiating targets that require different transportation containers), which will increase the processor's production costs and, consequently, the ^{99}Mo prices for downstream customers. This price increase will not be reflected in the ORC options contract and while it may not be significant, it should be taken into consideration in case of ORC activation/use.

While processors would be expected to pay for ORC options contracts, they would recuperate their costs through ^{99}Mo/^{99m}Tc prices to their customers further downstream. In essence, downstream prices would include a non-optional "reliability premium". End-users should be made aware of the need for reliability provisions and that their payments would include a portion to ensure a secure supply by supporting ORC. End-users should also clearly include provisions in their contracts with suppliers related to reliability that would be triggered in the event of non-deliverability of product, encouraging upstream reliability measures.

Economic effects of valuing and paying for outage reserve capacity

The approach to valuing and paying for ORC in this document is based on the premise that reactors holding it incur costs to provide this service and should be compensated appropriately for it. Otherwise, they would not have an incentive to hold ORC. Producers of ^{99}Mo who have access to ORC should pay for its share of overhead and capital costs, as well as fixed operating costs, when the ORC is not used. When it is used, the price of irradiation services would cover the variable operating costs as well.

To determine the economic effects of ORC, the NEA modelled two cases of a multipurpose (MP) reactor with 20% of its production capacity allocated to ^{99}Mo irradiations – one *with* capital costs and one *without* capital costs. The first case is consistent with the principle of full-cost recovery (i.e. includes sustainable pricing of irradiations and ORC), while the second case reflects the market situation in many current cases, where major reactors have completely depreciated their capital costs. Two scenarios were developed for each case – with 33% ORC[1] and 47% ORC[2] in the reactor. The two scenarios were compared to a reference case with no ORC.

Table 3.1 below show the levelised unit costs along the ^{99}Mo/^{99m}Tc supply chain in two scenarios for the case *with* capital costs included in the outage reserve capacity pricing, compared to a reference case. The costs prior to the 2009-10 supply shortage are also given for comparison. Table 3.2 presents the same information for the case *without* capital costs.

Table 3.1. Illustration of levelised unit costs for a MP reactor with 20% of its capacity allocated to ^{99}Mo production with capital costs, in EUR/6-day Ci EOP*

	From reactor	From processor	From generator	From radiopharmacy
Prices pre-shortage	44	317	374	1 810
Reference case: 20% MP, sustainable pricing, no ORC	142	415	471	1 908
20% MP sustainable pricing 33% ORC in reactor	207	480	537	1 974
20% MP sustainable pricing 47% ORC in reactor	260	533	590	2 026

* Values are rounded and medians presented for all scenarios. Values should only be used for illustrative purposes and should not be construed as true market prices.

1. Based on a derived model showing that a system with a somewhat effective, but not perfectly ideal co-ordination, with a large reactor in the fleet, could maintain n-1 outage reserve capacity levels, if each reactor kept, on average, 33% of its capacity as outage reserve capacity.
2. Based on a simple calculation of how much reserve capacity would have to be held at four of the "traditional five" reactors to account for the loss of the largest reactor in the system.

Table 3.2. Illustration of levelised unit costs for a MP reactor with 20% of its capacity allocated to ^{99}Mo production and no capital costs, in EUR/6-day Ci EOP*

	From reactor	From processor	From generator	From radiopharmacy
Prices pre-shortage	44	317	374	1 810
Reference case: 20% MP no capital costs, no ORC	56	329	385	1 822
20% MP no capital costs 33% ORC in reactor	79	352	409	1 846
20% MP no capital costs 47% ORC in reactor	98	371	427	1 864

* Values are rounded and medians presented for all scenarios. Values should only be used for illustrative purposes and should not be construed as true market prices.

4. LEU Conversion Project

The Market Impacts Study

In addition to the ongoing concerns about the long-term economic sustainability of the ^{99}Mo/^{99m}Tc supply chain, all current major ^{99}Mo-producing nations have agreed to convert to the use of LEU targets for ^{99}Mo production. This decision was made based on important non-proliferation reasons; however, the conversion will have potential impacts on the global supply chain – both in terms of costs and available production capacity. It is also important to note that global access to HEU for ^{99}Mo/^{99m}Tc production may not continue indefinitely[3], which necessitates the move to non-HEU based production by existing and new producers, and through the use of alternative technologies.

Recognising this situation and aware of the need to ensure a long-term secure supply of ^{99}Mo/^{99m}Tc, the NEA and its HLG-MR undertook a study to quantify the expected capacity and cost impacts of LEU-target conversion. This project also included an examination of potential policy options to ensure a reliable supply of ^{99}Mo/^{99m}Tc produced without HEU, consistent with the timeframes and policies of the HLG-MR.

To increase the understanding of the economic and supply chain impacts of converting to using LEU targets for ^{99}Mo production, the NEA examined the impact on individual facilities to develop an assessment of the impacts on the whole supply chain. A capacity model and an economic model of the supply chain were developed and used to assess the impact of conversion on global supply availability and costs, in comparison to a reference case.

Information for the assessment came from an expert working group made up of major supply chain participants, which met for two workshops. The information provided by the working group was supplemented by NEA interviews with individual supply chain participants and NEA's own knowledge of the supply chain.

Capacity modelling

The NEA modelled three different impact scenarios in an "all-in" situation, as well as two different "challenges" situations. The three impact scenarios applied high, low and very low impacts to the reference data for the three situations. Under the high (and low) impact scenario, the NEA applied the highest (and lowest) expected facility-specific impact on production capacity. The very low impact scenario assumes that the economic returns from ^{99}Mo irradiation services improves significantly (e.g. full-cost recovery and paid outage reserve capacity are fully achieved) such that reactors, where possible, displace non-^{99}Mo-related irradiations in order to return ^{99}Mo irradiation capacity to pre-conversion levels. These impact scenarios were then applied to the three "situations":

3. For example, the American Medical Isotopes Production Act of 2012, which was signed by President Obama into law on 2 January 2013, includes provisions to restrict the export of HEU from the United States for the purposes of medical isotope production by 2020.

- ***"All-in" situation***: shows the expected impact from LEU-target conversion on all current and potential irradiators and processors according to the facility-specific time schedules of operation, conversion (if applicable) and shutdown.
- ***Economic-challenges situation***: starts from the "all-in" situation and then assumes that the current unsustainable economic situation continues, such that only projects that could be constructed and operate without commercial funding proceed. The very low impact scenario was not applied for this situation.
- ***Technology-challenges situation***: starts from the "all-in" situation and then assumes that new technologies and new entrants face a higher risk in implementing their various projects. All three impact scenarios (high, low and very low) were applied for this situation.

Reactors were mostly affected by a reduction of ^{99}Mo production as a result of lower uranium-235 (^{235}U) content in the targets[4]. The expected impacts range from no reduction in irradiation capacity up to a reduction of 50%, depending on the facility. In addition, there is a corresponding reduction in available ORC. It was also expected that one irradiator will require one year of downtime in order to convert to LEU targets. These impacts were applied on a facility-specific basis to the reference data for the various impact scenarios to determine the impacts.

For the processors, the key incremental impact was the modified processing method, which is more time consuming in most cases; the lower ^{235}U content was an effect at the reactor stage that flowed through to the processors. The different processing method results in the reduction of bulk ^{99}Mo from increased decay, among other impacts. The expected reductions range from no impact up to 60%, depending on the processing facility. ORC will be affected at the processing stage during the conversion period since processors will need to take processing lines out of operation to introduce LEU based processing and then will generally have to operate both HEU- and LEU-based ^{99}Mo processing lines until consumer uptake increases to a level that allows for a switch to 100% LEU-based production. This transition will temporarily take capacity out of the system, as well as lead to capacity limitation for either HEU- or LEU-based processing which removes existing redundancy that exists. However, once production is completely from LEU targets, processing ORC should be fully available, but perhaps at lower levels as the new LEU processes may have lower capacity.

The expert working group agreed that there were no incremental capacity impacts on generator manufacturers or further downstream. However, it was recognised that generator manufacturers face logistical challenges during the conversion process from keeping production of generators from HEU- and LEU-based ^{99}Mo in separate batches until they receive health approvals for LEU generators for all of their markets.

Results: capacity impacts

Applying the range of expected facility- and time-specific impacts to the reference data illustrates the likely available global capacity and production of ^{99}Mo irradiators and processors. For both current irradiation capacity and processing production, conversion to using LEU targets does not create new long-term supply shortages; the shortages

4. It should be noted that the capacity study only examined the impacts of converting using "phase I" targetry – targets that are market or near-market ready. These targets have a higher density of ^{235}U, but are not high-density targets in the sense of "phase II" targetry (which would include such advanced target types as high-density foil targets). It may take a number of years before phase II targets are commercially viable and available. It was deemed by the expert working group that the decision to convert to phase II targetry would be a business decision based on whether the expected benefits of the added production would outweigh the expected costs of converting to using the advanced high-density targets.

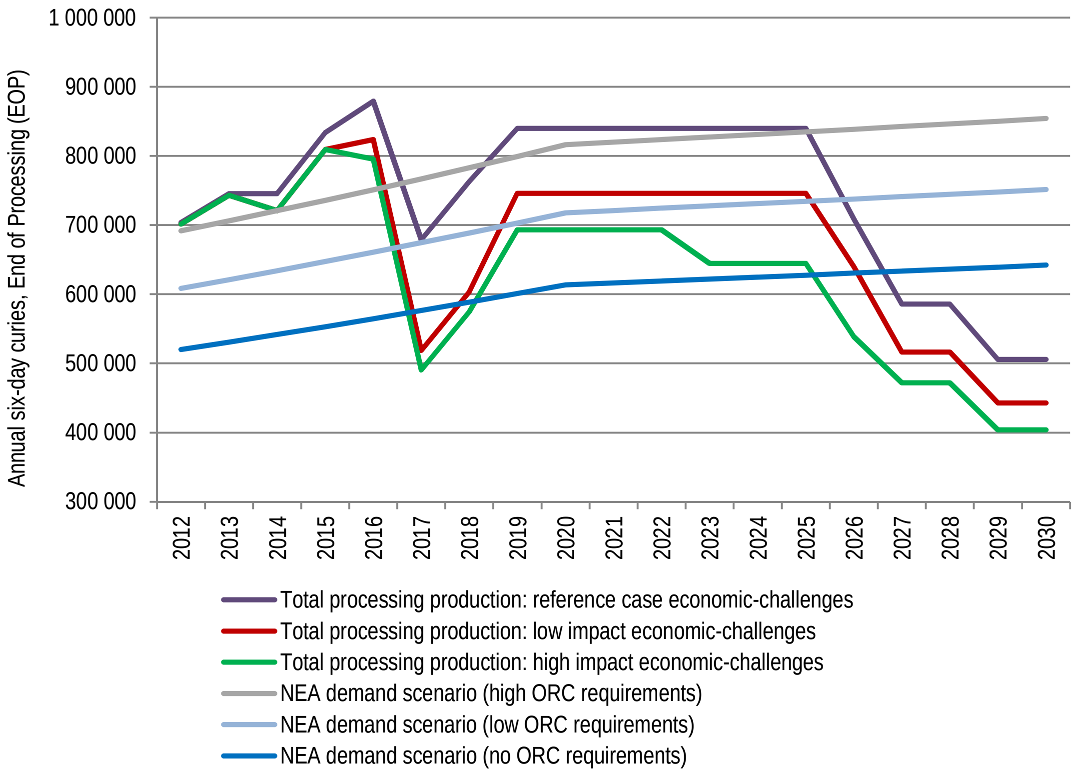
shown are already expected given the final shutdown of a number of existing facilities over the next decade. However, LEU conversion does intensify the shortages by reducing available capacity.

Under the "all-in" and technology-challenges situations, supply is sufficient over the time period to 2030 for both irradiator capacity and processing production. LEU-target conversion does reduce effective capacity and production, but not to levels that are of concern (i.e. below expected demand). However, there are two periods (2014 and 2017) when processor production under the technology-challenges situation is projected to be tight compared to demand with a high ORC requirement.

Of significant concern, though, are the results of the impact scenarios in the economic-challenges situation, where for both irradiation capacity and processing production, the supply is not sufficient to meet demand in the long term (see Figure 4.1). In this situation, LEU-target conversion brings earlier the timing of the expected long-term shortages, creating a significant shortfall in 2017 resulting from one irradiator that indicated a need to shut down for conversion. Between 2018 and 2025, LEU-target conversion predicts supply below the high-demand curve in Figure 4.1 (except for the reference case); by 2027 all the scenarios (including the reference case) predicts that supply drops below even the lowest demand curve.

These results are similar to the results from the NEA Economic Study (OECD/NEA, 2010). While it is clear that LEU-target conversion does reduce available capacity and production, the main concern for security of supply remains the unsustainable economic condition facing the supply chain (e.g. full cost recovery not achieved and paid ORC not implemented). In terms of capacity impacts, if the economic situation in the supply chain were to improve sufficiently to support sufficient commercial investment, LEU-target conversion should not create concerns about a secure ^{99}Mo supply.

Figure 4.1. Current and select new entrants processing production of ^{99}Mo vs. demand under the economic-challenges situation



Cost modelling

The cost modelling, like the capacity modelling, started with a reference case for each currently operating ^{99}Mo irradiation or processing facility, as well as two new entrants: the FRM-II and Russian reactors. Given the objective of determining the impact on costs from LEU conversion, other new entrants were not modelled, as they are planned to be non-HEU production facilities from the start of irradiations.

The facility-specific reference cases were developed with data provided by supply chain participants during the NEA Economic Study (OECD/NEA, 2010) and updated during this study. Where direct information was not provided, the NEA made assumptions about costs based on the results of the economic study. Using these data, the reference cases were developed using the levelised unit cost of ^{99}Mo (LUCM) methodology used in the economic study.

The NEA modelled the impacts by applying the high and low expected cost impact values to the reference case for the specific facility, based on the specific timelines of that facility for operation, conversion and shutdown. The high and low expected values were coupled with the related capacity scenarios to undertake the LUCM modelling (which takes into account changes in production). In general, high infrastructure cost values were applied to the low capacity impact scenario, as high upfront investment should minimise the capacity impact from conversion.

For the processor facility-specific LUCM modelling, the irradiators' LUCM values from the various scenarios were used as input costs (i.e. the costs of providing irradiation services) for the relevant processor scenario. The range of processors' LUCM changes was then applied down the supply chain to determine the resulting changes at each stage. As in the economic study, this assumes a 100% cost flow-through down the supply chain, and allows for the clear assessment of the impacts of LEU-target conversion cost changes through the supply chain and on the end-payer.

As with the capacity modelling, the expert working group determined that the main incremental cost impacts would be at the irradiator and processor stages of the supply chain. The cost impacts started at the uranium and target supply stages, which were modelled as processing cost increases given that processors are, in general, responsible for paying for targets. In this first stage, it was recognised that there would be an impact on the final cost of targets and on the research, development and qualification for these LEU targets.

For irradiators, the incremental cost impacts were related to the necessary infrastructure changes in the reactor. It was identified that either new irradiation rigs would be needed or the existing rigs would have to be modified to handle the different geometry of the new LEU targets, depending on the facility and the processor requirements. Cost impacts from reduced production (including required downtime) were calculated via the LUCM, and other identified costs impacts (such as regulatory approvals) were included in processor conversion project costs, as irradiators indicated that they would pass the costs on to processors.

Processors face a number of incremental cost impacts, including costs from: modifying or developing new containers for transporting irradiated LEU targets (which also includes regulatory approval costs for the containers), infrastructure changes required to process changed targets and to increase waste storage, operating impacts, and supporting generator manufacturers in obtaining health regulatory approvals. The costs for these various cost impact elements vary across facilities and sometimes within the facilities themselves (in terms of high and low expected or experienced impacts).

Results: cost impacts

Applying the range of expected facility- and time-specific cost impacts of the various impact elements to the facility reference case gives the expected results of the cost of converting to LEU targets for ^{99}Mo production. It should be noted that the reference case that is used for comparison is based on full-cost recovery. The original capital costs are assumed to be fully amortised at the reactors and processing facilities that are converting, and thus are not included.

The following table shows the range of expected impacts from the various stages of the supply chain, when compared to the reference case of full-cost recovery. It is clear from this study that LEU-based ^{99}Mo from a converted facility is more expensive than HEU-based ^{99}Mo from the same facility. The price increase, however, is less than 8% at the radiopharmacy level, but is much higher upstream.

Table 4.1. Range of percentage increases in costs of a 6-day curie of ^{99}Mo from the full-cost recovery reference case as a result of LEU-target conversion

	% increase in costs: range
From irradiator	3.6-36.8
From processor	6.3-42.8
From generator manufacturer	5.4-36.6
From radiopharmacy	1.1-7.8

Comparing the values in this table to those presented in the NEA Economic Study shows that the impacts from moving to full-cost recovery under any capital replacement scenario are expected to be larger than the impacts of LEU-target conversion. This means that LEU-based ^{99}Mo from a converted facility may in fact be less expensive than ^{99}Mo from a new facility with full-cost recovery (depending on the infrastructure scenario).

The price increases for LEU conversion translate to a reasonably small increase in relation to the reimbursement rate of the final diagnostic procedure. Based on a reimbursement rate of EUR 245 (a weighted average of global rates), the value of the radiopharmaceutical ^{99m}Tc increases from 4.46% of the reimbursement rate up to maximum of 4.8%. This translates to less than a EUR 1 increase[5] on a EUR 245 diagnostic test. It is necessary to realise, however, that this small increase must be funded, because it is important to support upstream changes. In a separate paper, the NEA has discussed how unbundling the reimbursement for the isotope from the radiopharmaceutical and the diagnostic procedure could be a tool for greater transparency on necessary price changes (OECD/NEA, 2012e).

A significant concern is that the cost burden of LEU conversion is falling primarily upon the supplier organisations that are presently having difficulty in achieving full cost recovery pricing for the existing HEU-based production process. LEU conversion adds additional capital costs as well as increased operational costs to the links of the supply chain already under most pressure and potentially make full-cost recovery pricing for LEU-based product even more difficult to implement. This can have an additional negative feedback effect upon moving the market to an economically sustainable model.

5. It is important to note that these values are based on global averages; the values may vary between procedures and regions such that the isotope cost increases could be much higher for specific procedures or in certain regions.

Need for policy action

Current experience in the supply chain, unfortunately, seems to demonstrate that customers/end-users have difficulty supporting even small changes in price. However, this support is necessary to ensure that the supply chain will have sufficient resources (and motivation) to convert to producing ^{99}Mo from LEU targets and to have sufficient capacity to ensure the long-term security of supply. In addition, the capacity study demonstrated that over the first few years of the conversion period, HEU-based ^{99}Mo will be available in sufficient quantities, and thus, with the price differences, it may be difficult to sell LEU-based ^{99}Mo. These two factors point to a need for governments to encourage non-HEU based ^{99}Mo production and consumer uptake, while always respecting the HLG-MR policy approach to ensure a long-term secure supply of $^{99}Mo/^{99m}Tc$.

LEU policy options

The NEA Market Impacts Study (OECD/NEA, 2012c), developed in collaboration with experts from the supply chain and with the HLG-MR, demonstrates the expected capacity and cost impacts of converting to using LEU targets for the production of ^{99}Mo. The findings show that LEU-target conversion will have an impact on capacity, but will not be the major factor that causes long-term shortages. The main concern is the continued economic situation in the $^{99}Mo/^{99m}Tc$ supply chain that is unsustainable for any investment, including LEU-based investment. As a result, achieving full-cost recovery pricing is a necessary (but insufficient) condition for ensuring long-term supply reliability.

The Market Impacts Study shows that $^{99}Mo/^{99m}Tc$ produced from converted facilities is more expensive than HEU-based ^{99}Mo, although the expected price increase downstream, at the radiopharmacy stage, is relatively small – less than 8%, compared to upstream. Evidence from this study also points to an important role for governments to encourage LEU-target conversion by providing incentives to producers and/or consumers, given that this process is occurring for non-economic reasons, to help supply chain participants to recover their additional costs from conversion. However, it is recognised that it is difficult to ensure that incentives provided at the consumer level will be transferred to the producers.

Purpose of policy options

The NEA was asked by its HLG-MR to examine the policy options that could be used by producing and/or consuming nations to encourage the uptake of $^{99}Mo/^{99m}Tc$ without HEU, while respecting the need for a reliable supply of these medical isotopes. An expert working group examined the various policy options, as part of the larger LEU conversion market assessment project. The objective of the group was to determine policy options that could potentially be used to ensure a reliable supply of $^{99}Mo/^{99m}Tc$ produced without HEU, consistent with the timeframes and policies of the HLG-MR. The work of the expert group resulted in the discussion document *Policy Options for Ensuring Long-term Supply Security of Molybdenum-99 and/or Technetium-99m Produced Without Highly Enriched Uranium Targets* (OECD/NEA, 2012d).

Broadly speaking, the policy options examined and described in this document have one of three broad objectives:

- making the option of purchasing or producing non-HEU-based $^{99}Mo/^{99m}Tc$ more attractive (an incentive);
- making the option of purchasing or producing HEU-based $^{99}Mo/^{99m}Tc$ less attractive (a deterrent);
- limiting access to HEU-based $^{99}Mo/^{99m}Tc$ (a deterrent).

For each of these objectives, there are policy options that would be directed more towards changing producer behaviour and production decisions, and others directed more towards changing consumer behaviour and purchasing decisions. In addition, some of the policy options should only be done individually to avoid "double-dipping"[6] into government support, while others could be compatible when coupled together.

This document represents a collection of the possible policy options, described briefly, with the advantages, disadvantages and potential variations for each. The purpose of this is to enable individual countries to examine the options in more detail, either individually or collectively. For example, further assessment would be required to determine the expected degree of impact from any of the suggested policy options, and the specific details of how to implement a policy option. While countries may have differing views on the various options, given their own economic, regulatory, or political situation, this discussion document attempts to provide a brief review of the options from the starting point of the HLG-MR policy approach to achieving a long-term reliable supply of ^{99}Mo/^{99m}Tc.

It should be noted that the policy options described in this document are not all meant to be enacted by governments represented on the HLG-MR. Some of the policies would be the responsibility of private companies (e.g. health insurers). Furthermore, all proposed policy options related to production from LEU targets start from the premise that there will be sufficient LEU available to global ^{99}Mo producers. Table 4.2 below presents a summary of the policy options to encourage LEU conversion.

Table 4.2. Policy options to encourage the conversion to LEU targets for ^{99}Mo/^{99m}Tc production

Description of policy option	Beneficial if coupled with:	Potential for concern if coupled with:
Making the option of purchasing or producing non-HEU ^{99}Mo/^{99m}Tc more attractive		
Premium pricing for non-HEU-based ^{99m}Tc, based on data from NEA's Market Impacts Study (through health care system reimbursement rates)	A labelling system	• Funding for non-HEU-based ^{99}Mo/^{99m}Tc production capacity • Direct funding for capital costs of conversion projects
Labelling for sources of non-HEU-based ^{99}Mo/^{99m}Tc	• Premium pricing • Tax incentives for non-HEU-based producers to help recover capital costs • Regulations or taxes on sales of HEU-based ^{99}Mo/^{99m}Tc • Preferential purchasing	No estimated direct impacts on/from other policies
Ensure expedient health regulatory approval for non-HEU-based ^{99}Mo/^{99m}Tc via a government mandate to health regulatory agencies (once approached by a commercial entity)	Any other policy as health approval is a prerequisite for market access	No estimated direct impacts on/from other policies
Funding for research and development of non-HEU-based ^{99}Mo/^{99m}Tc production (e.g. developing new [harmonised] high-density targets)	No estimated direct impacts on/from other policies	No estimated direct impacts on/from other policies

6. Double-dipping, in the context of this paper, refers to the situation where an entity would be paid twice for the same action. For example, double-dipping may occur if a processor were to receive a payment from government to cover their LEU-target conversion costs and the ^{99}Mo/^{99m}Tc produced from their facility were also to receive a premium payment for being sourced from a non-HEU-based sources, if the additional benefit was greater than required to create the incremental action.

Table 4.2. Policy options to encourage the conversion to LEU targets for ^{99}Mo/^{99m}Tc production *(continued)*

Description of policy option	Beneficial if coupled with:	Potential for concern if coupled with:
Making the option of purchasing or producing non-HEU ^{99}Mo/^{99m}Tc more attractive		
Funding for non-HEU-based ^{99}Mo/^{99m}Tc production capacity: • Financial support by governments for new non-HEU-based ^{99}Mo/^{99m}Tc production capacity (not operating costs), including relevant components of research reactors or non-reactor-based infrastructure and/or processing facilities • Increase government investments in capital for developing domestic non-HEU-based ^{99}Mo production (not operating costs)	Other policy actions as long as it does not result in double- dipping	• Premium pricing • Tax incentives for non-HEU-based producers to help recover capital costs
Direct funding for capital costs of conversion projects	No estimated direct impacts on/from other policies	• Premium pricing (for ^{99}Mo/^{99m}Tc from converted projects, but not from new projects) • Tax incentives for non-HEU-based producers to help recover capital costs
Tax incentives for non-HEU-based producers to help recover capital costs	A labelling system	• Premium pricing • Funding for non-HEU-based ^{99}Mo/^{99m}Tc production capacity • Direct funding for capital costs of conversion projects
Making the option of purchasing or producing HEU ^{99}Mo/^{99m}Tc less attractive		
Market must move to full cost recovery: • Governments require operators to move to full-cost recovery • Supply chain takes action to be able to support full-cost recovery, including through reimbursement rates	Premium pricing	No estimated direct impacts on/from other policies
Regulations or taxes on sales of HEU-based ^{99}Mo/^{99m}Tc	A labelling system	No estimated direct impacts on/from other policies
Limiting access to HEU-based ^{99}Mo/^{99m}Tc		
Preferential purchasing for non-HEU based ^{99}Mo and/or ^{99m}Tc through a government mandate: • Restrictions on health care funding being used for HEU-based ^{99}Mo/^{99m}Tc	A labelling system	No estimated direct impacts on/from other policies
The United States (as the major supplier of HEU) sets an end date on HEU exports or increases prices substantially (for HEU for ^{99}Mo production): • Variation could be a staged process of making access more difficult	No estimated direct impacts on/from other policies	No estimated direct impacts on/from other policies

To date, the United States and Canada are the only countries that have taken concrete policy steps to encourage non-HEU production. In the United States, the Centres for Medicare and Medicaid Services (CMS), the government agency that is responsible for reimbursement under the Medicare and Medicaid programmes, implemented a separate USD 10 payment to hospitals for each dose that utilises at least 95% non-HEU ^{99m}Tc in nuclear medicine procedures. This payment amount is based on estimates of the incremental costs to produce non-HEU by the entire ^{99}Mo/^{99m}Tc supply chain and calculated using a full-cost recovery methodology. The CMS proposal has been approved by the United States government and in effect since 1 January 2013. In addition, the United States has moved to restrict exports of HEU with the enactment of the American Medical Isotope Production Act 2012, which specifies a period of seven years, beginning in 2013, before it will cease such exports. In Canada, the federal government has invested more than CAD 40 million in support of non-HEU production in cyclotrons and linear accelerators.

5. Self-assessment of the global ^{99}Mo/^{99m}Tc supply chain

As a direct action to implement the sixth principle of the HLG-MR policy approach, in May 2012, the NEA conducted a review of the global ^{99}Mo/^{99m}Tc supply chain. The review was based on responses by supply chain participants to self-assessment questionnaires. The main objective of the review was to evaluate progress made by supply chain participants with the implementation of the HLG-MR policy approach and, in particular, the first three principles relating to full-cost recovery, outage reserve capacity and the role of governments in the ^{99}Mo/^{99m}Tc market. A total of 47 self-assessment questionnaires were sent to key supply chain participants – reactor operators, processors, generator manufacturers, nuclear medicine associations that represent end-users of ^{99}Mo/^{99m}Tc, and governments. Thirty-six responses were provided for an overall response rate of 77%.

While the vast majority of upstream market participants – reactor operators and processors – provided responses to the survey, the downstream segment of the industry (generator manufacturers and nuclear medical associations) was under-represented, which requires caution when interpreting the results for that segment. On the other hand, as the most significant changes for long-term sustainability are required upstream, it is very encouraging that all producing reactors and the vast majority (six out of seven) of processors provided responses, which increases the representativeness and credibility of the survey results.

Based on these results, the NEA produced a report, *Implementation of the HLG-MR Policy Approach: Results from a Self-assessment by the Global ^{99}Mo/^{99m}Tc Supply Chain* (OECD/NEA, 2013b). In addition to evaluating the progress made by supply chain participants in implementing the first three HLG-MR policy principles, the report describes the current state of the ^{99}Mo/^{99m}Tc market and identifies major issues preventing it from achieving economic sustainability in the long term. The report shows results for each key individual supply chain participant using two progress indicators, for full-cost recovery and outage reserve capacity, which enables data confidentiality to be maintained, while providing important information. The progress indicators recognise the degree of progress made by the various stakeholders using the following classifications:

- Fully implemented.
- Significant progress made.
- Some progress made.
- Not started.

It must be noted that an important component of full costs, namely waste management costs, were not fully considered in the NEA report, given the lack of sufficient information from the ^{99}Mo/^{99m}Tc supply chain on how these costs are taken into account. Hence these costs were excluded in the development of progress indicators for individual supply chain participants. Waste management costs from ^{99}Mo production are the focus of a separate, ongoing study by the NEA and the International Atomic Energy Agency (IAEA), whose results are expected to be published in a report later in 2013.

Full-cost recovery

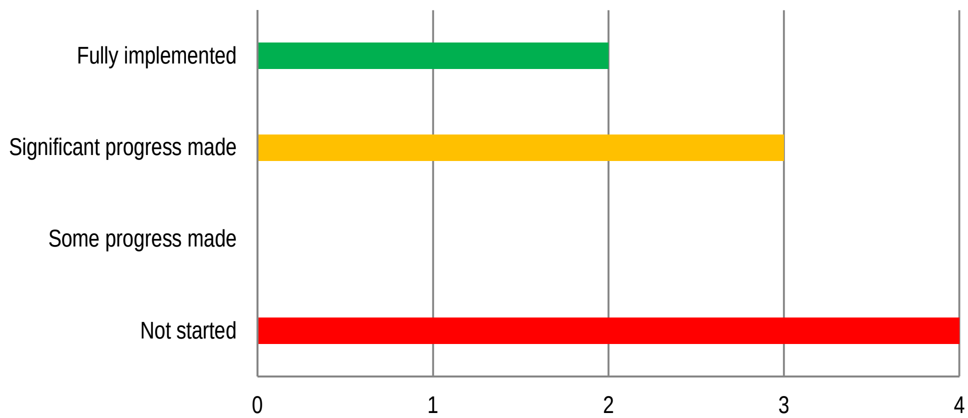
The review of the supply chain found that most reactor operators and processors have begun to implement full-cost recovery for ^{99}Mo production, although this process is happening at different speeds and with not always clearly defined timelines. However, government subsidies continue to hamper efforts to implement full-cost recovery everywhere. This is particularly evident at the reactor level, where some major ^{99}Mo-producing reactors still rely on subsidies, as full-cost recovery pricing has not been achieved. This sends a negative signal to the rest of the market and slows down full implementation. Additionally, some planned new, multipurpose reactors for ^{99}Mo production may be built with government support, which would further prevent the market from reaching economic sustainability through higher ^{99}Mo prices.

Only two out of the nine reactors[7] that are part of the global supply chain stated that they have fully implemented full-cost recovery. The rest are at interim stages of implementation or have not yet started the process. The three reactors in the Russian Federation (part of the same ^{99}Mo production project and, as such, counted as one reactor in the NEA report) are only irradiating for the domestic market and are not included. The operators of FRM-II reactor in Germany and the new Korean reactor were surveyed as well, but these reactors are not yet irradiating targets. Figure 5.1 shows the progress made by the nine producing reactors in implementing full-cost recovery.

Most global processors have implemented full-cost recovery or have made significant progress, which is in line with expectations, given that they are privately run companies operating for profit. One processor did not respond to the self-assessment survey. Figure 5.2 depicts the progress made by processors towards implementing full-cost recovery. However, it should be noted that where processors purchase from reactors, which are not charging or are not able to charge full-cost recovery price levels, this lack of full-cost recovery pricing affects the whole supply chain and may not be transparent. In addition, not all processors and generator manufacturers source and/or pay for outage reserve capacity (Principle 2) and thus, do not incur the associated costs.

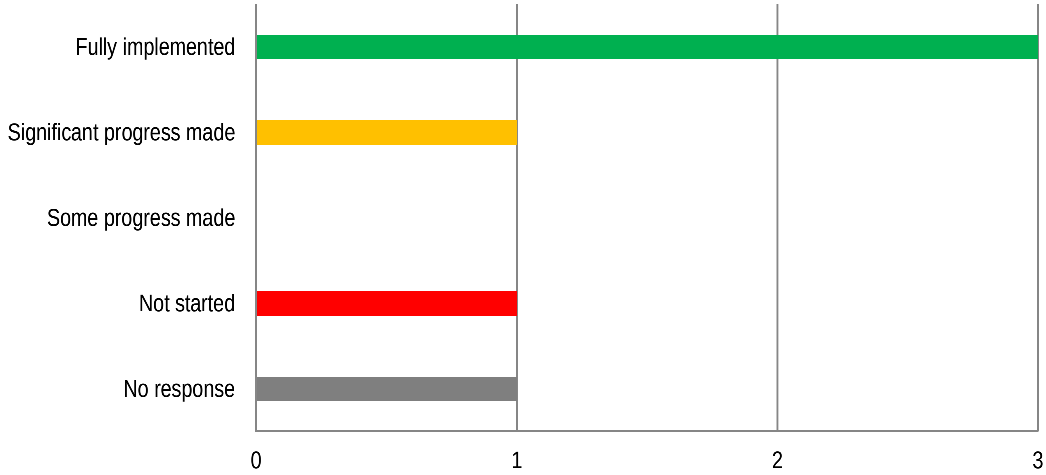
Further downstream, it is unclear to what degree generator manufacturers and end-users are implementing full-cost recovery, given the scarcity of responses provided to the self-assessment survey. Almost all generator manufacturers are private, for-profit companies, while end-users are usually reimbursed by governments for the radiopharmaceuticals or medical procedures using isotopes.

Figure 5.1. Full-cost recovery implementation, producing reactors



5. Argentina's RA-3 reactor is included, even though its ^{99}Mo production is significantly less than 1 000 six-day curies (Ci) per week.

Figure 5.2. Full-cost recovery implementation, processors



Outage reserve capacity

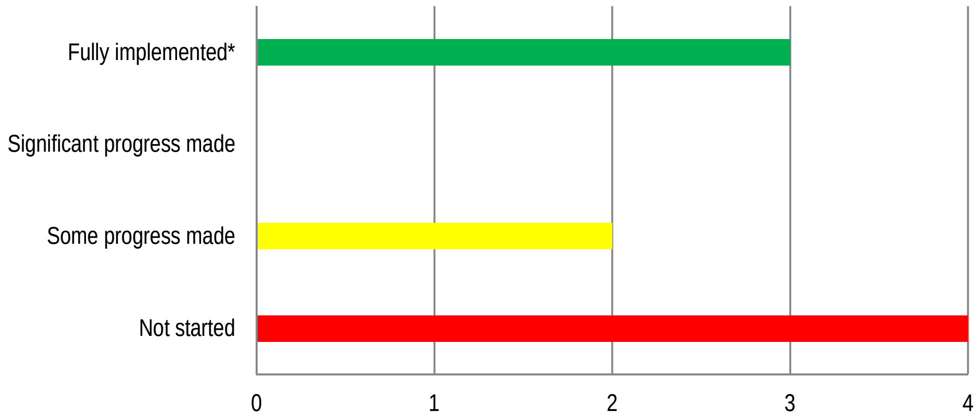
Despite some positive steps, outage reserve capacity is still not widely accepted and used by the market. This is reserve capacity specifically set aside by reactors to provide a contingency against *unexpected* or *extended* outages. Outage reserve capacity is different from operational reserve capacity. The latter accounts for the fact that reactors do not operate 100% of the time and, during planned outages, their normal production must be taken over by other reactors. Outage reserve capacity contributes significantly to the security of supply and should be appropriately valued and paid for[8]. However, this only occurs in a few cases globally at present. In some other cases, reactors are in the process of negotiating contracts with their processors for the provision and payment for outage reserve capacity. Yet in other cases, processors simply use spare (reserve) capacity at reactors, without or only partially paying for this service. It must also be noted that outage reserve capacity can be provided downstream by implementing demand management actions by generator manufacturers and end-users. Unfortunately, given the low response rate by downstream participants, the self-assessment report is unable to determine the degree (if any) to which such actions are being taken.

Only three out of the nine producing reactors globally (excluding the Russian Federation) stated that they have fully implemented outage reserve capacity, which means providing such capacity and receiving an adequate payment for it. One-half of the processors surveyed indicated that they have fully implemented or made significant progress on providing outage reserve capacity. Figures 5.3 and 5.4 present the current situation with respect to outage reserve capacity by reactor operators and processors, respectively.

---

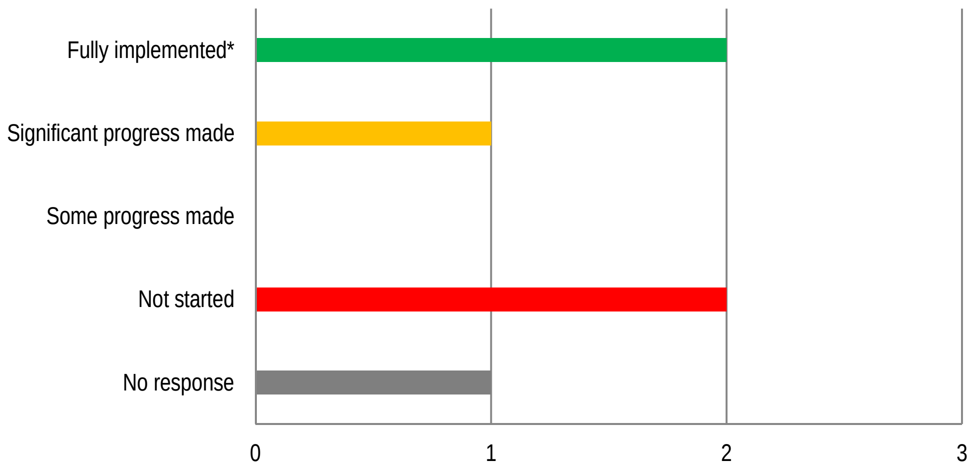
13. During its second mandate, the HLG-MR released a guidance document on the methodology of valuing and paying for outage reserve capacity – *Provision of Outage Reserve Capacity for* ^{99}*Mo Irradiation Services* (OECD/NEA, 2013).

Figure 5.3. 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 5.4. 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.

Governments' role in the ^{99}Mo/^{99m}Tc market

Governments are involved in the global ^{99}Mo/^{99m}Tc supply chain primarily at both ends – at the reactor and end-user levels. The vast majority of organisations represented in-between are commercial, for-profit entities. Although governments have historically subsidised research reactors (the dominant global source of ^{99}Mo at present and for the foreseeable future), many of them are beginning to withdraw their support and encourage reactors to fully commercialise ^{99}Mo production. Other governments, however, continue to subsidise ^{99}Mo production. While it is their prerogative to fund basic research at reactors, any commercial ^{99}Mo production **for the global market** should comply with the principle of full-cost recovery to avoid distorting the global market.

Tables 5.5 and 5.6 show the level of government support for ^{99}Mo production at producing reactors and the intended level of government support for planned new/replacement reactors and reactor-based projects[9], and modified existing reactors[10], with potential ^{99}Mo production capacity, based on information from the supply chain and the NEA's understanding of announcements by countries. The level of government support is classified as "full subsidy", "partial subsidy" or "no subsidy", and is expressed in terms of normal available irradiation capacity per week, as reported in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012c).

Figure 5.5. Government support for Mo-99 production, producing reactors

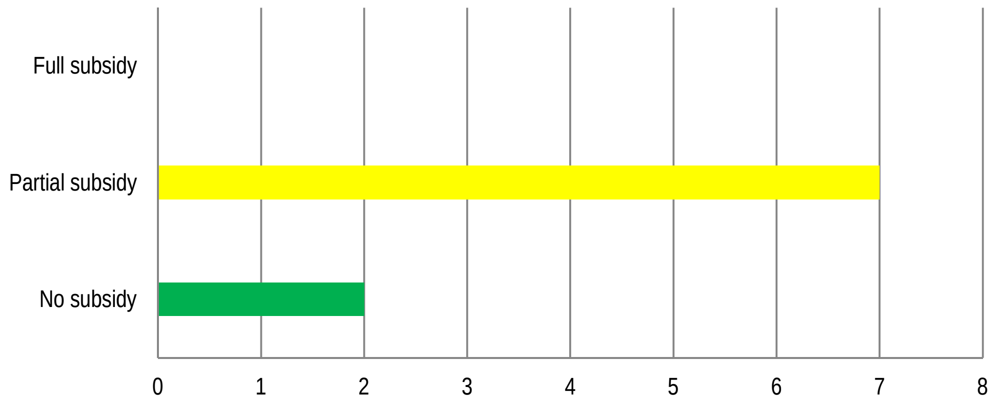
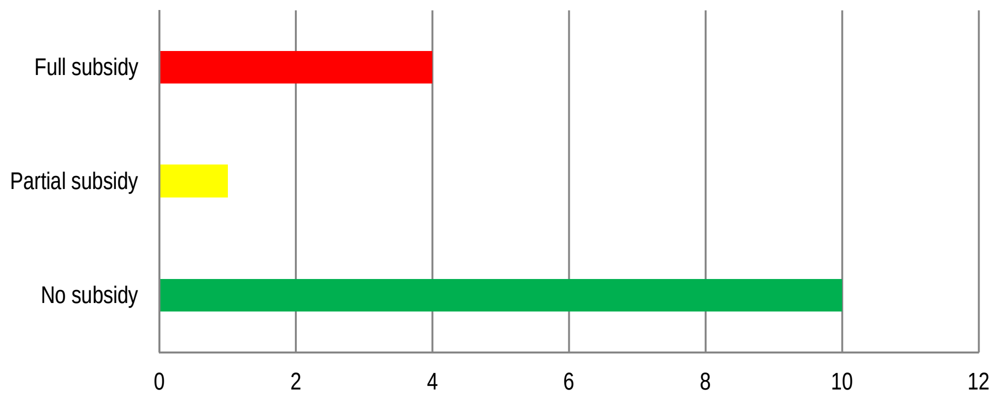


Figure 5.6. Government support for ^{99}Mo production at new/replacement reactors and reactor-based projects*



* Based on current understanding of the announcements by those countries.

9. In Argentina, Belgium, Brazil, France, Republic of Korea, the Netherlands, and the United States.
10. In the People's Republic of China, Germany, and the Russian Federation.

Further downstream, pressure on budgets has led to reductions in public spending on health care, also affecting nuclear medicine and isotope reimbursement. According to the self-assessment questionnaire responses, very few governments intend to or are already reviewing their reimbursement rates for medical isotopes. Notably, the reimbursement stage is where government action to (only slightly) increase or reallocate existing funds could conceivably make a big difference in terms of helping achieve security of supply of these important isotopes. However, the majority of governments have not yet taken any action, with two exceptions. The Belgian government is implementing a separate reimbursement for ^{99m}Tc in 2013, while the United States government has added a supplementary payment to reimburse hospitals for the higher cost of LEU-produced ^{99m}Tc, motivated by the desire to encourage conversion to LEU, but which is also designed to cover the costs of moving to full-cost recovery. Also, most Canadian hospitals already account for the isotope separately from the medical procedure, which achieves transparency in valuing the isotope.

The current state of the ^{99}Mo/^{99m}Tc market

The 2009-2010 medical isotope supply shortage has contributed to greater awareness of the underlying issues in the ^{99}Mo/^{99m}Tc market. Increased communication among supply chain participants, diversification of suppliers, improved co-ordination of reactor schedules, and more efficient isotope utilisation by end-users have all helped to increase the reliability of supply and the efficiency of ^{99}Mo/^{99m}Tc use. This has gone some way to addressing the identified vulnerabilities in the supply chain, but more remains to be done.

Positively, there are moves by supply chain participants and governments, with some defined timelines, to implement full-cost recovery for ^{99}Mo production. Although these are occurring at different speeds and not everywhere, government support for reactors is gradually being withdrawn, causing many of them to increase their irradiation prices. Sourcing and paying for outage reserve capacity, a critical component of supply reliability, is becoming a little more common and accepted by the supply chain, although more progress is needed.

However, the continuing below-full-cost-recovery prices prolong the unsustainable economic situation. During the 2009-10 supply shortage, ^{99}Mo prices increased significantly, but have since fallen to a point, where some producers describe competition in the market as "price-warring". This is clearly detrimental for the long-term reliability of supply. The main reasons for the prevailing suboptimal prices in the market seem to be:

- continued government subsidisation of ^{99}Mo production at reactors and some processors;
- long-term contracts at below-market prices;
- short-term exploitation of subsidised production and the practice of international reverse auctions, where suppliers compete on price;
- non-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; and
- untargeted reimbursement for the medical isotope at the end-user level.

Despite the stated commitment of all supply chain participants to the implementation of the HLG-MR policy principles, not everyone is acting with the required urgency or moving in the same direction. This makes it unlikely that the June 2014 deadline targeted by the HLG-MR for full implementation will be met.

6. Supply and demand update

In August 2012, the NEA released an updated ^{99}Mo supply and demand projection from 2012 to 2030. Since then, little new information has become available to necessitate significant changes to the update. According to the 2012 supply and demand update, the period of greatest concern is 2016-2020, when $^{99}Mo/^{99m}Tc$ supply is projected to be strained from scheduled permanent shutdowns of the NRU reactor in Canada (the reactor will cease to irradiate for ^{99}Mo production) and the OSIRIS reactor in France. Below is a summary of the 2012 ^{99}Mo supply and demand update.

Demand update

In 2011, the NEA released an assessment of future demand for $^{99}Mo/^{99m}Tc$ up to 2030 (OECD/NEA, 2011), based on data from a global survey and an assessment of that data by an expert advisory group. Since 2011, however, demand for ^{99}Mo has decreased from approximately 12 000 to approximately 10 000 six-day Ci per week due to a number of changes that occurred during the 2009-2010 supply shortage. These changes included: better use of available $^{99}Mo/^{99m}Tc$, more efficient elution of ^{99}Mo generators, greater use of alternative diagnostic tests/isotopes, and others. The NEA has thus revised its demand scenarios to reflect the updated estimate of current demand as 10 000 6-day ^{99}Mo curies from processors. However, the NEA has maintained the expected demand growth rate to 2030 presented in *An Assessment of Long-term Global Demand for Technetium-99m* (OECD/NEA, 2011)[11]. An additional change is the treatment of outage reserve capacity, as effectively increasing demand for irradiation and processor capacity. As a result, there is a range of values presented for demand, from a situation where no outage reserve capacity is demanded up to a high outage reserve capacity requirement (33%).

Supply update

The NEA has updated the list of current and new potential ^{99}Mo irradiation and processing projects. Based on the most recent information available in June 2012 (no significant changes since), the update includes: revisions to production start/end dates, additional potential projects and impacts of converting to using LEU targets for ^{99}Mo production. Figure 6.1 shows potential future supply versus projected demand in two cases: *(i)* where all currently planned new/replacement irradiation proceed and *(ii)* where only new projects based on full-cost recovery proceeds. Figure 6.2 depicts the same two cases with the additional effect of potential future processing capacity factored in.

The 2012 ^{99}Mo supply and demand update, unfortunately, does not present a more optimistic future scenario than previous projections – the concern about the uneconomic situation of the supply chain continues to dominate the potential for new projects. This results in the potential for long-term shortages within a decade. However, there are a number of potential projects that are in various stages of development. If the economics were to change and some of these projects proceed, the long-term supply of $^{99}Mo/^{99m}Tc$ should become reliable, which points to the need to implement the six HLG-MR policy principles in a timely and globally consistent manner.

11. The annual average growth rate is estimated at 2.1% for the period 2012-2020 and 0.5% for the period 2021-2030.

Figure 6.1. Current and potential new irradiator capacity and projected demand

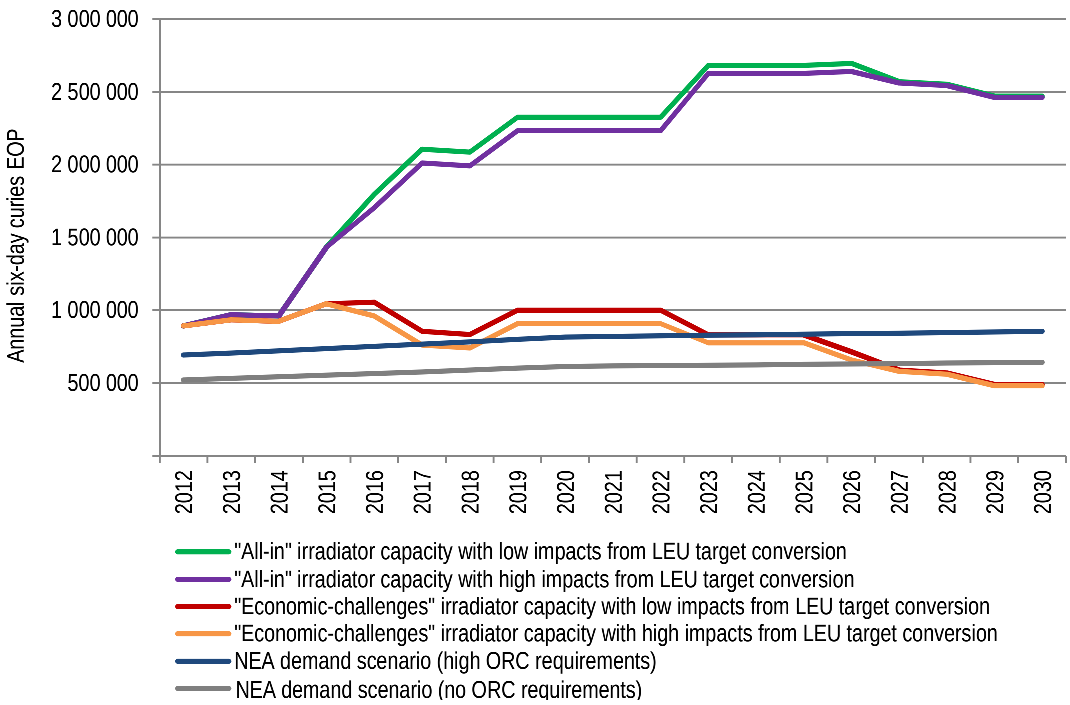


Figure 6.2. Current and potential new processing production and projected demand

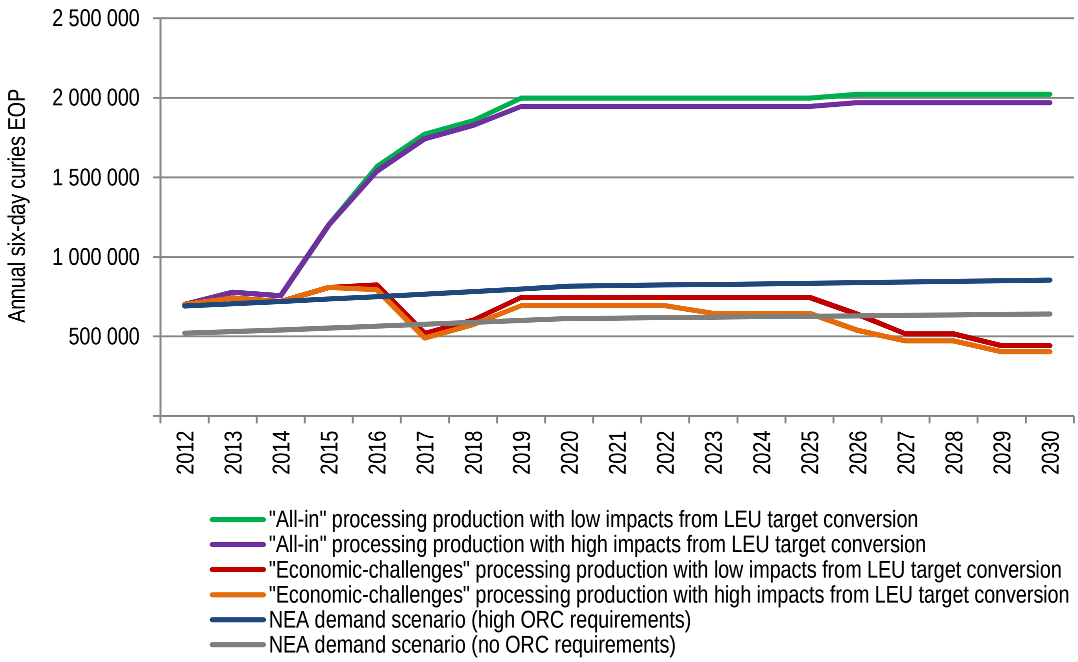


Figure 6.2 shows that projected supply is only slightly higher than demand in the 2013-2016 period, in an economic-challenges situation with a high outage reserve capacity requirement. Under the same scenario, from 2017 onwards, supply is projected to be less than demand.

7. Future outlook

At the third meeting of the second mandate of the HLG-MR in January 2013, members and delegated participants agreed to renew the mandate of the HLG-MR for a further two years (2013-2015) and asked the NEA Secretariat to develop a draft plan of activities for the new mandate. The plan is to include activities that address the major issues in the global supply chain and help the market achieve sustainability, in order to ensure a long-term reliable supply of $^{99}Mo/^{99m}Tc$.

Among the most pressing issues in the supply chain remain:

- achieving full-cost recovery pricing by all major supply chain participants;
- government subsidisation of reactors and some processors for ^{99}Mo production;
- potential shortage of production capacity in the 2016-2020 period, when two major reactors are expected to shut down permanently for ^{99}Mo production – NRU in 2016 and OSIRIS around the same time;
- maintenance of inadequate amounts of outage reserve capacity and insufficient payment for it; and
- untargeted reimbursement for ^{99m}Tc at the end-user level.

Another outstanding issue is the lack of sufficient information from all levels of the supply chain on progress towards the implementation of the HLG-MR policy principles. While the vast majority of irradiators and processors have shared a significant amount on their activities to support the work of the HLG-MR, there has been little, if any, useful information provided by most downstream supply chain participants – generator manufacturers, radiopharmacies and end-users. The HLG-MR has identified a need to engage more closely with generator manufacturers and government health officials to increase awareness of the issue of long-term $^{99}Mo/^{99m}Tc$ supply reliability, and seek their commitment to implementing the HLG-MR policy principles.

While most governments, where large reactors operate, have been gradually withdrawing financial support for ^{99}Mo production, this move has been on different timelines and not everywhere. Furthermore, the construction of new ^{99}Mo production infrastructure with public funds in new entrant countries could create over-capacity in the market, once these facilities become operational, while prolonging the current unsustainable economic situation. Until then, however, the opposite problem may occur – insufficient production capacity, with the planned, permanent closure of the NRU reactor for ^{99}Mo production and the permanent closure of the OSIRIS reactor. In the third HLG-MR mandate, the NEA intends to refine its 2012 projection for ^{99}Mo supply and demand by focusing on the potentially critical period, 2016-2020, the period before significant new/replacement capacity comes online.

To achieve economic sustainability in the market, thus ensuring the long-term reliable supply of $^{99}Mo/^{99m}Tc$, supply chain participants should continue to implement the six HLG-MR policy principles. In particular, the principles relating to full-cost recovery, outage reserve capacity and the role of governments in the market, since progress on them has been slower than progress on the other three principles. With regards to full-cost recovery, however, there may be a need to revisit the methodology for its calculation, recognising the following issues:

- the challenge for some reactors to recover full capital costs (attributed to ^{99}Mo production) in their irradiation prices;
- the governments' right to financially support basic nuclear research at multipurpose facilities; and
- the lack of private interest in funding new ^{99}Mo production infrastructure (unless the government shares costs).

There has been progress with the HLG-MR principles, relating to conversion to LEU targets, increased international collaboration, and periodic reviews of the supply chain since the publication of the HLG-MR policy approach in 2011. Conversion to the use of LEU targets is expected to be completed by 2015-2016, while international collaboration has improved, and there has been one comprehensive review of the supply chain.

In the third HLG-MR mandate, the NEA intends to conduct a second review (again through self-assessment) of the global ^{99}Mo/^{99m}Tc supply chain to gauge progress by supply chain participants on all six HLG-MR principles.

8. Conclusions

During its second mandate, the HLG-MR has made good overall progress on encouraging the implementation of the six policy principles by ^{99}Mo/^{99m}Tc supply chain participants, which were agreed at the end of the first mandate. Most supply chain participants have achieved or are moving towards full-cost recovery and outage reserve capacity, albeit at different speeds in different regions. Governments in major ^{99}Mo-producing countries are adopting a more indirect approach in their jurisdictions, including the gradual withdrawal of financial support for reactors, thus helping drive full commercialisation of isotope production. Furthermore, the process of converting from HEU to LEU targets for ^{99}Mo production is making progress, despite technical and economic challenges, communication among supply chain participants and the co-ordination of reactor schedules has improved since the 2009-2010 supply shortage. Also, the vast majority of key ^{99}Mo/^{99m}Tc stakeholders participated in a review of the global supply chain, which enabled an evaluation of progress made towards implementing the HLG-MR policy principles.

However, despite these positive developments, major issues remain in the ^{99}Mo/^{99m}Tc market. Continuing government subsidisation of reactors and some processors for ^{99}Mo production is slowing down the implementation of full-cost recovery and acceptance of outage reserve capacity. It is also providing a disincentive to the market to complete this process in a timely and globally consistent manner. Of particular concern is government support for new/replacement ^{99}Mo production infrastructure in new entrant countries. While it is a government's prerogative to fund infrastructure for research and development in their jurisdictions, any participation in the global ^{99}Mo/^{99m}Tc supply chain through exports of subsidised domestic production does not align with the HLG-MR policy principles and exacerbates the current unsustainable economic situation in the market. Additionally, untargeted reimbursement for ^{99m}Tc at the end-user level contributes to maintaining below-full-cost-recovery prices, thus jeopardising the long-term reliability of supply.

To fully implement the HLG-MR policy principles and increase the security of supply of ^{99}Mo/^{99m}Tc, governments should:

- continue to encourage full-cost recovery for ^{99}Mo production at all levels of the supply chain in their jurisdictions;
- continue to support the maintenance of adequate paid outage reserve capacity;
- provide appropriate incentives to producers to increase the share of LEU-produced ^{99}Mo in the market, given that this process is occurring for non-economic reasons;
- support the use of ^{99m}Tc by providing appropriate reimbursement for it;
- refrain from providing direct or indirect financial support to the industry, except at the end-user level for reimbursement.

Given the different pace of change in different regions, it is unlikely that the originally targeted deadline of June 2014 to implement all six HLG-MR policy principles will be met by all ^{99}Mo-producing countries. Although, it is encouraging that current key producers have committed to implementing the principles and are moving in that direction, new entrants have not yet made a similar commitment. This risks prolonging the existing unsustainable economic situation in the market and the long-term security of supply of ^{99}Mo/^{99m}Tc. Therefore, during the third mandate of the HLG-MR, there needs to be a debate within the group about the best way to achieve full implementation.

References

Available at: www.oecd-nea.org/med-radio/docs.

OECD/NEA (2010), *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain*, OECD, Paris, France.

OECD/NEA (2011), *The Supply of Medical Radioisotopes: The Path to Reliability*, OECD, Paris, France.

OECD/NEA (2012a), "2012 Supply and Demand Update on the Molybdenum-99 Market", OECD, Paris, France.

OECD/NEA (2012b), "Full-cost Recovery for Molybdenum-99 Irradiation Services: Methodology and Implementation", OECD, Paris, France.

OECD/NEA (2012c), *The Supply of Medical Radioisotopes: Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production*, OECD, Paris, France.

OECD/NEA (2012d), "The Supply of Medical Radioisotopes: Policy Options for Ensuring Long-term Supply Security of Molybdenum-99 and/or Technetium-99m Produced Without Highly Enriched Uranium Targets", OECD, Paris, France.

OECD/NEA (2012e), "Unbundling Payments for Radioisotopes from Radiopharmaceuticals and from Diagnostic Procedures: A Tool to Support the Implementation of Full-cost Recovery", OECD, Paris, France.

OECD/NEA (2013a), "Provision of Outage Reserve Capacity for Molybdenum-99 Irradiation Services", OECD, Paris, France.

OECD/NEA (2013b), "The Supply of Medical Radioisotopes: Implementation of the HLG-MR Policy Approach: Results from a Self-assessment by the Global ^{99}Mo/^{99m}Tc Supply Chain", OECD, Paris, France.

Appendix 1. HLG-MR Policy Principles

Principle 1: All ^{99m}Tc supply chain participants should implement full-cost recovery, including costs related to capital replacement.

Principle 2: Reserve capacity should be sourced and paid for by the supply chain. A common approach should be used to determine the amount of reserve capacity required.

Principle 3: Recognising and encouraging the role of the market, governments should:

- establish the proper environment for infrastructure investment;
- set the rules and establish the regulatory environment for safe and efficient market operation;
- ensure that all market-ready technologies implement full-cost recovery methodology; and
- refrain from direct intervention in day-to-day market operations as such intervention may hinder long-term security of supply.

Governments should target a period of three years to fully implement this principle, allowing time for the market to adjust to the new pricing paradigm, while not delaying the move to a secure and reliable supply chain.

Principle 4: Given their political commitments to non-proliferation and nuclear security, governments should provide support, as appropriate, to reactors and processors to facilitate the conversion of their facilities to low-enriched uranium (LEU) or to transition away from the use of highly enriched uranium (HEU), wherever technically and economically feasible.

Principle 5: International collaboration should be continued through a policy and information-sharing forum, recognising the importance of a globally consistent approach to addressing security of supply of $^{99}Mo/^{99m}Tc$ and the value of international consensus in encouraging domestic action.

Principle 6: There is a need for periodic review of the supply chain to verify whether $^{99}Mo/^{99m}Tc$ producers are implementing full-cost recovery and whether essential players are implementing the other approaches agreed to by the HLG-MR, and that the co-ordination of operating schedules or other operational activities have no negative effects on market operations.