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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

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This report would not have been possible without the contributions of a significant number of supply chain participants and stakeholders, including major reactor operators, major processors, generator manufacturers, and nuclear medicine associations representing radiopharmacies, hospitals and nuclear medicine professionals.

The Nuclear Energy Agency (NEA) greatly appreciates the effort in compiling and sending all information provided by supply chain participants on the self-assessment questionnaires. This information is a valuable resource for analysing the current state of the industry, identifying potential issues, and taking appropriate action to ensure the long-term security of supply of the key medical isotopes molybdenum-99 (^{99}Mo) and technetium-99m (^{99m}Tc).

This report was written by Mr Pavel Peykov and Dr Ron Cameron of the NEA Nuclear Development Division. Detailed review and comments were provided by the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR).

Disclaimer:

This report is based on information provided to the NEA directly by ^{99}Mo/^{99m}Tc supply chain participants through questionnaire responses and follow-up conversations. Assessments of the progress towards implementing the HLG-MR policy approach are based on this information and have not been verified independently.

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Executive summary

In June 2011, the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) released its policy approach to move the molybdenum-99 (^{99}Mo) and technetium-99m (^{99m}Tc) supply chain to a sustainable economic basis and to ensure the security of supply of medical isotopes. The policy approach seeks to address the fundamental problems that threaten reliable global supply of ^{99}Mo/^{99m}Tc, including the underlying unsustainable economics of the supply chain. It is based on six principles, which the HLG-MR agreed to implement within three years of releasing the policy approach (June 2014).

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 or to transition away from the use of highly enriched uranium, 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.

As a direct action to implement Principle 6, in May 2012, the Nuclear Energy Agency (NEA) sent self-assessment questionnaires to the ^{99}Mo/^{99m}Tc supply chain. The main objective of the self-assessment was to evaluate progress made by supply chain participants with the implementation of the HLG-MR policy approach and, in particular, the 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 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%. By place/role in the global supply chain, the NEA surveyed:

- eighteen governments;[1]
- twelve reactor operators (nine of which are currently part of the global supply chain);
- seven processors (six of which are currently part of the global supply chain);
- six generator manufacturers;
- three associations representing nuclear medicine professionals; and
- one industry association representing companies active in the fields of nuclear medicine and/or medical imaging.

Questionnaire analysis

This self-assessment report shows results for individual supply chain participants based on two of the policy principles, relating to full-cost recovery and outage reserve capacity. Progress against these principles was assessed using the following classifications:

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

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) is 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.

It must be noted that an important component of full costs, namely waste management costs, cannot be fully considered in this 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 are not considered in the development of progress indicators for individual supply chain participants. However, waste management costs from ^{99}Mo production are the focus of a separate study by the NEA and the International Atomic Energy Agency (IAEA), whose results are expected to be published in a report later in 2013.

Main findings

The self-assessment results and analysis in this report are based on information provided directly by supply chain participants and have not been verified independently. A synopsis of the main findings of this report, focusing on the first three principles of the

1. The regional government of the State of Bavaria was not sent a questionnaire, but provided a response. In addition, some governments responded through delegates from government-owned entities.

HLG-MR policy approach – full-cost recovery, outage reserve capacity and the role of governments in the market, is given in the following.

Full-cost recovery

Progress is being made to implement full-cost recovery by most, but not all, reactor operators and processors, although it 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. This sends a negative signal to the rest of the market and slows down full implementation. Additionally, planned new, multipurpose reactors may be built using government support for ^{99}Mo production in the future, which would further prevent prices from increasing to economically sustainable levels.

Only two out of the nine reactors 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 this report) are only irradiating for the domestic market and thus, are not included in the global supply chain. The operators of FRM-II reactor in Germany and the new Korean reactor were surveyed as well, but these reactors are not yet producing. Table E1 shows the progress made by the nine producing reactors in implementing full-cost recovery, expressed in terms of their normal available capacity, as reported in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012) – see Annex 1.

Table E1. Full-cost recovery implementation at producing reactors by normal available capacity

Progress indicator	Number of reactors	Normal available capacity per week (in 6-day Ci)	Share of total normal available capacity (in %)
Fully implemented	2	4 000	14.5%
Significant progress made	3	13 680	49.8%
Some progress made	0	-	-
Not started	4	9 800	35.7%

Table E2 presents the progress made by processors in implementing full-cost recovery, expressed in terms of their stated capacity, as reported in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012) – see Annex 1. The Russian Federation's production of bulk ^{99}Mo is intended only for the domestic market at present and does not impact the global supply chain; hence the country's processor is not included in the table.

Table E2. Full-cost recovery implementation at processors by capacity

Progress indicator	Number of processors	Capacity per week (in 6-day Ci)	Share of total capacity (in %)
Fully implemented	3	11 200	62%
Significant progress made	1	2 500	14%
Some progress made	0	-	-
Not started	1	900	5%
No response	1	3 500	19%

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. During the 2009-10 supply shortage, radiopharmacies and hospitals implemented efficiency measures or alternative modalities for the use of ^{99m}Tc, which helped reduce demand for the parent isotope (^{99}Mo) from about 12 000 to about 10 000 six-day Ci per week currently. Since the end of the supply shortage, ^{99}Mo demand has been relatively constant.

Outage reserve capacity

Despite some progress, outage reserve capacity is still not widely accepted and used by the market. Outage reserve capacity contributes significantly to the security of supply and should be appropriately valued and paid for. 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, this 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 (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. Table E3 shows the progress made by reactors in implementing outage reserve capacity, expressed, again, in terms of their normal available capacity, as reported in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2011).

Table E3. Outage reserve capacity implementation at producing reactors by normal available capacity

Progress indicator	Number of reactors	Normal available capacity per week (in 6-day Ci)	Share of total normal available capacity (in %)
Fully implemented	3	11 800	43%
Significant progress made	0	-	-
Some progress made	2	7 480	27%
Not started	4	8 200	30%

Table E4 presents the progress made by processors in implementing outage reserve capacity, expressed in terms of their stated capacity, as reported in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012). Again, the Russian Federation is not included in the table.

Table E4. Outage reserve capacity implementation at processors by capacity

Progress indicator	Number of processors	Capacity per week (in 6-day Ci)	Share of total capacity (in %)
Fully implemented	2	4 000	22%
Significant progress made	1	2 500	14%
Some progress made	0	-	-
Not started	2	8 100	45%
No response	1	3 500	19%

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 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 export should comply with the principle of full-cost recovery to avoid distorting the global market, i.e. governments should cease subsidisation of ^{99}Mo production at producing reactors and refrain from it at planned new or replacement reactors, or alternative production sources. Tables 5 and 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,[2] and modified existing reactors,[3] 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, 2012) – see Annexes 1 and 2.

Table E5. Level of government support for ^{99}Mo production at producing reactors

Level of government support	Number of reactors	Normal available irradiation capacity per week (in 6-day Ci)
Full subsidy	0	-
Partial subsidy	7	23 480
No subsidy	2	4 000

Table E6. Level of intended government support for ^{99}Mo production at new/replacement reactors/reactor-based projects

Level of intended government support	Number of reactors/reactor-based projects	Potential new/replacement normal available irradiation capacity per week (in 6-day Ci)
Full subsidy	4	5 000
Partial subsidy	1	1 800-2 000
No subsidy	10	38 650-40 900

Further downstream, pressure on budgets has led to reductions in public spending on health care, which has also affected nuclear medicine. According to the self-assessment questionnaire responses, very few governments intend to or are already reviewing their reimbursement rates for medical isotopes. The majority have not taken any action, with two exceptions. The Belgian government will be implementing a separate reimbursement for ^{99m}Tc in 2013, while the United States (US) 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.

2. In Argentina, Belgium, Brazil, France, Republic of Korea, the Netherlands, and the US.
3. In the People's Republic of China, Germany, and the Russian Federation.

Progress by region

The US and Europe account for two-thirds of global $^{99}Mo/^{99m}Tc$ demand (Europe is the largest producer, while the US is the largest consumer) and should be at the forefront of efforts to implement the HLG-MR policy principles. The US government has already taken action, which should encourage both full-cost recovery and LEU conversion in the supply chain. In Europe, the establishment of the European Observatory on the Supply of Medical Radioisotopes is a recognition of the importance of securing the supply of $^{99}Mo/^{99m}Tc$. However, concerted actions to implement the HLG-MR policy principles have yet to be agreed at the European Union level. The only exception is Belgium, as discussed above.

In Australia and South Africa, full-cost recovery and outage reserve capacity have already been implemented and the role of governments in ^{99}Mo production clearly defined as arm's-length. In Canada, the federal government has decided to cease ^{99}Mo production at the National Research Universal (NRU) reactor in 2016 and focus on developing domestic, non-reactor-based technologies for future supply. The Canadian government does, however, because of the long-term contract between Atomic Energy of Canada Limited (AECL) and Nordion, provide significant support to AECL for ^{99}Mo production.

In Asia and South America, some governments intend to continue to subsidise current and/or future ^{99}Mo production. Where such production is made for export and not solely for the domestic market, government subsidisation is not consistent with the HLG-MR policy principles and would prolong the existing unsustainable economic situation in the global supply chain.

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

Much greater awareness now exists of the underlying issues that led to the 2009-10 medical isotope supply shortage and of the need to implement the HLG-MR policy principles, which were designed to lead towards security of supply. Increased communication among supply chain participants, diversification of suppliers, improved co-ordination of reactor schedules, and more efficient utilisation of isotopes by end-users have all contributed to a more reliable supply and better use of $^{99}Mo/^{99m}Tc$. This has helped to address the identified vulnerabilities in the supply chain. More remains to be done, however.

On the positive side, 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, but more progress is needed.

However, the economic problems that manifested themselves during the 2009-10 supply shortage continue to exist. Reactor operators, partially subsidised by governments and, in some cases, fully amortised, contribute to market prices for irradiation services that compete at an advantage with others who already operate on full-cost recovery. Processors with access to subsidised irradiation services also have an advantage, potentially pushing other processors to lower their prices below a sustainable level. Further downstream, there is an additional challenge to achieve sustainable pricing – the inaction by governments to reimburse nuclear medicine procedures based on full-cost recovery, largely as a result of fiscal constraints.

The continuing below-full-cost-recovery prices exacerbate the unsustainable economic situation in the global ^{99}Mo/^{99m}Tc market. 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
- insufficient 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 agreed by the HLG-MR for full implementation will be met.

The continued fragility of the supply chain has been demonstrated by the unplanned and ongoing (for the foreseeable future) outage at the HFR reactor in Petten. The improved co-ordination of reactor schedules, the move to diversify suppliers, and some partial provision of outage reserve capacity have alleviated the negative impact of the HFR loss, but difficult times lie ahead, when other reactors enter maintenance periods. The supply situation will deteriorate further with the expected permanent shutdown of the NRU (for ^{99}Mo production) in 2016 and OSIRIS around the same time, with potential supply shortages on the horizon, as shown in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012). This clearly demonstrates the urgent need for governments to remove subsidies from the market and for supply chain participants to fully implement the HLG-MR policy principles in a timely and consistent manner.

Chapter 1. Introduction

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 ^{99}Mo and ^{99m}Tc. Since June 2009, the NEA and its High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) examined the causes of supply shortages and developed a policy approach, including principles and supporting recommendations to address those causes.

The "Economic Study" (OECD/NEA, 2011) of the molybdenum-99 (^{99}Mo) and technetium-99m (^{99m}Tc) supply chain published by the NEA clearly demonstrated that the pricing structure at nuclear research reactors prior to the most recent supply shortage in 2009-10 was not economically sustainable. Host nations traditionally subsidised the cost of irradiation services for ^{99}Mo production, along with experimental research at reactors. With a move away from subsidising ^{99}Mo production that often benefits foreign nations or foreign companies, pricing must recover the full cost of production to ensure economic sustainability and a long-term secure supply of medical isotopes. Appropriate pricing would also encourage an efficient use of the product, reducing wasted ^{99}Mo/^{99m}Tc and thus reducing excess production and the associated radioactive waste.

A key principle adopted by the HLG-MR was that all producers should move towards full-cost recovery and should implement the other principles adopted by the group. In February 2012, the NEA web-published a guidance document with a methodology for full-cost recovery and an associated Excel spreadsheet (OECD/NEA, 2012). This costing methodology identifies the essential elements that should be included when determining the full cost of ^{99}Mo irradiation services and how these elements should be allocated between various missions in the case of multipurpose facilities. The application of the costing methodology at all ^{99}Mo/^{99m}Tc-producing research reactors and other production technology facilities within the global supply chain will ensure a common approach to full-cost recovery.

The full-cost recovery methodology is not a price-setting mechanism; it defines the cost elements and allocation methods, but it does not dictate the value of those costs nor prices that would be expected or required under full-cost recovery. Given varying costs, ownership structures and national competition laws, international price-setting regulation would be difficult or impossible to implement. Nor is price setting necessarily desirable; a full-cost recovery methodology would still allow for downstream stakeholders to benefit from improvements in efficiencies that lower production costs and lead to lower prices (where sustainable).

During the first mandate of the HLG-MR (2009-2011), it was agreed that the NEA secretariat would undertake a review of the ^{99}Mo/^{99m}Tc supply chain, based on input from key supply chain participants. The second mandate of the HLG-MR (2011-2013) has confirmed this role, including a broad deliverable to evaluate the progress towards the implementation of the HLG-MR policy approach (described in the next chapter), including through the periodic review of the supply chain.

The mandate requires that "members will be expected to make a commitment to implement the HLG-MR policy approach and agree to undergo self-assessments as part of the periodic reviews of the supply chain". The mandate also charges reactor operators and processors to "work to ensure the implementation and ongoing application of the HLG-MR policy approach" and to "participate in self- assessment and the periodic review of supply chain's progress in implementing the HLG-MR policy approach".

This report provides information from the first self-assessment by supply chain participants and analyses the progress made towards the full implementation of the HLG-MR policy approach, with a particular focus on progress with the implementation of full-cost recovery, outage reserve capacity, and the role of governments in helping industry move towards long-term sustainability. The report is organised as follows:

Chapter 2 presents a brief summary of the HLG-MR policy approach, including the six policy principles that are critical to achieving long-term security of supply, and supporting recommendations.

Chapter 3 explains the objectives and methodology of the self-assessment review of the ^{99}Mo/^{99m}Tc supply chain.

Chapter 4 provides an analysis of the results and makes observations on current and projected future supply and demand for ^{99}Mo/^{99m}Tc.

Chapter 5 details each country's progress towards implementing the HLG-MR policy approach, including the governments' role in the market.

Chapter 6 summarises the progress made by the supply chain towards implementing full-cost recovery and outage reserve capacity.

Chapter 7 presents the conclusions of the self-assessment review of the ^{99}Mo/^{99m}Tc supply chain.

Chapter 2. HLG-MR policy approach

In June 2011, the HLG-MR released its policy approach to move the supply chain to a sustainable economic basis and to ensure the security of supply of medical isotopes. The policy approach seeks to address the fundamental problems that threaten reliable global supply of ^{99}Mo/^{99m}Tc, including the underlying unsustainable economic model of the supply chain, and makes recommendations. The policy approach is based on extensive research and analysis of the ^{99}Mo/^{99m}Tc supply chain that revealed a persistent market failure, which contributed to an unsustainable long-term situation. The HLG-MR identified four "pillars of reform":

- Market economics in the ^{99}Mo/^{99m}Tc supply chain need to be improved.
- Structural changes are necessary.
- The government role in the production of these key isotopes has to be clearly defined.
- An effective and co-ordinated international approach is necessary.

These pillars were then refined into six policy principles and supporting recommendations (presented below), which the HLG-MR believes are essential if the market is to be sustainable in the long run, ensuring a stable and secure supply of ^{99}Mo/^{99m}Tc.

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

Commercial arrangements in the supply chain, including contracts, must recognise and facilitate the implementation of full-cost recovery in order to move towards achieving economic sustainability.

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.

Supply chain participants, both public and private, should continue and improve annual co-ordination efforts through the Association of Imaging Producers and Equipment Suppliers (AIPES) or another similar mechanism to ensure the appropriate use of available capacity, recognising a minimum necessary volume level at all ^{99}Mo/^{99m}Tc producing facilities. New entrants to the supply chain should join these co-ordination efforts.

To support effective co-ordination, contracts between reactors and processors should allow for open access to ^{99}Mo irradiation services.

Demand-management options should be encouraged as they could participate to support effective co-ordination efforts.

Processors should voluntarily hold at every point in time outage reserve capacity equal to their largest supply (n-1 criterion), which can come from anywhere in the supply chain as long as it is credible, incremental and available on short notice.

Reserve capacity options should be transparent and verifiable to ensure trust in the supply chain.

Reactor operators, processors and generator manufacturers should review the current contracts to ensure that payment for reserve capacity is included in the price of ^{99}Mo.

Communication efforts, providing three months advance notice to downstream stakeholders on generator supply should continue. In addition, industry communication protocols regarding unplanned outages should be implemented by all industry participants and remain active.

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.

Governments should:

- in co-operation with health care providers and private health insurance companies, monitor radiopharmaceutical price changes in order to support the transparency of costs;
- periodically review payment rates and payment policies with the objective of determining if they are sufficient to ensure an adequate supply of ^{99m}Tc to the medical community;
- consider moving towards separating reimbursement for isotopes from the radiopharmaceutical products as well as from the diagnostic imaging procedures.

Governments should encourage continued supply chain participation in ^{99}Mo/^{99m}Tc production schedule co-ordination efforts, including making such participation mandatory if voluntary participation wanes or commitments are not respected.

Governments should monitor levels of outage reserve capacity maintained by the market and, if found to be below the set criterion, consider regulating minimum levels.

Governments should, where required, support financial arrangements to enable investment in ^{99}Mo/^{99m}Tc infrastructure using various forms of public-private partnerships with appropriate returns.

Governments should consider ^{99}Mo/^{99m}Tc production capacity requirements when planning multipurpose research reactors to ensure that the required capacity is available. However, the funding of the ^{99}Mo-related capacity development should be supported through the commercial market.

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 or to transition away from the use of highly enriched uranium, wherever technically and economically feasible.

Governments should consider encouraging as well as financing R&D related to LEU target conversion through participation in International Atomic Energy Agency (IAEA) efforts or by other means. They should address enriched uranium (LEU and HEU) availability and supply during and after conversion. They should also examine options to create a market justification to using LEU targets to ensure a level playing field between producers. In the meantime, they should consider financially addressing the price differential of ^{99}Mo produced with LEU targets in order to achieve agreed upon non-proliferation goals.

Governments should encourage the development of alternative (non-HEU) technologies to facilitate the diversity of the supply chain, wherever economically and technologically viable.

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.

Domestic and/or regional action should be consistent with the proper functioning of the global market.

The IAEA and its partners are encouraged to carry on international dialogue and efforts to ensure that safety and security regulations, and their application, relating to ^{99}Mo/^{99m}Tc production, transport and use are consistent across international borders. Regional (e.g. European Union) and domestic efforts towards facilitating transport and use of ^{99}Mo/^{99m}Tc in a safe and secure manner should continue.

Industry participants could consider international collaboration to achieve other goals as well, such as harmonisation of targets.

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.

An international expert panel should be established to evaluate the ^{99}Mo/^{99m}Tc supply chain every two years.

The six principles of the HLG-MR policy approach capture the key changes that need to occur in the market, while the supporting recommendations provide additional detail related to the implementation of the principles. The HLG-MR full findings and a comprehensive discussion of its policy approach can be found in the report, *The Supply of Medical Radioisotopes: The Path to Reliability*, available at: www.oecd-nea.org/med-radio/med-radio-series.html.

Chapter 3. Periodic review of the global $^{99}Mo/^{99m}Tc$ supply chain

Objectives

Conducting a periodic review of the $^{99}Mo/^{99m}Tc$ supply chain is a direct action to implement Principle 6 of the HLG-MR policy approach. The objectives of the periodic review are to analyse and report on the functioning of the $^{99}Mo/^{99m}Tc$ supply chain. The review (the results of which are presented in this report) is essential to determine whether the HLG-MR policy approach, especially the principles related to full-cost recovery, outage reserve capacity and governments' role in the market, is being implemented. It must be noted that an important component of full costs, namely waste management costs, cannot be fully considered in this report, given the lack of sufficient information from the $^{99}Mo/^{99m}Tc$ supply chain on how these costs are taken into account. However, waste management costs from ^{99}Mo production are the focus of a separate study by the NEA and the IAEA, whose results are expected to be published in a report later in 2013.

The review serves as a "monitoring mechanism" for the HLG-MR. To ensure that the policy approach succeeds, all stakeholders need to have confidence that the actions they are taking are being matched by all other players and this review will further that end by increasing awareness among all supply chain participants, including consumers/end-users. The review identifies those supply chain participants that are implementing or making good progress toward full implementation of the HLG-MR policy approach; it also highlights those players that are not making significant progress (or have not yet started). In this context, the report serves as a labelling tool, providing information for customers and governments on those participants that are encouraging long-term security of supply.

The information in the periodic review is very important for customers/end-users. Under the HLG-MR policy approach, end-users are being asked to pay for a reliable supply of medical isotopes. This report provides an indication to the end-user whether the isotope producers are making the appropriate efforts to provide the reliability for which they being asked to pay, thus giving a strong market incentive to supply chain participants to support outage reserve capacity and ongoing investments in infrastructure required for supply security.

In addition, the information in this report is useful for governments. One aspect of the HLG-MR policy approach is that governments should monitor the supply chain, especially related to full-cost recovery, the provision of outage reserve capacity, and reactor co-ordination. This report provides information to governments on whether participants are meeting the requirements of the policy approach and, if not, governments could then consider taking specific actions to encourage them to do so. Where the report identifies that one or more aspects of the HLG-MR policy approach are not being implemented as expected, the HLG-MR should examine the issues and recommend the appropriate steps to address these issues.

Furthermore, this report provides basic information on the status of the supply chain, including on available and planned capacity. Such information is useful to encourage efficient investment decisions, allowing market players to predict capacity needs with increased certainty, determine when infrastructure investments are required, and work to avoid bottlenecks in the supply chain.

This first progress report focuses on the status of implementation of the first three principles of the HLG-MR policy approach and provides a brief update on the supply chain. Future reports could focus on progress towards conversion from the use of HEU to LEU targets for ^{99}Mo production or ad hoc discussions on selected key topics affecting the supply chain, such as the growth of the use of alternative technologies or changes in reimbursement rates for medical isotopes.

Methodology

The NEA secretariat obtained information from key supply chain participants using a self-assessment approach. Supply chain participants were asked to fill out a questionnaire tailored to their place or role in the ^{99}Mo/^{99m}Tc supply chain. This means different questionnaires were sent to reactor operators, processors, generator manufacturers, nuclear medicine associations, and governments. The questionnaires (see Annexes 5-8) were designed to determine the commitment and actions of the participants in implementing the HLG-MR policy principles and recommendations. In addition, they were designed to seek a balance between:

- soliciting confidential information that supply chain participants may be hesitant to share versus the need for the NEA to have accurate information for the assessment; and
- creating a heavy burden on supply chain participants by asking for detailed information versus the NEA obtaining the detail necessary to assess progress.

Where required, the NEA followed up with responders to request more information or clarify submitted information. The NEA also contacted responders in cases of conflicting information provided by different supply chain participants on a particular question or topic.

As mentioned earlier, this first progress report focuses on the principles of full-cost recovery, outage reserve capacity, and governments' role in the market, including actions to ensure sufficiency of reimbursement rates for medical isotopes. The actions related to Principles 4-6 are noted through information provided by supply chain participants and general observations of the NEA Secretariat. Information that is not related to the implementation of the policy approach or is not necessary to assess the degree of implementation is not included in this report.

Self-assessment questionnaires were developed for the following supply chain stakeholders:

- governments;
- irradiators (reactor and alternative technology operators);
- processors;
- generator manufacturers;
- the following end-user associations:
  - National Association of Nuclear Pharmacists (NANP).
  - European Association of Nuclear Medicine (EANM).
  - Society of Nuclear Medicine and Molecular Imaging (SNMMI); and
- the Association of Imaging Producers and Equipment Suppliers (AIPES).

Upstream supply chain participants were asked the bulk of the questions, as that is where the most change needs to occur for the economic sustainability of the supply chain. Downstream participants were asked limited though important questions focused on a few specific issues.

The self-assessment questionnaires also provided an opportunity for supply chain participants to share their views and observations of the ^{99}Mo/^{99m}Tc market, and make comments and recommendations on how to ensure the long-term security of supply of medical isotopes. Annex 4 includes a list of comments by supply chain participants about the current state of the ^{99}Mo/^{99m}Tc market.

Reporting of results

This report shows results for each key individual supply chain participant using two progress indicators, for full-cost recovery and outage reserve capacity, which enable 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.

An example of the progress indicators is presented in Figure 3.1 below.

Figure 3.1. Example of progress indicators

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: Processor A

Full-cost recovery: Significant progress made

Comments:

Processor A's suppliers of irradiation services have implemented full-cost identification and have made significant steps to implement full-cost recovery by increasing prices over a two-year time period (by 2012). Processor A has accepted these actions and has worked with its client base to inform them of the related cost increases for their bulk ^{99}Mo. They have fully communicated to their clients the reasons for the necessary price increases. Processor A needs to continue the progress to full-cost recovery by fully paying for the waste costs from ^{99}Mo production at their facility; some government funding received currently goes to dealing with waste from ^{99}Mo production.

Outage reserve capacity: Not started

Comments:

Processor A currently does not source or pay for outage reserve capacity from its suppliers. They need to increase efforts to ensure a reliable supply by sourcing and paying for this capacity and seeking payment from their clients.

The evaluation of the above indicators inevitably has a degree of subjectivity, which is difficult to eliminate, given that each supply chain participant is at an almost unique stage of implementation of the HLG-MR policy principles. Each supply chain participant has been assigned an indicator that is closest to the actual progress made by them, based on the information they submitted in their self-assessment questionnaire, and as assessed against the NEA reports outlining the implementation of full-cost recovery and outage reserve capacity.[1] The NEA has not made any independent evaluation of the assessments reflected in the progress indicators except through follow-up conversations for clarification and in response to queries raised by other supply chain participants.

The NEA's recommended approach to ensuring full-cost recovery includes waste management costs and this is both justifiable and necessary for sustainability. However, we note that, at this stage, there is insufficient information to make credible judgements on the adequacy of inclusion of waste management costs in full-cost recovery. Hence this assessment has not taken these costs into account in assigning progress against the indicators. When further information is available, those judgements can be reassessed.

1. *Full-cost Recovery for Molybdenum-99 Irradiation Services: Methodology and Implementation* (OECD/NEA, 2012) and *Provision of Outage Reserve Capacity for Molybdenum-99 Irradiation Services* (OECD/NEA, 2013).

Chapter 4. Questionnaire results

In May 2012, the NEA sent self-assessment questionnaires to all major supply chain participants – nuclear research reactor operators, processors, generator manufacturers, nuclear medicine associations that represent the end-users of ^{99}Mo/^{99m}Tc, and governments. In total, 47 questionnaires were sent and 33 were completed and returned, for a response rate of 70%. In addition, two supply chain participants submitted partial responses without filling out a questionnaire and another supply chain participant submitted two responses in an alternative way. Counting these extra responses increases the response rate to 79%. By place/role in the global supply chain, the NEA surveyed:

- eighteen governments;[1]
- twelve reactor operators (nine of which are part of the global ^{99}Mo/^{99m}Tc supply chain);
- seven processors (six of which are part of the global ^{99}Mo/^{99m}Tc supply chain);
- six generator manufacturers;
- three associations representing nuclear medicine professionals; and
- one industry association representing companies active in the fields of nuclear medicine and/or medical imaging.

Table 4.1 shows a list of all supply chain participants who were sent self-assessment questionnaires, also indicating the ones who responded and the ones who did not.

Table 4.1. List of self-assessment questionnaire recipients

Government of Argentina via the National Commission for Atomic Energy (CNEA)	Completed questionnaire
CNEA (irradiator) – Argentina	Completed questionnaire
CNEA (processor) – Argentina	Completed questionnaire
Government of Australia via the Australian Nuclear Science and Technology Organisation (ANSTO)	Completed questionnaire
ANSTO (irradiator) – Australia	Completed questionnaire
ANSTO (processor) – Australia	Completed questionnaire
Government of Belgium	Completed questionnaire
Nuclear Research Centre SCK-CEN – Belgium	Completed questionnaire
Institute for Radioelements (IRE) – Belgium	Completed questionnaire
Government of Brazil via the National Nuclear Energy Commission/Institute of Energy and Nuclear Research (IPEN)	Completed questionnaire
Government of Canada	Completed questionnaire
Atomic Energy of Canada Limited (AECL)	Completed questionnaire

1. The regional government of the State of Bavaria was not sent a questionnaire, but provided a response. In addition, some governments responded through delegates from government-owned entities.

Table 4.1. List of self-assessment questionnaire recipients *(continued)*

Nordion – Canada	Completed questionnaire
European Commission, Directorate-General for Energy	Completed questionnaire
Government of France via the Commissariat à l'énergie atomique et aux énergies alternatives (CEA)	Completed questionnaire
CEA – France	Completed questionnaire
IBA Group – France	**No response provided**
Government of Germany	Completed questionnaire
Technical University of Munich – Germany	Completed questionnaire
Government of Japan via the Japan Radioisotope Association	Completed questionnaire
Japan Radioisotope Association/FUJIFILM RI Pharma Co. Ltd.	Completed questionnaire
Government of the Republic of Korea	**No response provided**
Korea Atomic Energy Research Institute (KAERI)	**No response provided**
Government of the Netherlands	Completed questionnaire
Nuclear Research and consultancy Group (NRG) – Netherlands	Completed questionnaire
Covidien/Mallinckrodt (processor) – Netherlands	**No response provided**
Covidien/Mallinckrodt (generator manufacturer) – Netherlands	**No response provided**
Government of Poland via the National Centre for Nuclear Research (NBCJ)	Completed questionnaire
NBCJ – Poland	Completed questionnaire
Government of the Russian Federation	**No response provided**
Rosatom (irradiator) – Russian Federation	Provided alternative response
Rosatom (processor) – Russian Federation	Provided alternative response
Government of South Africa via the South African Nuclear Energy Corporation – NECSA	Partial response provided
NECSA – South Africa	Completed questionnaire
NTP Radioisotopes – South Africa	Completed questionnaire
Government of Spain	**No response provided**
Molypharma – Spain	**No response provided**
Government of the United Kingdom (UK)	Completed questionnaire
GE Healthcare – UK	**No response provided**
Government of the United States (US)	Completed questionnaire
Lantheus Medical Imaging – US	Completed questionnaire
Association of Imaging Producers and Equipment Suppliers (AIPES)	Completed questionnaire
European Association of Nuclear Medicine (EANM)	**No response provided**
National Association of Nuclear Pharmacies (NANP) – US	Completed questionnaire
Society of Nuclear Medicine and Molecular Imaging (SNMMI) – US	Partial response provided
Government of the Czech Republic	**No response provided**
Research Centre Rez – Czech Republic	Completed questionnaire

Of the 37 total responses, 15 came from governments or through their delegates from government-owned entities, 11 from reactor operators, 6 from processors, 2 from generator manufacturers, 2 from nuclear medicine professional associations, and 1 from an industry association. Table 4.2 below shows a breakdown of questionnaire responses and response rates by supply chain participant group.

Table 4.2. Responses and response rates by supply chain participant group

	Number of responses	Response rate (in %)
Governments*	15	79%
Reactor operators	11	92%
Processors	6	86%
Generator manufacturers	2	33%
Associations	3	75%

* Includes the regional government of the State of Bavaria.

While participants at all four major levels of the ^{99}Mo/^{99m}Tc supply chain – reactor operators, processors, generator manufacturers, and nuclear medical associations representing the end-users – completed the questionnaires, the downstream segment of the industry (generator manufacturers and nuclear medical associations) is under-represented in the responses, which requires caution when interpreting the results in this report related to that sector. For example, no generator manufacturers in Europe or the European Association of Nuclear Medicine responded to a self-assessment questionnaire. As Europe accounts for over 20% of the global market for ^{99m}Tc, an important part of the downstream ^{99}Mo/^{99m}Tc supply chain is missing in the report. On the other hand, although changes are required at all levels of the supply chain, to achieve long-term security of ^{99}Mo/^{99m}Tc supply, the magnitude of required changes is the greatest in the upstream segment of the market. Therefore, it is very encouraging that all major producing reactors who irradiate targets for ^{99}Mo production and the vast majority (six out of seven) of processors surveyed, including all but one large processor, provided responses, which increases the representativeness and credibility of the survey results.

Progress on implementing the HLG-MR policy approach

The responses by supply chain participants indicate that most are moving towards full-cost recovery for the production of ^{99}Mo, if they have not implemented it yet. However, this process is occurring at different speeds in different regions and not everywhere. Some, such as Australia and South Africa, are already producing ^{99}Mo on a commercial, full-cost recovery basis, while others have just begun moving in that direction. Yet, there are also countries that are not intending to move towards full-cost recovery or not planning to in the short term. For example, Canada has decided to discontinue ^{99}Mo production from the National Research Universal (NRU) reactor when its current licence expires in 2016 and is unable to implement full-cost recovery for ^{99}Mo production at the NRU given the contract terms between AECL and Nordion. However, alternative production technologies under development in Canada would be expected to operate on a full-cost recovery basis post-2016. The Russian Federation is taking steps to become a significant ^{99}Mo producer in the future, but has not yet made commitments to implement full-cost recovery neither at the reactor nor the processor level.

Since the 2009-10 supply shortage, reactors have significantly improved co-ordination of their operating schedules and communicated relevant information further downstream, which has helped downstream participants prepare for any potential disruptions in irradiation services, and has facilitated the introduction of other reactors' unused (reserve) capacity. This increased co-ordination has contributed to a reduced risk of supply shortages, although it does not directly affect the fundamental economic situation in the supply chain.

At the processor and generator manufacturer levels, most supply chain participants are for-profit, commercial entities that take full account of their costs related to ^{99}Mo production.[2] Their pricing structures incorporate a full-cost recovery methodology, which is what Principle 1 of the HLG-MR policy approach refers to. However, where they purchase from reactors, which are not charging or not able to charge full-cost recovery 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 at reactors (Principle 2) and thus, do not incur associated costs. Admittedly, some processors have already signed or are in the process of negotiating contracts for outage reserve capacity, with a corresponding payment, but this is still not a widespread practice in the market. As a result, the price of ^{99}Mo does not fully reflect all production costs, including the costs of providing outage reserve capacity.

Governments

Fifteen governments[3] responded to the self-assessment questionnaires. Of those, eight are from countries with reactors that are currently irradiating targets for ^{99}Mo production. In the wake of the 2009-10 supply shortage and the subsequent work by the HLG-MR to identify the reasons for the shortage, and recommend an appropriate course of action, governments have become much more aware of the economic situation in the global ^{99}Mo/^{99m}Tc supply chain and the need to move to full-cost recovery. Consequently, they have been gradually reducing or eliminating financial support for ^{99}Mo production, and directing or encouraging reactor operators to implement full-cost recovery. The withdrawal of public financial support, however, is occurring at an uneven pace across reactors, which slows down full implementation, as some reactors and processors are hesitant to significantly increase prices before others. It must also be noted that the withdrawal of support is occurring at a different pace across different types of costs related to ^{99}Mo production at reactors. For example, governments seem to be moving more quickly in reducing support for costs for specific ^{99}Mo irradiation services and reactor operational costs related to ^{99}Mo production than they are for capital or decommissioning costs. In fact, governments continue to provide various forms of capital support to reactors (e.g. loans or direct payments), including for new ^{99}Mo production infrastructure.

Further down the ^{99}Mo/^{99m}Tc supply chain, pressure on budgets in many countries has led to reductions in public spending on health care, also affecting nuclear medicine. The government responses to the questionnaires indicate that very few are planning to or are already reviewing their reimbursement rates for medical isotopes. The majority have not taken any action to consider the potential unbundling of reimbursement for the isotope from the radiopharmaceutical and/or the nuclear medicine procedure. Of the governments who responded, only the Belgian government plans to implement a separate reimbursement for ^{99m}Tc in the near future, while the US government has added a supplementary payment, motivated by the desire to encourage conversion from HEU to LEU, but which is also designed to cover the costs of moving to full-cost recovery. Most other governments are more or less maintaining the status quo. In Canada, most hospitals already account for isotopes separately and have "unbundled" them from the medical procedure to increase the level of awareness in the health care system.

Reactors

Of the eleven reactor operators who responded to a self-assessment questionnaire, only two have already implemented full-cost recovery for ^{99}Mo-related irradiation services. Five operators are at interim stages of implementation and four operators have not started the process yet. The FRM-II reactor operator intends to implement full-cost recovery, when the reactor begins irradiating targets for ^{99}Mo production, which is

2. There are exceptions, which are discussed later in the report.
3. Includes the regional government of the State of Bavaria.

expected in 2015-16. Although progressing, the process of implementing full-cost recovery at reactors is slower than desirable and does not appear on track to be completed by June 2014 (as agreed by the HLG-MR) for several reasons. First, not all reactor operators are implementing full-cost recovery at the same pace and with the same timelines, which makes those who are ahead wary of potential strong competition by those who are behind in the process. Currently, there is no international, legally binding mechanism to ensure that all reactor operators implement full-cost recovery by the agreed time. Second, an indication from some countries that they will continue to provide support to their reactors generates unfavourable market signals for other reactors, through a downward pressure on prices, to implement full-cost recovery. Third, the simultaneously occurring process of conversion to the use of LEU targets for ^{99}Mo production has created new technical challenges for reactors (and processors), increasing their costs and making it more difficult to implement full-cost recovery with reduced government support and in the absence of a functioning market for LEU-produced ^{99}Mo.

Most new or replacement, multipurpose reactors also intended for ^{99}Mo production, and alternative technologies for ^{99}Mo production, have stated an intention to implement full-cost recovery, although it remains to be seen if all of them do so. There have been indications that some new production sources in Belgium, Canada, France and the US will operate on a commercial basis. However, it is unclear whether planned, new reactors in the Republic of Korea, Brazil and Argentina, or existing reactors being reconfigured for ^{99}Mo production (in the People's Republic of China and the Russian Federation) will implement full-cost recovery. Anecdotal evidence from supply chain participants suggests that this may not happen in all new reactors, which could erect a new hurdle in the process to implement full-cost recovery at the reactor level. Should that be the case, it would also significantly increase the available ^{99}Mo production capacity globally which, combined with a constant or only slowly increasing demand, would put existing ^{99}Mo producers at all levels of the supply chain under pressure to offer lower prices in order to stay in business. Such a scenario would potentially create significant undesirable levels of over-capacity in the market in the future and could force some participants to exit.

Processors

Currently, there are four major processors in the world – Nordion (Canada), Covidien/Mallinckrodt (the Netherlands), NTP Radioisotopes (South Africa) and the Institute for Radioelements (IRE, Belgium). Together, they account for almost the entire global supply of bulk ^{99}Mo. In addition, ANSTO (Australia), CNEA (Argentina) and JSC Isotope (Russian Federation) plan to or already sell smaller amounts abroad. All but one of these processors receive irradiated targets directly from reactors and produce bulk ^{99}Mo. Nordion is unique in the global supply chain in that it only purifies the ^{99}Mo, which has been initially extracted from irradiated targets by Atomic Energy Canada Limited (AECL).

The NEA received responses to the self-assessment questionnaire from six of the seven processors (three responses from the four major processors). All except JSC Isotope are part of the global ^{99}Mo/^{99m}Tc supply chain. The commercial entities among these organisations (most of them) have already incorporated a full-cost recovery methodology in their pricing structures. However, where they purchase from reactors, which are not charging or not able to charge full-cost recovery levels, this lack of full-cost recovery pricing in the whole supply chain may not be transparent. Additionally, not all of them maintain and/or pay for outage reserve capacity. As mentioned in the section on reactors, not paying at all or sufficiently for outage reserve capacity (which improves the reliability of supply) puts downward pressure on ^{99}Mo prices.

In addition to the current processor capacity, plans are underway in several countries to build new processing facilities. However, at present it is not clear whether all of these projects will materialise and when, which makes it challenging to forecast changes in processing capacity and production in the future. The NEA has published a comprehensive analysis with scenarios for the projected impacts on ^{99}Mo production capacity and costs from conversion to LEU targets in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012). The study is available online at: www.oecd-nea.org/ndd/reports/2012/7129-leu.pdf.

Generator manufacturers

Unfortunately, very few responses were received from generator manufacturers and consequently, the NEA has limited usable information and can only make general statements about the state of this part of the ^{99}Mo/^{99m}Tc supply chain and its progress towards implementing the HLG-MR policy approach at this time. A common theme in the received responses is the sharp increase in ^{99}Mo prices during the 2009-10 supply shortage and their subsequent fall, following the return of the NRU and HFR reactors to service. In addition, generator manufacturers are experiencing resistance from radiopharmacies and hospitals to any proposed increases in generator prices. Furthermore, there is no indication so far that generator manufacturers are attempting to implement any demand-side measures to maintain and pay for outage reserve capacity. This indicates that they may not correctly value outage reserve capacity.

Nuclear medicine associations

Similar to generator manufacturers, the information provided by nuclear medicine associations was not comprehensive or detailed enough to enable a sufficiently robust analysis. During the 2009-10 supply shortage and the concerns about future supply reliability, radiopharmacies and hospitals acted to increase the efficiency of ^{99m}Tc use in nuclear medicine procedures. Such actions included obtaining higher yields per generator by changing procedure schedules, increasing the use of smaller generators, and switching to the use of non-^{99}Mo diagnostics. As a result, demand has decreased from about 12 000 six-day curies of ^{99}Mo EOP per week to about 10 000 six-day curies of ^{99}Mo currently. Given current industry practices, the types of ^{99m}Tc generators on the market and the current prospects for alternative imaging modalities, it is doubtful whether further significant efficiencies at the radiopharmacy/hospital level can be achieved. This means that the demand for ^{99}Mo is not likely to decrease below the current level, at least not in the short term.

Chapter 5. Country assessment

This chapter presents a brief profile of each country and any facilities in them that submitted a completed questionnaire(s) in response to NEA's request for information on the global implementation of the HLG-MR policy approach. The countries are described according to their place in the global $^{99}Mo/^{99m}Tc$ supply chain and the progress they have made in implementing full-cost recovery and outage reserve capacity, while also assessing the role of governments in helping the supply chain move towards long-term economic sustainability. The latter refers primarily to adopting policies that eliminate subsidies for ^{99}Mo production, while ensuring appropriate reimbursement for ^{99m}Tc used in nuclear medicine procedures.

In countries with operating reactors, the country section includes a brief description of the reactor, its production in a normal week of operation, and the percentage of current global demand for $^{99}Mo/^{99m}Tc$ that this production is equivalent to. Current global demand is estimated at 10 000 six-day curies EOP[1] per week. It should be noted that reactors irradiate targets for ^{99}Mo production in cycles of several weeks each, followed by downtime. Therefore, the production volumes in this report should not be considered as weekly averages or attributed to a particular year of operation. For example, if a reactor produces 2 000 six-day curies in a normal week of operation, it is assessed to provide 20% of current global demand, although **not** 20% of the current average weekly global demand, because it does not irradiate targets every week of the year. The normal reactor production volumes are taken from *The Supply of Medical Radioisotopes: The Path to Reliability* (OECD/NEA, 2011) – see Annex 3.

Given that the most significant changes for economic sustainability need to occur upstream, only organisations involved at the reactor and processor level are assessed by the NEA on their progress towards implementing the HLG-MR policy approach, using indicators for full-cost recovery and outage reserve capacity. A "report card" is then created for each organisation assessing the degree of progress made on full-cost recovery and outage reserve capacity. Generator manufacturers operate on a commercial basis (i.e. cost recovery plus profit). The limited information they have provided does not indicate if they take any demand-side measures related to outage reserve capacity. No "report cards" have been produced for generator manufacturers. Further downstream, at the radiopharmacy/hospital level, insufficient information is available to be able to provide an accurate assessment of progress towards full-cost recovery. A complicating factor is the bundling of the radioisotope in the radiopharmaceutical and/or the nuclear medicine procedure for reimbursement by health care insurance plans, which makes it challenging to determine whether full-cost recovery for the isotope is occurring.

Argentina

Argentina is a relatively small but important regional supplier of ^{99}Mo in South America. The country's RA-3 reactor produces around 300 six-day curies in a typical week when operating, which is equivalent to approximately 3% of current global demand. The RA-3 is one of only three reactors in the world, (the others being OPAL in

1. At the end of processing (EOP) of irradiated targets.

Australia and SAFARI-1 in South Africa[2]), that use LEU for both fuel and targets. The reactor and associated processor of irradiated targets and bulk ^{99}Mo plant are operated by the Argentine National Commission for Atomic Energy (CNEA). CNEA, a government-controlled entity, plays a pivotal role in the supply of medical radioisotopes in its domestic and regional markets. It has responsibility for both the reactor and processor, thus vertically integrating target irradiation and bulk ^{99}Mo production. Neither the reactor nor the processor provides outage reserve capacity to the global supply chain.

The RA-3 reactor and the processor receive direct government support for ^{99}Mo production, most of which is directed to the CNEA Waste Management Division. The government also provides capital funding for refurbishment and infrastructure needs. Notwithstanding the financial support, CNEA has indicated that it is currently addressing specific components of a full-cost recovery methodology for the operations of RA-3 and the moly plant in the future. However, no concrete actions have been taken yet. Increases in the price of bulk ^{99}Mo have been driven by higher input costs and not a specific move towards full-cost recovery.

Based on CNEA's responses to the HLG-MR self-assessment questionnaires, the organisation appears to be at an early stage in the process of implementing the HLG-MR policy approach. The government continues to play a prominent role in the ^{99}Mo/^{99m}Tc supply chain in Argentina, primarily through direct funding of ^{99}Mo production. Argentina produces ^{99}Mo/^{99m}Tc largely for its domestic market (with small exports to Brazil and other South American countries), and has a limited impact globally. CNEA's progress towards implementing the HLG-MR policy approach with respect to full-cost recovery and outage reserve capacity is presented in the box below.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: CNEA – Argentina (irradiator and processor)

Full-cost recovery: Not started

Comments:

CNEA is looking at the issue of full-cost recovery for the provision of irradiation services and bulk ^{99}Mo production by addressing cost components. It needs to develop a full-cost recovery a methodology or use the HLG-MR methodology, and implement this methodology for both irradiation services and bulk ^{99}Mo production. Direct government support is received by the reactor and processor, mainly for waste management. A planned new reactor (RA-10) appears to be fully funded by the government.

Outage reserve capacity: Not started

Comments:

CNEA does not provide outage reserve capacity to the global supply chain. As a regionally important irradiator and processor, however, it should consider entering into backup capacity agreements with other irradiators and/or processors.

A review of health reimbursement rates is currently underway in Argentina, which will provide the government with potentially useful information to determine whether a move to separate reimbursement for medical isotopes is practical and feasible. At the moment, it is unclear how long the review will take and what its outcomes will be, but it could reveal whether existing ^{99m}Tc-related health care funding is sufficient to cover the costs of irradiation and processing services upstream.

2. The SAFARI-1 reactor has not completely converted to LEU targets at the time of writing of this report and still also irradiates HEU targets.

Argentina is planning to build a new reactor (RA-10) and radioisotope production plant. RA-10 will irradiate targets for ^{99}Mo production with a capacity of 2 500-3 000 six-day curies per week. The new reactor appears to be fully funded by the government and could be integrated in the global ^{99}Mo/^{99m}Tc supply chain by 2018.

Australia

Australia is a global supplier of irradiation services and bulk ^{99}Mo. Similar to Argentina, irradiations and bulk ^{99}Mo production in Australia are vertically integrated, i.e. managed by one entity. The Australian National Science and Technology Organisation (ANSTO) operates the OPAL reactor and an associated processing facility, which produces 1 000 six-day curies EOP in a typical week when the reactor is operating. Australia's bulk ^{99}Mo production meets approximately 10% of current global demand. OPAL is the youngest and one of just two reactors worldwide (the other one is RA-3 in Argentina) that irradiate only LEU targets for ^{99}Mo production. Despite its geographical distance from major markets, ANSTO exports ^{99}Mo in addition to selling domestically. Although ANSTO is a government agency, its ^{99}Mo production activities are commercialised and based on the full-cost recovery principle. Furthermore, the Australian government has directed ANSTO to not create unfair competition in its commercial operations, including ^{99}Mo sales.

ANSTO has a reciprocal agreement with South Africa for the provision of outage reserve capacity, when the OPAL reactor is not operating, which is charged at commercial rates. ANSTO is also part of global reactor scheduling efforts to help ensure the availability of enough irradiation capacity for continuous ^{99}Mo production, thus improving the reliability of supply.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: ANSTO – Australia (irradiator and processor)

Full-cost recovery: Fully implemented

Comments:

ANSTO is applying a full-cost recovery methodology for both its irradiation services and bulk ^{99}Mo production (with the exception of final waste disposal and storage), which is reflected in the prices it charges. When a new long-term waste treatment and storage facility is built, as per the Australian government's commitment, ANSTO plans to include these costs as well in its full-cost recovery methodology.

Outage reserve capacity: Fully implemented

Comments:

ANSTO maintains a reciprocal arrangement with NTP in South Africa for the provision of outage reserve capacity. Australia's geographical position, however, imposes limits on the effectiveness of its outage reserve capacity arrangements. Only outage reserve capacity maintained with other processors can be realistically executed.

The Australian government announced in September 2012 that it would finance the construction of a new processing facility and a waste treatment facility, which would enable ANSTO to increase the volume of bulk ^{99}Mo production and permanently and safely encapsulate the final waste from processing. Apart from this capital support, which will be repaid, the government has largely not intervened in ^{99}Mo production activities. However, further down the ^{99}Mo/^{99m}Tc supply chain in Australia, the government could play a more active role by examining the potential for separation of reimbursement for ^{99m}Tc from reimbursement for the radiopharmaceutical and the nuclear medicine procedure. At the moment, no actions are being taken to that effect.

ANSTO's progress report indicators are presented in the box above.

Belgium

The BR-2 reactor in Belgium is the largest irradiator (in terms of six-day curie production in a typical week when operating) of targets for ^{99}Mo production in the global ^{99}Mo/^{99m}Tc supply chain. The reactor was commissioned in 1961 and produces 5 200 six-day curies EOP in a typical week of operation, which is over half of current global demand.[3] Over its operational life to date, the reactor has undergone major refurbishments and is expected to remain online into the 2020s. There are plans for BR-2 to be replaced at the end of its operating life by a new reactor (MYRRHA), which is currently in the design stage.

The Belgian Nuclear Research Centre SCK-CEN operates BR-2 and irradiates HEU targets for ^{99}Mo production. The irradiated targets are sent for processing to the Institute for Radioelements (IRE) in Belgium and Covidien/Mallinckrodt in the Netherlands. The reactor is currently in the process of converting to the use of LEU targets, which is expected to be completed by 2015-16. Even though the Belgian government is not directly involved in the ^{99}Mo/^{99m}Tc supply chain, it provides support (through subsidies) for part of the costs associated with target irradiation and processing, including capital, decommissioning and waste management costs. It must be noted, however, that the government has recognised the need for full-cost recovery and directed both SCK-CEN and IRE to move towards its implementation. In other words, the Belgian government is gradually moving away from financially supporting ^{99}Mo production.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: SCK-CEN – Belgium (irradiator)

Full-cost recovery: Significant progress made

Comments:

SCK-CEN has designed a full-cost recovery methodology and is gradually implementing it at the BR-2 reactor for the provision of its irradiation services through a phase-in period, which will end in 2013. To achieve full-cost recovery, it has significantly increased its prices for ^{99}Mo-related services to processors in the two years to 2012 and fully communicated the reasons for these increases to its customers. SCK-CEN needs to continue its progress towards full-cost recovery, while also including refurbishment and decommissioning/dismantling costs. SCK-CEN is planning to recover full costs for irradiations at the new MYRRHA reactor, which is scheduled to be commissioned in the 2020s.

Outage reserve capacity: Fully implemented

Comments:

SCK-CEN is providing outage reserve capacity to processors and recovers the fixed cost of this reserve capacity as well as the variable cost of irradiation, when this capacity is activated.

Both SCK-CEN and IRE are taking steps to implement full-cost recovery for ^{99}Mo production despite some price resistance from downstream supply chain participants. SCK-CEN intends to cover all of the reactor's operational costs related to ^{99}Mo production by 2013. Costs related to depreciation of the latest reactor refurbishment and decommissioning are also included in SCK-CEN's cost methodology, but will likely not be fully recovered until market conditions improve, i.e. until other global supply chain participants implement full-cost recovery as well, and prices increase (see SCK-CEN's progress indicators above). In addition to unsustainably low prices, another challenge for SCK-CEN and IRE in implementing full-cost recovery is the costs associated with a move

3. Additional irradiation capacity was installed at the reactor in April 2010 to increase its available capacity to 7 800 six-day curies per week EOP; however, it is unclear what the normal reactor production will be as a result.

to convert to using LEU targets. Belgium's commitment to nuclear security and non-proliferation necessitates such a move, which is currently underway.

SCK-CEN has agreements with processors for the provision of outage reserve capacity and receives payment for maintaining spare irradiation positions (fixed costs) and any additional production when required (variable costs). IRE also maintains outage reserve capacity at several reactors and has a backup agreement with another processor, ensuring continuous production in the event of an unexpected or extended reactor shutdown. IRE's progress indicators are shown in the box below.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: IRE – Belgium (processor)

Full-cost recovery: Significant progress made

Comments:

IRE has experienced significant price increases for irradiation services from reactors while, at the same time, resistance from its customers to increases of its price of bulk ^{99}Mo. IRE is moving towards the implementation of full-cost recovery, partly through higher efficiency of its operations, and should continue to do so by also including waste management and all capital costs.

Outage reserve capacity: Significant progress made

Comments:

IRE is maintaining outage reserve capacity at several reactors, although not paying all of these reactors for the provision and use of this reserve capacity. IRE also has a backup agreement with a processor to provide/receive production capacity in the event of an unexpected or extended reactor shutdown.

Further downstream, Belgium has already introduced a framework for separate reimbursement for ^{99m}Tc from the radiopharmaceutical and the diagnostic procedure. The government expects to fully implement this new system in 2013.

Brazil

Brazil is primarily involved downstream in the ^{99}Mo/^{99m}Tc supply chain, purchasing bulk ^{99}Mo from processors on the international market and manufacturing ^{99m}Tc generators for elution in domestic hospitals and clinics. Purchases of bulk ^{99}Mo are made by the Brazilian Nuclear Energy Commission (CNEN) through international reverse auctions, where processors bid to supply a given volume and the lowest price is accepted, in accordance with Brazilian laws and regulations for government purchases. Brazil is already applying a full-cost recovery methodology at the generator manufacturer level despite downward pressure on medical reimbursement rates.

Although not a supplier of ^{99}Mo yet, Brazil is planning to build domestic production capacity (a new reactor for irradiations and a processing plant) to ensure the country meets its own demand, which is projected to grow in the future. The country does not intend to produce ^{99}Mo for export. The new multipurpose research reactor will be financed by the Brazilian government, while for the new ^{99}Mo processing plant, a public-private partnership is also a possibility under discussion. Both facilities are expected to become operational by 2018.

Canada

Canada's National Research Universal (NRU) is one of the largest (and oldest) reactors for irradiation of uranium targets for ^{99}Mo production in the world. When operating, the reactor can supply almost half of current global demand for ^{99}Mo, making it an important participant in the global supply chain. This importance was underscored during the reactor's extended outage between May 2009 and August 2010, which coupled with an extended outage at another major irradiator – the HFR reactor in the Netherlands – resulted in a severe disruption in the global supply of ^{99}Mo, creating shortages of this key medical isotope. Since its return to service, the NRU has been operating below its historical level of production.

Canada's current production of ^{99}Mo is unique in the world in that Atomic Energy Canada Limited (AECL), the operator of the NRU, not only irradiates targets, but also performs the initial extraction of the isotope prior to sending it for purification to Nordion Inc., a Canadian commercial entity. Nordion then sells the purified bulk ^{99}Mo to generator manufacturers. This relationship is governed by a long-term agreement and this limits the ability of AECL to change its pricing and implement full-cost recovery for target irradiation and ^{99}Mo production. To cover the full costs of target irradiation and initial ^{99}Mo extraction (including a share of reactor operations and indirect costs), AECL receives direct financial support from the Canadian government.

This said, the Canadian government supports the policy objective of full-cost recovery and intends to discontinue ^{99}Mo production from the NRU in 2016. To prepare for this, the government is investing in the accelerated development of non-reactor-based technologies (cyclotrons and linear accelerators) for direct production of ^{99}Mo/^{99m}Tc. In the case of cyclotrons, ^{99m}Tc is produced directly, which given its short half-life of only six hours, would be problematic to export. The government intends to apply the principles of full-cost recovery in non-reactor-based isotope production post-2016. Canada anticipates a gradual market transition from NRU supply to supply from alternative technologies and other new and existing global producers.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: AECL – Canada (irradiator)

Full-cost recovery: Not started

Comments:

AECL will not be in a position to implement full-cost recovery at the NRU reactor, given its contract with Nordion and the decision to cease target irradiation for ^{99}Mo production in 2016. Government funding is received to cover shortfalls of revenues from irradiations. The Canadian government is supporting the development of alternative ^{99}Mo production technologies, which would be expected to operate on a full-cost recovery basis post-2016.

Outage reserve capacity: Not started

Comments:

Although AECL has capacity that could theoretically be used in outage situations, it is not paid for.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: Nordion – Canada (processor)

Full-cost recovery: Fully implemented – given contract with AECL

Comments:

As a commercial entity, Nordion is fully recovering its costs in the production of bulk ^{99}Mo and making a profit (as per the company's 2011 Annual Report). Waste management costs are covered through the long-term agreement with AECL.

Outage reserve capacity: Not started

Comments:

Given the unique relationship between AECL and Nordion, where AECL supplies more than just irradiation services to Nordion, Nordion does not separately pay for outage reserve capacity from AECL or other global reactors.

The combination of the long-term contract between AECL and Nordion, and Canada's impending cessation of medical isotope production from the NRU, means that AECL will not be recovering all of its costs of ^{99}Mo production prior to 2016 and will need continued government support. As a commercial entity, Nordion is already operating on a full-cost recovery basis, based on its long-term contract with AECL. AECL and Nordion maintain excess capacity for the global supply chain, although it is not paid for. AECL's and Nordion's progress indicators on full-cost recovery and outage reserve capacity are presented in the boxes above.

In Canada, health care delivery (including reimbursement policy) is a constitutional responsibility of the provinces and territories. As such, the Canadian government is taking steps to make the provinces aware of the evolving conditions in the global ^{99}Mo/^{99m}Tc supply chain and the issues and challenges with achieving secure isotope supply in the future. In Canada, most physicians are paid on a fee-for-service basis, while the costs of the procedures per se (e.g. equipment, technicians, nurses, consumables) are covered by the hospital budget. Furthermore, as is the case in most hospitals in the country, the isotopes are accounted for separately from the procedures. In short, the isotopes' costs are already "unbundled" and appropriately reported to achieve the level of awareness in the health care system proposed by the NEA. Consequently, no further actions are planned on this front by Canada.

Czech Republic

The Czech Republic is a relatively new participant in the global ^{99}Mo/^{99m}Tc supply chain. Its LVR-15 reactor, operated by the Research Centre Rez, began irradiating targets for isotope production in 2010 and currently supplies these targets to IRE for processing. Although the reactor has a capacity of 2 800 six-day curies EOP per week, it produces about 1 200 six-day curies in a normal week of operation, which is equivalent to 12% of current global demand. Given its low utilisation for target irradiation, the reactor provides significant outage reserve capacity. This reserve capacity is only partially paid for and the revenues do not cover the costs to the reactor of providing this service.

In the coming months, the LVR-15 reactor operator is planning to go through a process that is expected to result in the implementation of a full-cost recovery methodology for irradiation services, even though it has not been directed or encouraged to do so by the Czech government. At the time of writing of this report, the reactor covers only a portion of its total costs related to target irradiation for ^{99}Mo production. Rez's progress indicators are shown in the box below.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: Research Centre Rez – Czech Republic (irradiator)

Full-cost recovery: Not started

Comments:

Rez has not yet initiated a move towards full-cost recovery, but is planning to do so in the coming months. Rez needs to begin using a full-cost recovery methodology for its irradiation services at the earliest possible time.

Outage reserve capacity: Some progress made

Comments:

Rez provides outage reserve capacity to a processor, primarily due to the reactor's low utilised capacity for ^{99}Mo irradiations. The processor makes a partial payment to Rez for the amount of reserved capacity, but it does not fully cover the costs of the actual capacity used.

European Union

Following the global shortage of ^{99}Mo/^{99m}Tc in 2009-10, the Council of the European Union concluded that the medium- and long-term security of supply of medical radioisotopes in the European Union (EU) was at risk, given the ageing fleet of research reactors and the existing unsustainable economic situation in the market. The Council encouraged the European Commission to take measures to monitor the market, work with interested stakeholders, including the NEA, and provide regular updates to the Council and the European Parliament on actions taken to improve the reliability of supply of ^{99}Mo/^{99m}Tc in the EU. In June 2012, the European Observatory on the Supply of Medical Radioisotopes was established to work on strategies and policies for a sustainable and secure supply of medical radioisotopes in the EU. The purpose of the European Observatory is based on four general strategic objectives:

- to support secure ^{99}Mo/^{99m}Tc supply for the medium and long term across the EU, including effective co-ordination of reactor scheduling and emergency measures, and global communication to all stakeholders in case of a shortage;
- to ensure that the ^{99}Mo/^{99m}Tc supply issue is given high political visibility in international and national institutions, organisations and bodies;
- to encourage the creation of a sustainable economic structure of the ^{99}Mo/^{99m}Tc supply chain through supporting the implementation of the full-cost recovery methodology developed by the HLG-MR; and
- to establish periodic reviews of the ^{99}Mo/^{99m}Tc supply chain and capacities with all stakeholders across the EU, taking into account the worldwide need of supply, and to forecast future needs.

The European Observatory is also working to encourage EU health care funding systems to provide appropriate reimbursement for isotopes in medical procedures to help in the move towards full-cost recovery and economic sustainability in the ^{99}Mo/^{99m}Tc market in the EU. The Observatory is also focused on the identification of risks that could occur during the HEU-LEU target conversion process and making recommendations with relevant policy options to avoid any discontinuity in the supply chain caused or induced by the conversion process.

France

France is a major supplier of irradiated targets for ^{99}Mo production through its OSIRIS reactor, which typically produces 1 200 six-day curies EOP per week when operating. This is equivalent to 12% of current global demand. However, OSIRIS has been in service for over 45 years and is approaching its retirement. It is licensed to operate until 2015, although a reactor life extension for a few years beyond 2015 is presently under consideration. The French Alternative Energies and Atomic Energy Commission (CEA – Commissariat à l'énergie atomique et aux énergies alternatives), the reactor operator, is planning to replace OSIRIS and has begun construction of a new, multipurpose reactor (Jules Horowitz – JHR) that will also irradiate targets for ^{99}Mo production, with the support of the French government.

The French government has encouraged CEA to move towards full-cost recovery for its isotope production and the latter has responded by implementing a methodology similar to the one recommended by the NEA. CEA is fully recovering its irradiation costs for ^{99}Mo production, excluding capital costs. Capital costs are intended to be included in CEA's full-cost recovery methodology applied at JHR, when it enters into service in the latter part of this decade. Given that OSIRIS is primarily used for nuclear research, it does not maintain permanent outage reserve capacity and consequently, is not paid for it. Some irradiation capacity though, becomes available occasionally, depending on experimental research missions, and could be used for ^{99}Mo production. The progress indicators for France are presented in the box below.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: CEA – France (irradiator)

Full-cost recovery: Significant progress made

Comments:

CEA has completed a process to move towards full-cost recovery of its irradiation services for ^{99}Mo production at the OSIRIS reactor, excluding capital costs. CEA intends to recover the full costs of irradiations (including capital costs) at the new JHR reactor, which is currently under construction, to be commissioned in 2018.

Outage reserve capacity: Not started

Comments:

CEA has not dedicated outage reserve capacity at the OSIRIS reactor, although reserve capacity is available occasionally depending on the schedule of other reactor missions. CEA does not require a payment from processors for using this capacity. Dedicating outage reserve capacity at OSIRIS could increase the security of supply of irradiated targets to processors should another reactor shut down unexpectedly or for an extended period.

Further down the ^{99}Mo/^{99m}Tc supply chain, the French government expects to begin an assessment of different diagnostic imaging modalities in the near future, with a view to addressing ^{99m}Tc funding in the national health care system. It is unclear, however, what steps, if any, have been taken to date in that direction. In other words, it remains to be seen what decision the government will make with regards to separate funding for the isotope from the radiopharmaceutical and the diagnostic procedure.

Germany

Germany is not currently producing ^{99}Mo, but expects to join the global supply chain in 2015-16 irradiating LEU targets to be processed elsewhere in Europe (at present, there are no plans to build processing capacity in Germany). The FRM II research reactor at the Technische Universität München (TUM) has been modified to accommodate target irradiation and is projected to produce 1 950 six-day curies EOP in a normal week of operation, which would be equivalent to about 20% of current global demand. The German Federal and Bavarian State governments have directed the reactor operator, TUM, to implement full-cost recovery for future ^{99}Mo production and indicated that public financial support will only be given for basic research activities. The reactor is also planned to provide outage reserve capacity to processors on a commercial basis, i.e. fully recover its costs for this service.

Japan

Japan participates in the ^{99}Mo/^{99m}Tc supply chain as a generator manufacturer and consumer of ^{99m}Tc at hospitals. The country does not currently have a reactor used for target irradiation for ^{99}Mo production or a processing facility. As such, Japan does not have control over upstream activities and is largely a price-taker for bulk ^{99}Mo produced elsewhere. The Japanese government and the Japan Radioisotope Association meet periodically to discuss global ^{99}Mo/^{99m}Tc market conditions and their implications for Japanese generator manufacturers, hospitals and patients. At present, no actions are being taken in the country to examine ^{99m}Tc funding or separation of this funding from the radiopharmaceutical or the diagnostic procedure.

Japanese generator manufacturers have implemented full-cost recovery in their operations given their commercial status in the market.

Netherlands

The Netherlands plays an important role in the entire global ^{99}Mo/^{99m}Tc supply chain from target irradiation to distribution of ^{99m}Tc generators to hospitals. The HFR research reactor in Petten produces 4 680 six-day curies EOP in a normal week of operation, equivalent to 47% of current global demand. HFR uses LEU fuel but irradiates HEU targets, which it ships to two processors, Covidien/Mallinckrodt and IRE, for the production of bulk ^{99}Mo. Covidien/Mallinckrodt also manufactures ^{99m}Tc generators for distribution. The HFR reactor, along with both Covidien/Mallinckrodt and IRE, is in the process of converting to use LEU targets, with a target for full conversion by 2015-16.[4]

The Dutch government supports and encourages the Nuclear Research and consultancy Group (NRG), the HFR reactor operator, to implement full-cost recovery for ^{99}Mo production, but continues to provide some funding to cover general operational and waste/decommissioning costs at the HFR reactor through the European Commission. Furthermore, as the owner of the HFR reactor, the European Commission is responsible for its decommissioning. NRG is working towards the implementation of full-cost recovery for target irradiation services at the HFR and intends to achieve this as soon as possible. The current plan for decommissioning starts around 2023 and it is anticipated that as the HFR is decommissioned, a new replacement reactor, PALLAS, will start irradiating LEU targets for ^{99}Mo production. It is the Dutch government's and NRG's intention that irradiation for ^{99}Mo production at PALLAS is undertaken on a commercial basis.

Even though HFR has outage reserve capacity available, only a small portion of the costs for providing this service are recovered. NRG has started negotiations with processors to pay for outage reserve capacity. These negotiations are ongoing, but it is not clear at the moment what the outcome will be. In a market with a downward pressure on prices, it remains a challenge to convince customers to pay for a service that they do not always see as essential to their operations. The Dutch progress indicators on implementing the HLG-MR policy approach are presented in the box below.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: NRG – Netherlands (irradiator)

Full-cost recovery: Significant progress made

Comments:

NRG is revising its cost methodology for irradiation services to be consistent with the HLG-MR full-cost recovery methodology. It has significantly increased its prices and communicated the reasons to its customers. NRG should continue to move towards full-cost recovery, including capital, overhead, operational, and decommissioning costs.

Outage reserve capacity: Some progress made

Comments:

NRG holds outage reserve capacity when irradiation positions are not fully utilised by processors. It also holds additional irradiation channels that are not used in all irradiation cycles. However, little of this capacity is currently paid for. To ensure the reliability of supply and comply with the principle of full-cost recovery, NRG needs to implement a pricing mechanism for all of its outage reserve capacity.

4. Covidien/Mallinckrodt is working to achieve full conversion by 2015, while IRE has indicated that it will likely convert by 2016.

Further down the supply chain, the Dutch government recognises that prices for ^{99}Mo/^{99m}Tc will increase over time (including the prices of radiopharmaceuticals), as the market moves towards full-cost recovery. However, it has taken no action to date to examine ^{99m}Tc funding. It should also be mentioned that the Dutch health care system makes it challenging to separate ^{99m}Tc funding from the radiopharmaceutical and the diagnostic procedure, given that medicine prices are part of the total hospital budget, leaving hospitals with some bargaining power on prices.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc
Company/organisation name: Covidien/Mallinckrodt – Netherlands (processor/generator manufacturer)
Full-cost recovery: NO RESPONSE – unable to judge the implementation status of full-cost recovery
Outage reserve capacity: NO RESPONSE – unable to judge the implementation status of outage reserve capacity
Comments:
The NEA is unable to assess the company's progress and commitment to implementing the HLG-MR policy principles.

Poland

Poland is a relatively new ^{99}Mo/^{99m}Tc supply chain participant, providing irradiation services since 2010 in its MARIA reactor to one processor in Europe. The reactor uses HEU fuel and targets[5] to produce between 700 and 1 600 six-day curies EOP in a normal week of operation, which is equivalent to 7-16% of current global demand. Poland is planning a build a new processing facility with a capacity of 1 000 six-day Ci/week and is currently seeking financing for it. The new facility is expected to enter operation in 2017.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc
Company/organisation name: NCBJ – Poland (irradiator)
Full-cost recovery: Not started
Comments:
NCBJ is interested in developing and implementing a full-cost recovery methodology for irradiation services, however, no concrete action has been taken yet to begin this process. Some government funding is received for target irradiations in the MARIA reactor. NCBJ needs to establish and implement a process to move to full-cost recovery in the near future and reduce its dependence on government support.
Outage reserve capacity: Not started
Comments:
The MARIA reactor does not provide outage reserve capacity, although it is capable of increasing the number of irradiation cycles and the number of targets loaded into the irradiation channels. The reactor should maintain reserve capacity in cases of unexpected or extended outages at other reactors, and implement a pricing mechanism for it.

Although the Polish government does not provide targeted financial support to the National Centre for Nuclear Research (NBCJ), the reactor operator, for ^{99}Mo irradiation services, current reactor costs attributed to ^{99}Mo production are partially covered by public funds. The government also provides financial support for certain activities related

5. The reactor is currently converting to LEU fuel and targets, with expected completion of this process for fuel by early 2014 and targets – by 2016-17.

to waste management. At the time of writing of this report, the government had not directed NCBJ to implement full-cost recovery for irradiation services at MARIA. Despite NCBJ's interest in doing so and its participation in the activities of various international working groups whose mandates include full-cost recovery, it has taken no concrete actions to date to identify the reactor's full costs related to ^{99}Mo production and introduce a full-cost recovery pricing mechanism. The irradiation capacity of MARIA is currently under-utilised, creating significant room for maintaining outage reserve capacity, which however, is not being contractually provided or paid for at the moment. Poland's progress indicators on full-cost recovery and outage reserve capacity are shown in the box above.

The Polish government has not acted to examine the funding of ^{99m}Tc-related nuclear medicine procedures or consider separating the reimbursement for the isotope from the radiopharmaceutical and the diagnostic procedure. Available funding for nuclear medicine needs in Poland is insufficient at present and the expectation that full-cost recovery implementation would lead to higher prices throughout the supply chain would make this issue even more challenging in the future.

Russian Federation

The Russian Federation is striving to become an important, global ^{99}Mo/^{99m}Tc supply chain participant at all levels. Although it produces only small amounts of ^{99}Mo at present (at two reactors, with a third reactor used as a backup), it is aiming to achieve production of 1 800-2 000 six-day curies EOP in the next few years. This would be equivalent to 18-20% of current global demand. The Russian Federation also intends to convert from using HEU to LEU targets for irradiations by 2018. The subdivision of the Radiation Technologies Program – the Joint Stock Company (JSC) Isotope (a wholly owned subsidiary of the State Atomic Energy Corporation ROSATOM) – promotes and markets the production of radioisotopes manufactured by other subsidiaries of ROSATOM.

At present, Russian ^{99}Mo producers are mostly financed from their own operational budgets – with small financial help from external sources. For example, ROSATOM provides financial support only for nuclear power plant safety and scientific research. ROSATOM's progress indicators are presented in the box below.

Progress towards ensuring a long-term reliable supply of ^{99}Mo/^{99m}Tc

Company/organisation name: ROSATOM – Russian Federation (irradiator, processor and generator manufacturer)

Full-cost recovery: Some progress made

Comments:

At the reactor and processor levels, ROSATOM recovers the ^{99}Mo-specific marginal costs and operational costs attributed to ^{99}Mo production. It needs to adopt a methodology that recovers all costs of ^{99}Mo production by the time it is expected to become part of the global supply chain.

Outage reserve capacity: NO RESPONSE

Comments:

No information was provided by ROSATOM regarding the provision of or payment for outage reserve capacity.

South Africa

South Africa is an important participant in the global ^{99}Mo/^{99m}Tc supply chain as an irradiator and processor. The South African Nuclear Energy Corporation (NECSA) owns and operates the SAFARI-1 reactor and NTP Radioisotopes (NTP), a subsidiary of NECSA, produces bulk ^{99}Mo from targets irradiated in the reactor. SAFARI-1 has been using LEU fuel since 2009 and producing ^{99}Mo from the irradiation of LEU targets since 2010. LEU-based ^{99}Mo has been used for the production of ^{99m}Tc generators in the US and elsewhere. In a typical week when operating, NTP produces 2 500 six-day curies EOP, of which approximately 30% is LEU-based ^{99}Mo. This is equivalent to 25% of current global demand. NTP expects to fully convert to LEU targets by 2014, pending health approvals for all its customers to use LEU-based ^{99}Mo.

NTP, as the producer and supplier of ^{99}Mo, pays fully for the services provided by its parent company, NECSA. NTP has implemented a full-cost recovery methodology and receives no financial support from the South African government for activities related to ^{99}Mo production. Its full-cost recovery methodology has provisions for waste management costs, including payments to NECSA for waste disposal. At the same time, NECSA (and in turn, the government) derives a benefit from the profits made by NTP, as well as from the fact that NTP is responsible for the full operational cost of SAFARI-1. In addition, NTP has comprehensive backup agreements with other processors in the global supply chain for the provision of outage reserve capacity (through which it has access to other reactors), which is paid for on a commercial basis, while SAFARI-1 and NTP's ^{99}Mo processing plant also maintain such capacity. NECSA's and NTP's progress report indicators are presented in the boxes below.

Progress towards ensuring a long-term reliable supply of $^{99}Mo/^{99m}Tc$

Company/organisation name: NECSA – South Africa (irradiator)

Full-cost recovery: Fully implemented (except as noted below)

Comments:

NECSA in its role as a reactor operator has implemented full-cost identification and applied it to the price they charge NTP for irradiation services. The price for irradiation services has significantly increased, but this is mainly due to other factors, such as higher input costs, as opposed to full-cost recovery. The processor has accepted the higher price and the reasons for it, and applied full-cost recovery itself, including capital and waste management costs. NECSA's full-cost recovery methodology does not include provisions for full decommissioning and decontamination.

Outage reserve capacity: Fully implemented (but see comment below)

Comments:

NECSA holds outage reserve capacity and charges it as part of the overall irradiation rates for the use of the reactor, based on its full-cost recovery methodology. Thus, NECSA charges its customer (NTP) regardless of whether the outage reserve capacity is used.

Progress towards ensuring a long-term reliable supply of $^{99}Mo/^{99m}Tc$

Company/organisation name: NTP – South Africa (processor)

Full-cost recovery: Fully implemented

Comments:

NTP pays full costs to use the SAFARI-1 reactor, with an allowance for outage reserve capacity. NTP applies full-cost recovery, including capital and waste management costs. The company faces strong price competition for its bulk ^{99}Mo from other processors who have not yet implemented full-cost recovery. This has recently led to decreasing ^{99}Mo prices, creating the need to absorb some of the additional costs internally.

Outage reserve capacity: Fully implemented

Comments:

NTP has backup agreements with other processors in the supply chain and charges a premium for bulk ^{99}Mo produced in excess of the amounts stipulated in contracts. However, it does not pay for reserve capacity, other than on a reciprocal basis.

United Kingdom (UK)

The UK participates in the global $^{99}Mo/^{99m}Tc$ supply chain as a generator manufacturer and end-user of ^{99m}Tc in nuclear medicine procedures. Given that UK-based generator manufacturers are all commercial entities, this report assumes that they are already operating on the basis of full-cost recovery. Further downstream, the UK government does not plan to undertake a review of the ^{99m}Tc reimbursement system in the country at present. Health care delivery in the UK has been devolved to local Clinical Commissioning Groups, which are outside the scope of this report.

The government commissioned a report on the UK's future requirements for ^{99m}Tc and radioisotope supply options, which was published in January 2011. The report's recommendations were accepted in full and are being taken forward by the Department of Health, which is working with manufacturers and stakeholders to: explore the possibility of additional (weekend) production of ^{99m}Tc, explore technology and software solutions, and support the National Health Service in organisational and workforce changes. The recommendations are expected to mitigate the effects of any future radioisotope supply shortages in the UK.

United States (US)

The US is an important consumer of ^{99m}Tc, accounting for almost one-half of global demand. However, similar to the UK, the US is currently only involved down the $^{99}Mo/^{99m}Tc$ supply chain, as a generator manufacturer and consumer of ^{99m}Tc. In this report, the US-based generator manufacturers, as commercial entities, are assumed to be applying full-cost recovery. Although the country has two of the world's largest generator manufacturers, its ^{99}Mo supply is still dependent on foreign imports from Canada, Europe, South Africa and Australia. To reduce this dependence, while advancing non-proliferation goals, the US is developing its own domestic capacity for producing ^{99}Mo using non-HEU, both reactor- and non-reactor-based technologies. For example, the first of several new commercial projects in the US is expected to be completed in the next three to four years. In addition, the US government has focused its efforts on supporting existing $^{99}Mo/^{99m}Tc$ producers to convert from the use of HEU targets to LEU targets.

The US government supports the HLG-MR policy approach and, in fact, is the only government that has taken actions to implement all six principles. With no current domestic production of ^{99}Mo, the US government is encouraging demand-side changes in the market to help it move towards LEU conversion, while ensuring the application of full-cost recovery. The US government examined the feasibility of a separate payment for the isotope from the radiopharmaceutical and the diagnostic procedure, but has determined that a separate payment supporting full-cost recovery is the appropriate way to implement reimbursement policy changes within the US system at this time.

The Centres for Medicare and Medicaid Services (CMS), the US 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. By estimating the cost to produce ^{99m}Tc from non-HEU ^{99}Mo, the CMS has effectively "unbundled" the incremental isotope costs (for full-cost recovery and conversion to LEU) from the other costs of the diagnostic procedure, even if the proposed payment will only be made for doses utilising non-HEU ^{99m}Tc. The CMS proposal has been approved by the US government and in effect since 1 January 2013. Although the CMS is not the only organisation responsible for reimbursement of ^{99m}Tc-based radiopharmaceuticals (in fact, private insurance companies account for a significant portion of reimbursement for nuclear medicine procedures in the US), it tends to set an example with its reimbursement policies, which is later followed by private companies.

Chapter 6. Summary of progress towards implementing full-cost recovery and outage reserve capacity

This chapter provides a review of the progress made by reactors and processors in the global ^{99}Mo/^{99m}Tc supply chain towards implementing full-cost recovery (excluding waste management costs) and outage reserve capacity, and the degree of support by governments for ^{99}Mo production through direct and indirect subsidies. The charts below summarise the progress indicators from the previous chapter, with the caveat that these indicators have not been independently assessed, but are based on information provided directly by supply chain participants. The assessment is the most accurate description of the global situation to date. Government support for ^{99}Mo production is presented only at the reactor level, given that the majority of processors are private, for-profit companies or government business enterprises with commercial goals. A three-level scale is used to describe the degree of government support for ^{99}Mo production – "no subsidy", "partial subsidy", and "full subsidy".

Figures 6.1 and 6.2 present the progress made by reactors on full-cost recovery and outage reserve capacity. Eleven reactor operators (including all nine currently producing reactors in the global supply chain) submitted responses to the self-assessment questionnaire, but the FRM-II reactor in Germany and the three Russian reactors (that are part of the same ^{99}Mo production project and thus, counted as one reactor throughout this report) have been excluded from the figures. FRM-II does not yet irradiate targets for ^{99}Mo production, although its operator intends to implement full-cost recovery from the start of irradiations in 2015-16. The Russian reactors irradiate only for the domestic market and do not impact the global supply chain at present.

Figure 6.1. Full-cost recovery implementation, producing reactors

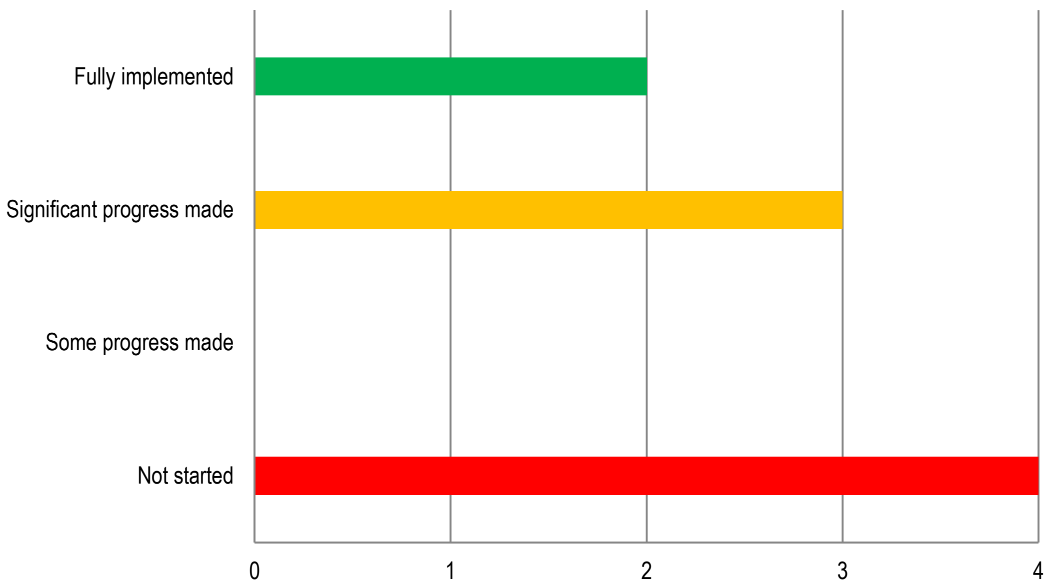
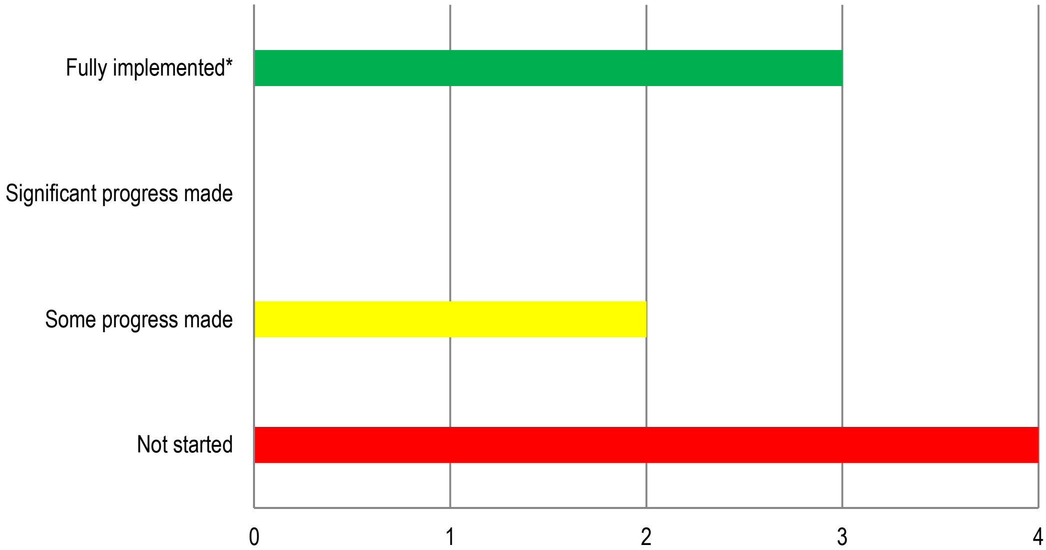


Figure 6.2. Outage reserve capacity implementation, producing reactors



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

Figures 6.3 and 6.4 show the progress made by global processors on full-cost recovery and outage reserve capacity. Russian production is not included, as it is intended only for the domestic market and does not impact the global supply chain at present.

Figure 6.3. Full-cost recovery implementation, processors

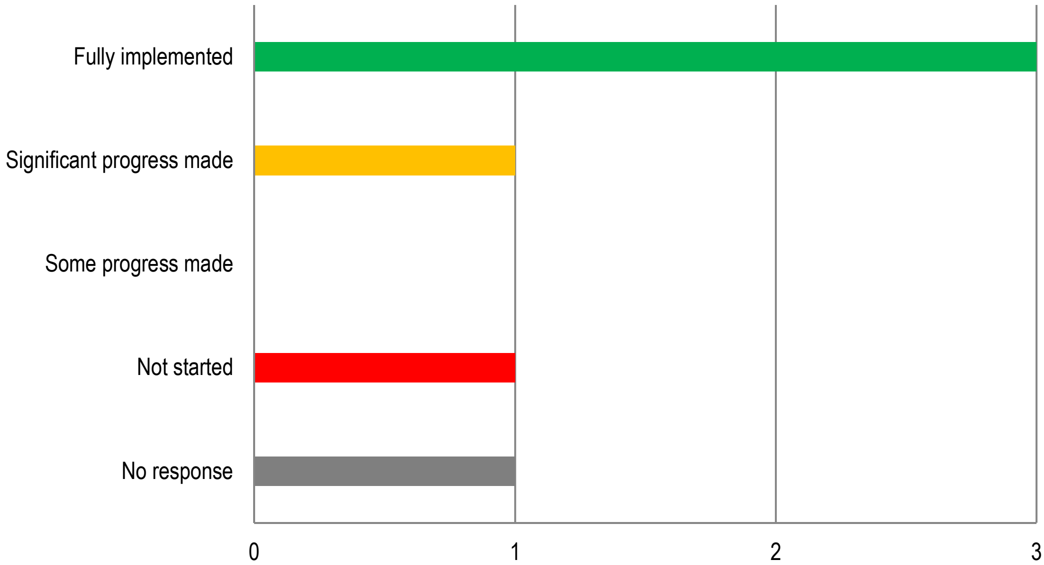
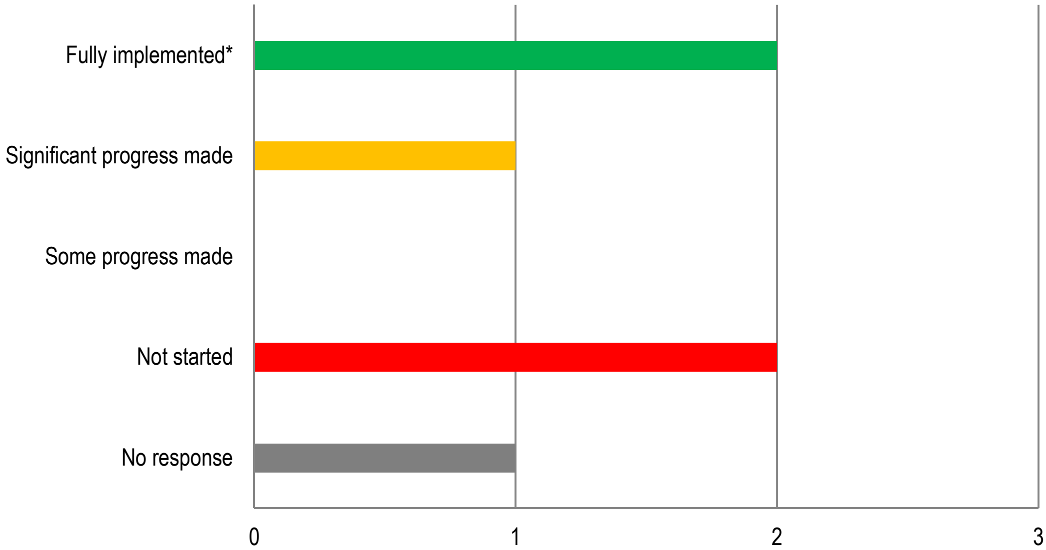


Figure 6.4. Outage reserve capacity implementation, processors



* "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 6.5 depicts the existing level of government support for ^{99}Mo production at producing reactors and as indicated by the supply chain. It includes the nine reactors that are currently part of the global $^{99}Mo/^{99m}Tc$ supply chain. Figure 6.6 shows the intended level of government support at new/replacement reactors and reactor-based projects, based on the understanding of announcements by countries. It includes new/replacement reactors and reactor-based projects intended for ^{99}Mo production.

Figure 6.5. Government support for Mo-99 production, producing reactors

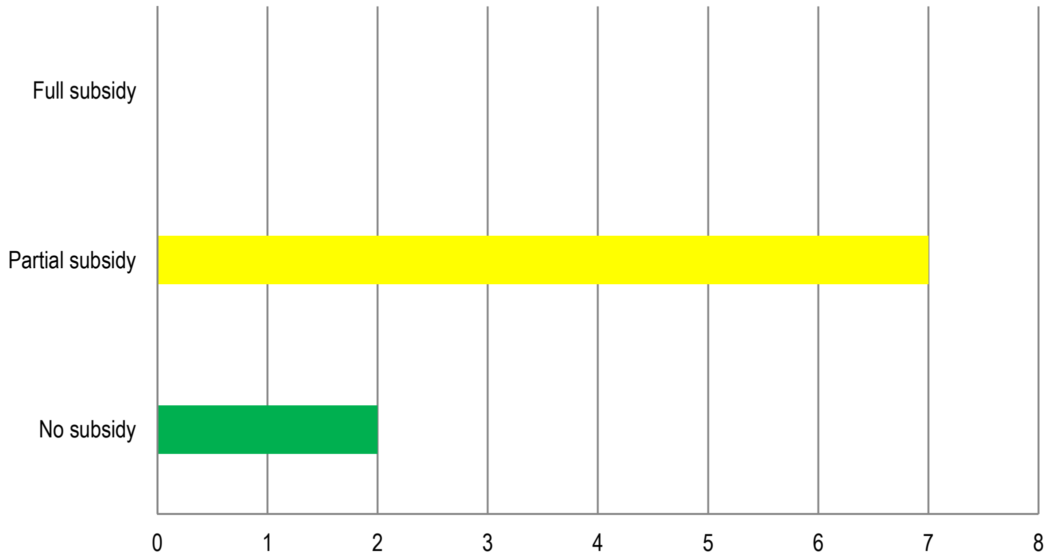
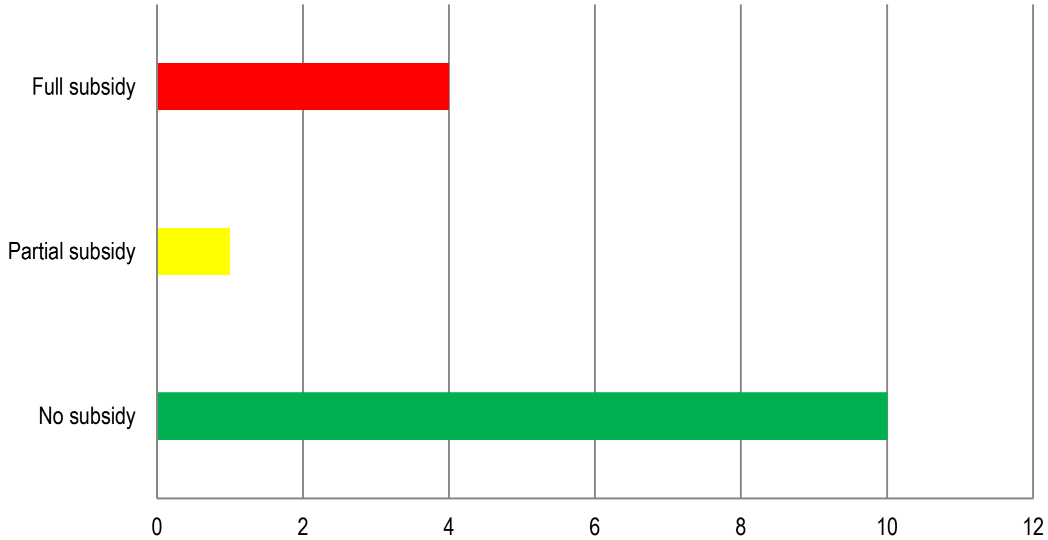


Figure 6.6. Government support for ^{99}Mo production at new/replacement reactors and reactor-based projects*



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

Chapter 7. Conclusions

This self-assessment is the first review of the implementation of the HLG-MR policy principles by the supply chain. It is based on information supplied by a wide variety of stakeholders and the NEA appreciates the willingness of these stakeholders to provide information.

The results provide a mixed picture, but generally indicate that progress towards implementation is slower than desirable and behind the original timetable set by the HLG-MR in June 2011. As a result, market players have access to reactors and processors with different cost structures for producing ^{99}Mo or ^{99m}Tc and this is causing significant price differences in the market.

The NEA is aware that the involvement of different types of organisations (governments, government-owned entities and private companies), with diverse and sometimes conflicting interests, at different levels of the same supply chain, creates unique challenges to achieve economic sustainability in the ^{99}Mo/^{99m}Tc market. The work of the HLG-MR and its stakeholders has lead to progress towards addressing and overcoming these challenges. However, much remains to be done globally to secure the supply of medical radioisotopes in the long term, from eliminating government subsidies for ^{99}Mo production to providing appropriate reimbursement rates for isotopes in radiopharmacies and hospitals. To date, voluntary commitments have not resulted in fully effective actions towards implementing the HLG-MR policy approach and there may be a need for governments to take more direct action.

The unsustainable economic situation in the global ^{99}Mo/^{99m}Tc supply chain is exacerbated by continuing below-full-cost-recovery prices. 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
- insufficient reimbursement for the medical isotope at the end-user level.

The continued fragility of the supply chain has been demonstrated by the unplanned and ongoing (for the foreseeable future) outage at the HFR reactor in Petten. The improved co-ordination of reactor schedules, the move to diversify suppliers, and some partial provision of outage reserve capacity have alleviated the negative impact of the HFR loss, but difficult times lie ahead, when other reactors enter maintenance periods.

The situation will deteriorate further with the expected permanent shutdown of the NRU (for ^{99}Mo production) in 2016 and OSIRIS around the same time, with potential supply shortages on the horizon, as shown in *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012). This clearly demonstrates the urgent need for governments to remove subsidies from the market and for supply chain participants to fully implement the HLG-MR policy principles in a timely and consistent manner.

A sustainable ^{99}Mo/^{99m}Tc market will likely be based on a network of research reactors for the foreseeable future, until new alternative technologies become commercially deployable on a large scale. Given the current reliance on ageing reactors for most of the global ^{99}Mo supply, plans for their replacement (e.g. MYRRHA, PALLAS) are important developments for ensuring security of supply. There are also other new projects for ^{99}Mo/^{99m}Tc production capacity (e.g. Australia, Canada, People's Republic of China, Republic of Korea, Russian Federation, and the US) that could help create future global irradiation supply. However, this capacity must be based on full-cost recovery to avoid over-capacity, which can only act to drive down prices to levels at which some producers will not be able to recover their costs.

The simultaneous transition to full-cost recovery and conversion to using LEU targets for ^{99}Mo production is creating technical and economic difficulties for some supply chain participants. Given that this conversion process is an externality, government support to these supply chain participants (e.g. through financial incentives) would be consistent with the HLG-MR principles. However, the US government is the only government that has taken concrete action to date, recognising the importance of LEU conversion.

In the downstream segment of the supply chain, tight budgets are making it difficult for governments to maintain or increase reimbursement rates for isotopes. However, without a (small) increase in the price for end-users, there is a risk that medical isotopes will continue to be undervalued, with negative economic consequences for the upstream segment of the supply chain as well. Again, little has been done by governments to address the issue of appropriate reimbursement, with the exception of Belgium and the US.

More broadly, governments should continue to redefine the "social contract" with the medical isotope industry and help it move to sustainability, through appropriate incentives and effective regulation. In addition, they should cease subsidising ^{99}Mo production at existing reactors and refrain from doing that at planned new/replacement reactors or for alternative technologies, as this endangers the universal implementation of full-cost recovery and could create undesirable additional capacity in the supply chain.

Finally, judging by the few responses from generator manufacturers and end-users to the self-assessment questionnaires, there appears to be a disconnection between the upstream and downstream segments of the ^{99}Mo/^{99m}Tc supply chain and uncertainty in terms of their commitment to applying the HLG-MR policy approach. The HLG-MR and its stakeholders need to engage downstream supply chain participants more effectively in the process of moving towards economic sustainability in the market. Otherwise, the future security of supply could be in danger.

References

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

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

US Department of Health and Human Services, Centers for Medicare and Medicaid Services (2012), *Payment Adjustment Policy for Radioisotopes Derived From Non-Highly Enriched Uranium Sources*, Federal Register, Volume 77, Number 221, 15 November 2012, Part II.

Annex 1. Current irradiators and processors

Table 1A.1. Current irradiators

Reactor	Targets	Normal available capacity per week (6-day Ci)[1]	Estimated stop production date
BR-2	HEU	7 800	2026
HFR	HEU	4 680	2022
LVR-15	HEU	2 800	2028
MARIA	HEU	1 920	2030
NRU	HEU	4 680	2016
OPAL	LEU	1 000	>2030
OSIRIS	HEU	1 200	2015 or later
RA-3	LEU	400	2027
SAFARI-1	HEU[2]/LEU	3 000	2025

1. What is possible under normal operations, without major changes to the reactor or sacrifices to other irradiation missions.
2. NTP HEU targets are enriched to approximately 45%, compared to the industry standard of 90-93%.

Table 1A.2. Current processors

Processor	Targets	Capacity per week (6-day Ci)[1]	Expected date of conversion to LEU targets
AECL/NORDION	HEU	7 200	Not expected[2]
ANSTO HEALTH	LEU	1 000	Started as LEU
CNEA	LEU	900	Converted
COVIDIEN	HEU	3 500	2015
IRE	HEU	2 500	2015
NTP	HEU[3]/LEU	3 000	2014[4]

1. Actual production is often less, as processing capacity is technically available 52 weeks while irradiated targets are not delivered 52 weeks of the year for all processors. When determining processor production, irradiator limitations are taken into account where they exist. This may have the effect of some processing capacity not being fully used, if there is not sufficient irradiator capacity to supply the processor with irradiated product.

2. The Canadian government has announced that it will not produce ^{99}Mo at the NRU reactor after 2016, therefore it does not expect to convert to using LEU targets for the production of ^{99}Mo.

3. NTP HEU targets are enriched to approximately 45%, compared to the industry standard of 90-93%.

4. NTP can already produce LEU-based ^{99}Mo but does not expect 100% production from LEU targets until 2014, as their customers required time to obtain the necessary health regulatory approvals.

Annex 2. Potential new/replacement, reactor-based irradiation capacity

Irradiation source	Targets/technology[1]	Expected normal available capacity per week (6-day Ci)[2]	Expected first full year of production[3]
RIAR[4] (Russian Federation)	HEU in CRR[5]	1 800-2 000	2013-2015
NorthStar[6]/MURR (United States)	Non-fissile in CRR	750-3 000	2013-2016
B&W MIPS (United States)	LEU solution in AHR	4 400	2015
FRM-II (Germany)	LEU in CRR	1 950	2016
Morgridge/SHINE (United States)	LEU solution with DTA and SAHR	3 000	2016
China Advanced RR	LEU in CRR	1 000	2017
OPAL[7] (Australia)	LEU in CRR	3 600	2017
Coqui (United States)	LEU in CRR	7 000	2017
Brazil MR	LEU in CRR	1 000	2018
Korea, Republic of	LEU in CRR	1 000	2018
Jules Horowitz Reactor (France)	LEU in CRR	2 400	2019
RA-10 (Argentina)	LEU in CRR	2 000	2019
MYRRHA (Belgium)	LEU in ADS	6 250	2024
PALLAS (Netherlands)	LEU in CRR	7 300	2025
SAFARI-II (South Africa)	LEU in CRR	3 000	2026

1. CRR = conventional research reactor; AHR = aqueous homogeneous reactor; DTA = deuterium-tritium accelerator; SAHR = subcritical aqueous homogeneous reactor; ADS = accelerator-driven system research reactor.

2. What is possible under normal operations, without major changes to the reactor or sacrifices to other irradiation missions.

3. Assumed full-scale production starts one year after commissioning unless available information indicates differently, estimated by project proponents.

4. The project includes three reactors, two of which will be used to irradiate for continuous ^{99}Mo production, with the third being a backup.

5. At the HLG-MR meeting in July 2012, the Russian delegate reported approval of a plan to convert to LEU targets for ^{99}Mo production within five years.

6. Produces low-specific activity ^{99}Mo that requires use of NorthStar's generator to produce ^{99m}Tc.

7. New production as a result of new processing capacity, "replaces" OPAL's current capacity of 1 000 six-day Ci/week.

Annex 3. Major current ^{99}Mo producing reactors

Reactor name	Location	Annual operating days	Normal production per week when operating[1]	Fuel/targets[2]	Date of first commissioning
BR-2	Belgium	120	5 200[3]	HEU/HEU	1961
HFR	Netherlands	300	4 680	LEU/HEU	1961
LVR-15[4]	Czech Republic	190	1 200	LEU[5]/HEU	1989
MARIA[4]	Poland	–	700-1 500	HEU/HEU	1974
NRU	Canada	300	4 680	LEU/HEU	1957
OPAL	Australia	290	1 000	LEU/LEU	2006
OSIRIS	France	180	1 200	LEU/HEU	1966
RA-3	Argentina	336	300	LEU/LEU	1967
ROSATOM[6]	Russian Federation	365	900	HEU/HEU	1961-1970
SAFARI-1	South Africa	305	2 500	LEU/LEU[7]	1965

1. Six-day curies of ^{99}Mo EOP during weeks when reactor is operating.

2. Fuel elements and targets are classified as either LEU, containing less than 20% of ^{235}U, or HEU, which contains greater than 20% ^{235}U (in some cases greater than 93%).

3. Does not account for increase in capacity since April 2010 with the installation of additional irradiation capacity. This increases BR-2 available capacity to approximately 7 800 6-day curies EOP; however it is not yet clear what normal production will be at the facility with this new capacity.

4. These reactors started production in 2010 so some data are not yet available.

5. The LVR-15 reactor has used fuel elements that are enriched to <20% ^{235}U since 2011.

6. The project includes three reactors, two of which would be used to produce ^{99}Mo in a continuous fashion, with the third being a backup.

7. SAFARI-1 is in the process of converting to using LEU targets (from targets with 45% ^{235}U) and expects to complete conversion by 2014, pending all their customers receiving health approval to use their LEU-based ^{99}Mo.

Annex 4. Comments by supply chain participants

Continued government support for reactors

Supply chain participants, particularly those upstream, are concerned about the ongoing government support for some reactors. These reactors are able to operate without implementing full-cost recovery because of government support for their ^{99}Mo-related operations. The result is a dampening effect on prices and a slowing down of the process towards full-cost recovery.

Economic loss and reduced competitiveness due to non-universal application of full-cost recovery

Supply chain participants are concerned about the uneven pace of moving towards full-cost recovery and the lack of a mechanism to ensure that everybody completes the process on similar timelines. A related concern is that some reactors (including newly built ones) may never implement full-cost recovery, in particular, because capital costs were covered by governments.

Access to cheaper (non-full-cost recovery) irradiation services by some processors

Processors with access to fully amortised reactors that also receive government subsidies are able to reduce their input costs and charge lower prices for bulk ^{99}Mo. This creates a downward pressure on bulk ^{99}Mo prices, which is transmitted further down the supply chain, resulting in prices for ^{99m}Tc at the end-user level that do not reflect full-cost recovery.

Pressures in the middle of the supply chain

Processors and generator manufacturers report being squeezed by increasing prices for irradiation services at reactors and resistance to price increases from customers further down the supply chain, i.e. radiopharmacies and hospitals. Higher irradiation prices in the past two years have not been matched by a corresponding increase at the radiopharmacy and hospital level. Consequently, participants in the middle of the supply chain, particularly processors, have felt the brunt of this pressure and have had to absorb much of their higher input costs internally.

Misplaced concerns about capacity

In the wake of the 2009-10 supply shortage, it is claimed that some supply chain participants mistakenly perceived the lack of supply reliability as equal to the lack of capacity and began allocating resources to build new capacity (e.g. reactors), in some cases funded by governments. It was frequently mentioned that some of this new capacity is not being built according to the principle of full-cost recovery and could undermine its implementation.

Push for LEU conversion creates additional costs for some producers

Although most major ^{99}Mo-producing countries have committed to converting to the use of LEU targets for ^{99}Mo production by the end of 2015, for many producers, this process is long and fraught with technical and economic difficulties. In addition, there is some anxiety among producers, who are currently converting, about the continued availability of HEU for targets until conversion is completed.

Concerns that non-recovery of costs upstream is hidden downstream

Where processors purchase from reactors, which are not charging or 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. As a result, the price of ^{99}Mo reported further down the supply chain does not fully reflect all production costs, including the costs of providing outage reserve capacity.

Annex 5. Self-assessment questionnaire – governments

Please indicate any information provided that you consider requires protection as confidential or that cannot be provided because of confidentiality obligations.

Questions related to the implementation of full-cost recovery (Principle 1[1])
1. Do you provide financial support (directly or indirectly) to a reactor or alternative technology operator that is part of the $^{99}Mo/^{99m}Tc$ supply chain?
2. If so, what is that support used for? Have you provided any direction to that operator to not use that financial support for direct or indirect costs related to their ^{99}Mo irradiation services or other related services?
3. Do you provide financial support (directly or indirectly) to a processor that is part of the $^{99}Mo/^{99m}Tc$ supply chain?
4. If so, what is that support used for? Have you provided any direction to that processor to not use that financial support for direct or indirect costs related to their ^{99}Mo production?
5. Are there any other actions that have been taken to move towards full-cost recovery that have not been captured in the questions above? If so, please describe.
6. Are you faced with any barriers that are impeding your efforts to implement full-cost recovery? If so, please describe.
Questions related to ensuring sufficiency of health care funding to support ^{99m}Tc-based procedures (Principle 3)
7. Have you undertaken any actions to examine the sufficiency of ^{99m}Tc-related health care funding (e.g. reimbursement rates or isotope budgets) under your jurisdiction, recognising the need for ^{99}Mo irradiation service providers to move to full-cost recovery? If so, please describe.

1. The principles and the supporting recommendations can be found in the documents referred to in the introduction to the questionnaire (at www.oecd-nea.org/med-radio/med-radio-series.html); Principles 1 to 3 and recommendations are also provided at the end of the questionnaire for ease of reference.

8. Have you taken any actions to examine the feasibility of moving to separate funding (e.g. reimbursement rates) for isotopes from radiopharmaceutical products, and both of those separate from diagnostic imaging procedures? If you have deemed it not feasible to separate funding, have you identified any other methods to provide transparency in relation to the various component prices of the diagnostic imaging procedure?
Note: One of the objectives of the second mandate of the HLG-MR is to determine if the policy approach developed during the first mandate requires some changes, after experience working to implement the approach. The following question allows for you to provide your thoughts.
9. With your experience and your observations of the supply chain, will the implementation of the policy approach lead to an increase in supply security? Are there any aspects of the policy approach that should be revisited as they are not appropriate or not achieving their expected results domestically, regionally and/or globally? Please provide details, your reasoning on why the aspect should be revisited, and your suggested reform, if possible.
10. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy approach?
11. Would you like the NEA to call you to discuss any of your responses in more detail?

Annex 6. Self-assessment questionnaire – irradiators

Please indicate any information provided that you consider requires protection as confidential or that cannot be provided because of confidentiality obligations.

Questions related to the implementation of full-cost recovery (Principle 1[1])
1. Has your government directed you, or indicated their desire for you, to implement full-cost recovery? Please provide details.
2. Are you applying the full-cost methodology developed by the HLG-MR, accounting for all the elements described in the methodology? If not, are you implementing a process for ensuring full-cost recovery? Please describe your full-cost identification process including the share of common costs allocated to ^{99}Mo production.
3. Are you responsible for the handling, management and/or disposal of waste from the extraction or purification of ^{99}Mo from the irradiated target? If so, do you recover your full costs from the processor for all services? What is the range of waste management services provided (e.g. local short-term storage, interim storage, or final disposition)?
4. If possible, can you please indicate your annual operational costs for 2011 for providing ^{99}Mo irradiation and related services, based on the full-cost identification methodology? Please indicate the currency (for this and future questions). What was your revenue from providing ^{99}Mo irradiation services for 2011?
5. If you cannot respond to question 4, please indicate if your costs for ^{99}Mo irradiation and related services are fully covered by your revenue from these services. If not, can you please describe your transition to full-cost recovery, including the timelines to achieving full-cost recovery and what percentage of costs is currently fully recovered?
6. Capital Investments a. Have you incurred any capital costs over the last two years (ending April 2012)? b. If so, what was the funding structure for that investment (for example, private sector funding, government funding)? c. If the funding came from government, are you required to pay government back? d. If so, what are the details of the pay-back requirements? Is the pay-back period tied to the life of the infrastructure?

1. The principles and the supporting recommendations can be found in the documents referred to in the introduction to the questionnaire (at www.oecd-nea.org/med-radio/med-radio-series.html); Principles 1 to 3 and recommendations are also provided at the end of the questionnaire for ease of reference.

7. Have you increased your prices for providing ^{99}Mo related services over the last two years (ending April 2012)? If so, what has been the degree (or percentage) of the overall average price increase over the two year period, and the reason for that price increase?
8. Does the government provide any funding to your facility for providing ^{99}Mo related services, either directly or indirectly as identified in the HLG-MR full-cost recovery methodology?
9. If you have faced barriers to implementing full-cost recovery, could you please describe those barriers?
10. Through your observations in the domestic and/or global market, are there clear indications that others are implementing full-cost recovery? If not, please provide any information that would allow the NEA to assess and examine these concerns.
Questions related to the implementation of sourcing, valuing and paying for outage reserve capacity (Principle 2)
11. Do you provide ORC to the supply chain? Please describe.
12. Does your pricing of ORC cover the full costs of provision of that service? Are your costs covered when required to use that ORC?
13. What has been the response of processors to paying for ORC?
14. Through your observations in the market, is the voluntary co-ordination of reactor scheduling effective in minimising periods of low irradiation service supply?
Note: One of the objectives of the second mandate of the HLG-MR is to determine if the policy approach developed during the first mandate requires some changes, after experience working to implement the approach. The following question allows for you to provide your thoughts.
15. With your experience and your observations of the supply chain, will the implementation of the policy approach lead to an increase in supply security? Are there any aspects of the policy approach that should be revisited as they are not appropriate or not achieving their expected results domestically, regionally and/or globally? Please provide details, your reasoning on why the aspect should be revisited, and your suggested reform, if possible.
16. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy approach?
17. Would you like the NEA to call you to discuss any of your responses in more detail?

Annex 7. Self-assessment questionnaire – processors

Please indicate any information provided that you consider requires protection as confidential or that cannot be provided because of confidentiality obligations.

Questions related to the implementation of full-cost recovery (Principle 1[1])
Note: The NEA is seeking to understand and validate whether the supply chain has implemented full-cost recovery and what are the barriers to implementation. One indicator of implementing full-cost recovery would be an increase in costs for irradiation services. Understanding that costs can increase for a variety of reasons, and long-term contracts can delay cost increases, the NEA would like to know if you have seen an increase in costs because of the implementation of full-cost recovery, and if so, what pressures you are faced with in accepting these cost increases. The NEA understands that the degree of actual price increase may not be able to be communicated; however, if you could at a minimum provide a qualitative description of price increases through the questions below, it would be helpful.
1. Price increases: a. Have your suppliers of irradiation services increased their prices over the last two years (ending April 2012)? b. If possible, please indicate the degree (or percentage) of the overall average price increase over the two years? c. If not possible, could you please indicate if the price increases have been significant or minor? In this context, a significant price increase is considered to be what is the minimum required to implement full-cost recovery for irradiation services. The NEA study, *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain,* indicated that the cost of irradiation services would have to increase by 20% or more to be in line with what is required for full cost recovery.
2. Reasons for price increases: a. If you have seen price increases, have you received appropriate information on the reasons for any prices increases? b. If so, can you please describe those reasons? c. In particular, are you aware of whether these price increases relate to reactors moving to full-cost recovery?
3. Barriers to accommodation: a. If you have been faced with price increases, have you been able to pass the price increases through to your customers? b. Have you had to absorb some of the irradiation service cost increases internally? c. If you have not been able to pass through the price increases, what has been the barrier? d. If possible, could you indicate the degree of price increases on your bulk ^{99}Mo as a result of the increases in prices of irradiation services that occurred over the last two years (ending April 2012)?

1. The principles and the supporting recommendations can be found in the documents referred to in the introduction to the questionnaire (at www.oecd-nea.org/med-radio/med-radio-series.html); Principles 1 to 3 and recommendations are also provided at the end of the questionnaire for ease of reference.

4. Additional sources of funding:
    a. Can you please describe your financial obligations for the management of wastes from your facility from the extraction and/or purification of ^{99}Mo from irradiated targets, if any? This should include any responsibilities that you have to the organisations(s) that handles, manages, stores or disposes (final) the waste after it leaves your facility.
    b. Please indicate if your payments to other organisations are based on full-cost recovery for their waste management services?
    c. Do you receive any financial support from the government for the waste management process?
    d. What is the range of waste management services provided (e.g. local short-term storage, interim storage, or final disposition)?
    e. Do you receive any other direct financial support from your government?
    f. If so, does this support your ^{99}Mo supply business? Please describe.
    g. If not, please indicate for what purposes the financial support is used.

5. Market behaviour:
    a. Through your observations in the domestic and/or global market, are there clear indications that others are implementing full-cost recovery?
    b. If not, please provide any information that would allow the NEA to assess and examine these concerns

Questions related to the implementation of sourcing, valuing and paying for outage reserve capacity (Principle 2)

6. Please describe how you source outage reserve capacity? Do you meet the criteria of holding levels of ORC at n-1 at every point in time? If not, can you please describe your plan for achieving complete sourcing and paying for ORC at n-1 levels, including the timelines when you expect to be fully compliant with this policy principle.

7. If your ORC comes from reactors, how do they charge you for the provision of ORC?

8. Do you provide ORC for any other processors? If so, does your sourcing of ORC within your supply chain account for the provision of ORC to those other processors, in addition to your own ORC requirements?

9. If you have not been able to fully implement the ORC system as recommended, can you please describe the barriers/challenges to implementation?

10. If you are implementing the ORC system, could you please describe how you charge customers for the provision? For example, do you charge a separate fee or a premium or is the cost incorporated in your price of bulk ^{99}Mo?

11. Through your observations in the domestic and/or global market, are there clear indications that others are implementing the HLG-MR recommendation on ORC? If not, please provide any information that would allow the NEA to assess and examine these concerns.

12. Through your observations in the market, is the voluntary co-ordination of reactor scheduling effective in minimising periods of low irradiation service supply?
13. In your opinion, are these scheduling efforts being used to intentionally limit supply at levels lower than demand (potentially to increase prices)?
Questions related to ensuring sufficiency of health care funding to support ^{99m}Tc-based procedures (Principle 3)
14. Have you seen any indications of efforts to ensure that ^{99m}Tc-related health care funding (e.g. reimbursement rates or isotope budgets) are sufficient to support the move to full-cost recovery by those providing the ^{99}Mo product (such as research reactors)?
Note: One of the objectives of the second mandate of the HLG-MR is to determine if the policy approach developed during the first mandate requires some changes, after experience working to implement the approach. The following question allows for you to provide your thoughts.
15. With your experience and your observations of the supply chain, will the implementation of the policy approach lead to an increase in supply security? Are there any aspects of the policy approach that should be revisited as they are not appropriate or not achieving their expected results domestically, regionally and/or globally? Please provide details, your reasoning on why the aspect should be revisited, and your suggested reform, if possible.
16. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy approach?
17. Would you like the NEA to call you to discuss any of your responses in more detail?

Annex 8. Self-assessment questionnaire – generator manufacturers

Please indicate any information provided that you consider requires protection as confidential or that cannot be provided because of confidentiality obligations.

Questions related to the implementation of full-cost recovery (Principle 1[1])
Note: The NEA is seeking to understand and validate whether the supply chain has implemented full-cost recovery and what are the barriers to implementation. One indicator of implementing full-cost recovery would be an increase in costs from your suppliers. Understanding that costs can increase for a variety of reasons, and long-term contracts can delay cost increases, the NEA would like to know if you have seen an increase in costs because of the implementation of full-cost recovery, and if so, what pressures you are faced with in accepting these cost increases. The NEA understands that the degree of actual price increase may not be able to be communicated; however, if you could at least provide a qualitative description of price increases, it would be helpful.
1. Price increases: a. Have your suppliers of bulk ^{99}Mo increased their prices over the last two years (ending April 2012)? b. If possible, please indicate the degree (or percentage) of the overall average price increase over the two years? c. If not possible, could you please indicate if the price increases have been significant or minor? In this context, a significant price increase is considered to be what is the minimum required to implement full-cost recovery for irradiation and processing services. The NEA study, *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain,* indicated that the cost from processors would have to increase by 30% or more to be in line with what is required for full cost recovery. d. If prices have not increased, have you received any indication that prices are expected to increase once your current contracts with suppliers have expired?
2. Reasons for price increases: a. If you have seen price increases, have you received appropriate information on the reasons for any prices increases? b. If so, can you please describe those reasons? c. In particular, are you aware of whether these price increases relate to reactors moving to full-cost recovery? d. Have you seen any evidence of price cutting activities from specific suppliers since the return to full supply capacity? If so, please describe.

1. The principles and the supporting recommendations can be found in the documents referred to in the introduction to the questionnaire (at www.oecd-nea.org/med-radio/med-radio-series.html); Principles 1 to 3 and recommendations are also provided at the end of the questionnaire for ease of reference.

3. Barriers to accommodation:
    a. If you have been faced with price increases, have you been able to pass the cost through to your customers?
    b. Have you had to absorb some of the bulk ^{99}Mo cost increases internally?
    c. If you have not been able to pass through your cost increases, what has been the barrier?
    d. If possible, could you indicate the degree or significance of price increases on your generators as a result of the increases in costs of bulk ^{99}Mo over the past two years (ending April 2012)? In this context a significant price increase is considered to be what is required to implement full-cost recovery for irradiation and processing services. The NEA economic study indicated that the cost from generator manufacturers would have to increase by 25% or more to be in line with what is required for full cost recovery.

Questions related to the implementation of sourcing, valuing and paying for outage reserve capacity (Principle 2)

4. Do you have confidence that the processors in your supply chain have sourced ORC? Please provide any details on why you have that confidence. For example, have you been provided information on the backup capacity that your providers have sourced?

5. Are you required to pay a separate fee or premium related to support ORC? Please describe.

6. Are you providing any ORC to processors through demand side management on the part of your customers or others?

7. Is your company routinely providing the market with three months' advance notice of anticipated availability of generator supply?

Questions related to ensuring sufficiency of health care funding to support ^{99m}Tc-based procedures (Principle 3)

8. Have you seen any indications of efforts to ensure that ^{99m}Tc-related health care funding (e.g. reimbursement rates or isotope budgets) are sufficient to support the move to full-cost recovery by those providing the ^{99}Mo product (such as research reactors)?

Note: One of the objectives of the second mandate of the HLG-MR is to determine if the policy approach developed during the first mandate requires some changes, after experience working to implement the approach. The following question allows for you to provide your thoughts.

9. With your experience and your observations of the supply chain, will the implementation of the policy approach lead to an increase in supply security? Are there any aspects of the policy approach that should be revisited as they are not appropriate or not achieving their expected results domestically, regionally and/or globally? Please provide details, your reasoning on why the aspect should be revisited, and your suggested reform, if possible.

10. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy approach?

11. Would you like the NEA to call you to discuss any of your responses in more detail?