Nuclear Development
NEA/SEN/HLGMR(2014)4
July 2014
www.oecd-nea.org

The Supply of Medical Radioisotopes

Results from the Second Self-assessment of the Global $^{99}Mo/^{99m}Tc$ Supply Chain

OECD
BETTER POLICIES FOR BETTER LIVES

NEA
NUCLEAR ENERGY AGENCY

Table of contents

List of figures

List of tables

Acknowledgements

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 OECD 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.

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 is based on six principles, which the HLG-MR agreed to implement by June 2014.

As a direct action to implement Principle 6, in February 2014, the OECD Nuclear Energy Agency (NEA) conducted a second self-assessment of the ^{99}Mo/^{99m}Tc supply chain. The main objective of the second self-assessment was to evaluate progress made by supply chain participants since the first self-assessment in 2012 with the implementation of the six HLG-MR policy principles. A total of 62 questionnaires were sent to key supply chain participants (15 more than in the first self-assessment) – reactor operators, processors, generator manufacturers, nuclear medicine associations that represent end-users of ^{99}Mo/^{99m}Tc, and governments. Fifty-two responses were provided (16 more than in the first self-assessment) for an overall response rate of 84% (compared to 77% in the first self-assessment). By place/role in the global supply chain, the NEA surveyed:

- twenty-four government ministries and departments[1];
- thirteen reactor operators (nine of which are currently part of the global supply chain);
- nine processors (six of which are currently part of the global supply chain);
- eight generator manufacturers;
- seven societies nuclear medicine professionals, including three national societies; and,
- one industry association representing companies active in the fields of nuclear medicine and/or medical imaging.

Questionnaire analysis

This self-assessment report, like the first, shows results for individual supply chain participants based on two of the HLG-MR 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;

1. In the first self-assessment, the same questionnaire was sent to governments. This time, targeted questionnaires were sent separately to government ministries responsible for research reactors and health. With regards to the responses, 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.

- Some progress made;
- Not started.

A large majority of governments and supply chain participants responded to the second self-assessment at each level of the supply chain. Particularly encouraging is the increased participation by generator manufacturers, which reflects their closer involvement in the work of the HLG-MR since the first self-assessment.

Unlike the first self-assessment, this report includes waste management costs in assessing progress towards full-cost recovery, as more information was provided by the supply chain. Hence these costs are considered in the development of progress indicators for individual supply chain participants. In this report, countries and organisations are deemed to be covering waste management costs for the purpose of implementing full-cost recovery if they are paying for waste treatment and interim storage, and are setting aside funds for final waste disposal and storage, according to their domestic legislative provisions. It must be noted that the bulk of waste management costs, except in Australia, South Africa and Belgium, are currently being paid by governments.

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 is given in the following.

Full-cost recovery

Progress towards implementing full-cost recovery by reactor operators and processors has been slow since the first self-assessment. The most significant development in the past two years has been the achievement of full recovery for operational costs related to ^{99}Mo production by more reactors through higher prices. However, the (relatively high) capital, decommissioning and waste management costs are still subsidised to a large extent by governments. Furthermore, is it unclear in the self-assessment results whether higher prices for ^{99}Mo irradiations and consequently, higher revenues have resulted in reactor improvements aimed at increased supply reliability.

Although reduced, government subsidies continue to be a barrier to efforts to implement full-cost recovery everywhere. This sends a negative signal to the rest of the market and slows down full implementation. Also, planned new reactor and processor infrastructure is being built with public funds, which further undermines the process towards economic sustainability.

Only two out of the nine reactors that are part of the global supply chain have fully implemented full-cost recovery (no change since the first self-assessment in 2012). The rest are at interim stages of implementation or have not yet started the process. The operators of the FRM-II reactor in Germany and the new Korean reactor were surveyed as well, but these reactors are not yet producing. Also, the reactors at the Research Institute for Atomic Reactors (RIAR) and the Karpov Institute of Physical Chemistry (IPC) in the Russian Federation irradiate primarily for the domestic market.

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 *Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the* ^{99}*Mo/*^{99}*Tc Market, 2015-2020* (NEA, 2014). The values are compared to those from the first self-assessment in 2012.

Table E2 presents the progress made by processors that are part of the global supply chain in implementing full-cost recovery, expressed in terms of their stated operational capacity, as reported in *Medical Isotope Supply in the Future: Production Capacity and Demand*

Forecast for the ^{99}Mo/^{99}Tc Market, 2015-2020 (NEA, 2014). The values are again compared to those from the first self-assessment in 2012. There has been very little progress at the processor level, reportedly due to resistance to price increases from the downstream supply chain and insufficient actions on isotope reimbursement.

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

Progress indicator	Number of reactors, 2014 (2012)	Normal available capacity per week in 6-day Ci, 2014 (2012)[1]	Share of total normal available capacity in %, 2014 (2012)[2]
Fully implemented	2 (2)	4 000 (4 000)	14% (15%)
Significant progress made	3 (3)	14 880 (13 680)	53% (50%)
Some progress made	2 (0)	7 480 (0)	26% (-)
Not started	2 (4)	1 900 (9 800)	7% (36%)

1. The normal available capacity of OSIRIS has been revised up from 1 200 to 2 400 six-day curies/week at the end of processing (EOP). The normal available capacity of MARIA has been revised down from 1 920 to 1 500 six-day curies at the end of processing. The reactor operator of MARIA is working to increase this capacity to 2 200 six-day curies EOP from January 2015. The net result from these revisions is an increase of total normal available capacity by 780 six-day curies/week.

2. Total normal available capacity is the sum of all normal available capacities of producing reactors. Shares may not add to 100% due to rounding.

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

Progress indicator	Number of processors, 2014 (2012)	Capacity per week in 6-day Ci, 2014 (2012)[1]	Share of total capacity in %, 2014 (2012)[2]
Fully implemented	3 (3)	8 680 (11 200)	52% (62%)
Significant progress made	1 (1)	3 500 (2 500)	21% (14%)
Some progress made	0 (0)	-	-
Not started	1 (1)	900 (900)	5% (5%)
No response	1 (1)	3 500 (3 500)	21% (19%)

1. IRE's capacity has been revised up from 2 500 to 3 500 six-day curies/week, while Nordion's capacity has been revised down from 7 200 to 4 680 six-day curies/week. The net result is a reduction in processing capacity by 1 520 six-day curies/week.

2. Shares may not add to 100% due to rounding.

At the generator manufacturer level and further downstream, there has been an increase in responses, showing greater involvement in the work of the HLG-MR. A common theme in the received generator manufacturer responses was the strong competition in the market, which makes it challenging to increase the prices of generators to radiopharmacies or hospitals. As commercial entities, generator manufacturers are expected to fully recover their costs of producing ^{99m}Tc generators plus a profit. However, to the extent that below-full-cost-recovery prices are passed down the supply chain from subsidised reactors, generator manufacturers do not pay the "true" cost of ^{99}Mo.

In this self-assessment, end-users reported higher prices from their suppliers over the last two years without a corresponding increase in reimbursement, except for the additional payment of USD 10 in the United States for non-highly enriched uranium (HEU) ^{99}Mo. This has put pressure on hospital budgets and may lead to a noticeable substitution of ^{99m}Tc-based radiopharmaceuticals with others in the future. However, despite the higher prices, many end-users report that they have been able to absorb the higher costs.

Outage reserve capacity

Despite some noticeable progress since the first self-assessment, outage reserve capacity is still not universally 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 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, only paying for this service when they use it, when they should be paying for the fixed costs of maintaining this reserve capacity too.

Only four of the nine producing reactors stated that they have fully implemented outage reserve capacity. Table E3 shows the progress by reactors, expressed in terms of their normal available capacity, as reported in *Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the* ^{99}*Mo/*^{99}*Tc Market, 2015-2020* (NEA, 2014).

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

Progress indicator	Number of reactors, 2014 (2012)	Normal available capacity per week in 6-day Ci, 2014 (2012)	Share of total normal available capacity in %, 2014 (2012)[1]
Fully implemented	3 (3)	11 800 (11 800)	42% (43%)
Significant progress made	1 (0)	2 800 (-)	10% (-)
Some progress made	1 (2)	4 680 (7 480)	17% (27%)
Not started	4 (4)	8 980 (8 200)	32% (30%)

1. Shares may not add to 100% due to rounding.

Table E4 presents the progress made by processors in implementing outage reserve capacity, expressed in terms of their stated capacity, as reported in *Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the* ^{99}*Mo/*^{99}*Tc Market, 2015-2020* (NEA, 2014).

Table E4. Outage reserve capacity implementation at processors by capacity

Progress indicator	Number of processors, 2014 (2012)	Capacity per week in 6-day Ci, 2014 (2012)	Share of total capacity in %, 2014 (2012)
Fully implemented	3 (2)	7 500 (4 000)	45% (22%)
Significant progress made	0 (1)	- (2 500)	- (14%)
Some progress made	0 (0)	- (-)	- (-)
Not started	2 (2)	5 580 (8 100)	34% (45%)
No response	1 (1)	3 500 (3 500)	21% (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 ^{99}Mo producers represented in-between are commercial, for-profit entities. Although governments have been reducing their support for ^{99}Mo irradiations at reactors, much remains to be done to achieve universal implementation of full-cost recovery. Despite real progress since the adoption of the HLG-MR policy principles, some governments continue to subsidise ^{99}Mo production. While it is their prerogative to fund basic research at reactors, any commercial ^{99}Mo production as part of the global supply chain should comply with the principle of full-cost recovery to avoid distorting the global market. Tables E5 and E6 below show the level of government support for ^{99}Mo production at producing reactors and the intended level of government support for future ^{99}Mo/^{99m}Tc production projects, 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 *Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ^{99}Mo/^{99}Tc Market, 2015-2020* (NEA, 2014). It should be noted that Table E5 hides the fact that governments have been steadily reducing support for ^{99}Mo production at existing reactors, which however, is balanced by the worrying sign of intentions to continue government subsidisation, revealed in Table E6.

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

Level of government support	Number of reactors, 2014 (2012)	Normal available irradiation capacity per week (in 6-day Ci), 2014 (2012)
Full subsidy	0 (0)	- (-)
Partial subsidy	7 (7)	24 260 (23 480)
No subsidy	2 (2)	4 000 (4 000)

Table E6. Level of intended government support for ^{99}Mo/^{99m}Tc production, projects under development, 2014

Level of intended government support	Number of new/replacement ^{99}Mo/^{99m}Tc projects	Potential new/replacement normal available production capacity per week (in 6-day Ci)
Full subsidy	4	6 500
Partial subsidy	2	1 300
No subsidy[1]	11	32 000

1. May include government loans or other support to be paid back by the ^{99}Mo/^{99m}Tc producer.

Further downstream, 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 early 2015, while the United States (US) government has added a supplementary payment to reimburse hospitals for the higher cost of non-HEU-produced ^{99m}Tc, motivated by the desire to encourage conversion to low-enriched uranium (LEU), but which is also designed to cover the costs of moving to full-cost recovery.

Progress by region

With the exception of some European producers taking steps in the direction of full-cost recovery and outage reserve capacity, little progress has been made elsewhere since the first self-assessment in 2012.

The United States and Europe account for approximately two-thirds of global ^{99}Mo/^{99m}Tc demand (Europe is the largest producer, while the United States 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 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 support to AECL for ^{99}Mo production.

In Asia and South America, governments intend to continue to subsidise current and future ^{99}Mo production. Where producers are part of the global supply chain, 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

The results from the second self-assessment of the global ^{99}Mo/^{99m}Tc supply chain are similar to those from the first self-assessment, showing slower-than-desired progress towards implementing the six HLG-MR policy principles, which has led to missing the deadline of June 2014 for full implementation, agreed by the governments represented on the HLG-MR. With the exception of Principles 5 and 6, governments and supply chain participants have not taken sufficient action and the ^{99}Mo/^{99m}Tc market continues to be unsustainable.

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. However, to date, voluntary commitments have not resulted in sufficiently effective actions towards implementing the HLG-MR policy approach and there is a need for governments to take more direct action. This conclusion was also made in the first self-assessment report, which underlines that work remains to be done to help the market become sustainable.

The supply shortages, albeit small and isolated, that occurred in late 2013 as a result of the simultaneous outage of the HFR reactor, the Petten processing plant, and NTP's processing plant demonstrated yet again the continued fragility of the supply chain. Only the effective, co-operative action taken by producers within the Association of Imaging Producers and Equipment Suppliers (AIPES) and additional paid outage reserve capacity in the market prevented more widespread and longer shortages. However, the short-term outlook for supply is not favourable. The planned permanent shutdown of OSIRIS at the end of 2015 and the NRU (for ^{99}Mo production) in 2016 will make the global supply situation more uncertain, with less available production capacity. There is an elevated risk of shortages in the 2015-2017 period, as shown in *Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ^{99}Mo/^{99}Tc Market, 2015-2020* (NEA, 2014), although timely and coordinated actions by the supply chain could minimise this risk.

A sustainable ^{99}Mo/^{99m}Tc market will likely be based on a network of research reactors in the foreseeable future. Despite the promise of alternative ^{99}Mo/^{99m}Tc production technologies, such as linear accelerators and cyclotrons, whether they will be widely deployed on a commercial basis remains to be seen. Given the current reliance on ageing reactors for most of the global ^{99}Mo supply, plans for their replacement or building new reactors are important developments for ensuring the security of supply. However, this new/replacement capacity must be based on full-cost recovery to avoid over-capacity in the market, which can only act to drive down prices to levels at which some producers may be forced to exit the market.

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, forcing them to extend their timelines for full conversion. As the LEU 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 and Belgian governments are the only governments that have taken concrete action to date. The lack of government financial support for LEU conversion has resulted in higher costs for some ^{99}Mo producers and may have contributed, along with technical challenges, to their delay in not only converting but also implementing full-cost recovery, given the existing downward price pressures in the market.

Much of the experience since the 2009-2010 supply crisis has shown that short-term commercial considerations (e.g. increasing or retaining market share) continue to trump long-term sustainability, resulting in unhealthy competition and inefficient market outcomes. Furthermore, some governments are still subsidising ^{99}Mo production, despite their commitment to the HLG-MR principles. This sends negative signals to potential investors in future commercially based production and jeopardises the long-term security of supply by potentially perpetuating below-full-cost-recovery prices and creating undesirable additional capacity. Clearly, voluntary actions to date by HLG-MR supply chain participants have been insufficient to secure ^{99}Mo/^{99m}Tc supply and it may be time for more direct action by HLG-MR governments.

Chapter 1. Introduction

At the request of its member countries, the OECD Nuclear Energy Agency (NEA) became involved in global efforts to ensure a secure supply of $^{99}Mo/^{99m}Tc$. Since June 2009, the NEA and its High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) examined the issues that led to supply shortages and developed a policy approach, including six principles and supporting recommendations to address those issues. The governments of HLG-MR member countries agreed to implement the policy approach, within three years of its adoption, i.e. by June 2014.

In the second mandate of the HLG-MR (2011-2013), the NEA secretariat undertook a review of the $^{99}Mo/^{99m}Tc$ supply chain, based on input from key supply chain participants, with a focus on full-cost recovery, outage reserve capacity and the governments' role in the market. The results from this first self-assessment were published in *Implementation of the HLG-MR Policy Approach: Results from a Self-assessment by the Global $^{99}Mo/^{99m}Tc$ Supply Chain* (NEA, 2013a). In its third mandate (2013-2015), the HLG-MR has continued to evaluate progress towards the implementation of the six policy principles and encourage governments and supply chain participants to take actions for secure supply of $^{99}Mo/^{99m}Tc$ in the future.

This report provides information from the second self-assessment by supply chain participants and analyses the progress made towards the implementation of the HLG-MR policy approach, compared with the first self-assessment. The focus of the second self-assessment is on all agreed policy principles (Principle 6 calls for periodic reviews of the supply chain and is being implemented by undertaking the self-assessment.) The report is organised as follows:

Chapter 2 presents a brief summary of the HLG-MR policy approach, including the six 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 capacity 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 since the first self-assessment.

Chapter 7 presents the conclusions of the second 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 radioisotopes. The policy approach seeks to address the fundamental problems that threaten reliable global supply of ^{99}Mo/^{99m}Tc and is comprised of six policy principles, and supporting recommendations presented below.

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/supply-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 and the progress made by supply chain participants towards an economically sustainable market. The review, the results of which are presented in this report, is essential to determine if and to what extent the HLG-MR policy approach is being implemented.

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. The review identifies supply chain participants who have implemented or are making good progress toward full implementation of the HLG-MR policy approach, compared to the first self-assessment in 2012. It also notes those who are not making significant progress (or have not yet started). Where the report identifies that one or more aspects of the HLG-MR policy approach are not being implemented as agreed, the HLG-MR should examine the issues and recommend appropriate steps to address these issues.

This is the second progress report to analyse the status of implementation of the six HLG-MR policy principles and it also provides a brief update on the supply chain. Like the first progress report, the main focus is on full-cost recovery, outage reserve capacity and the governments' role in the market. However, this second report also includes a limited discussion on progress with the conversion to LEU targets for ^{99}Mo production.

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. The questionnaires (see Annexes 2-6) were designed to determine the commitment and actions of the participants in implementing the HLG-MR policy principles. In addition, they were designed to seek a balance between requesting a time commitment to complete a questionnaire, including soliciting confidential information, and the need for the NEA to have sufficient and accurate information. Where required, the NEA followed up with responders to request more information or clarify submitted information.

Self-assessment questionnaires from the first self-assessment were modified and sent to the following supply chain stakeholders:

- governments;
- irradiators (reactor and alternative technology operators);
- processors;
- generator manufacturers; and,
- end-user/industry associations.

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 (see Annex 1).

Reporting of results

Similar to the first self-assessment, the second self-assessment report shows results for each key individual supply chain participant using two progress indicators, for full-cost recovery and outage reserve capacity. This enables data confidentiality to be maintained, while providing important information and maintaining consistency for direct comparisons of progress between the two self-assessments. The progress indicators recognise the degree of progress made 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 taken significant steps to implement full-cost recovery by increasing prices. Processor A has accepted these actions and has worked with its clients to inform them of the related cost increases for their bulk ^{99}Mo. They have fully communicated to their clients the reasons for the price increases. Processor A needs to continue the progress to full-cost recovery by fully paying for the waste management 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 by sourcing and paying for this capacity to help ensure a reliable supply.

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. Each supply chain participant has been assigned an indicator that is closest to the actual progress made by them, based on the information they provided in their self-assessment questionnaire, and as assessed against the NEA reports on the methodologies for full-cost recovery and outage reserve capacity (NEA, 2012; 2013b). The NEA has not made any independent evaluation of the assessments reflected in the progress indicators except through follow-up conversations with respondents for clarification.

Chapter 4. Questionnaire results

In February 2014, the NEA sent self-assessment questionnaires to all major supply chain participants – nuclear research reactor operators, processors, generator manufacturers, nuclear medicine associations that represent end-users of ^{99}Mo/^{99m}Tc, and governments. In total, 62 questionnaires were sent and 52 were completed and returned, for a response rate of 84%. By place/role in the global supply chain, the NEA surveyed:

- twenty-four ministries/departments in fifteen governments (including the European Commission)[1];
- thirteen reactor operators (nine of which are part of the global ^{99}Mo/^{99m}Tc supply chain);
- nine processors (six of which are part of the global ^{99}Mo/^{99m}Tc supply chain);
- eight generator manufacturers;
- seven societies representing nuclear medicine professionals, including five national societies; 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 (Ministry of Economy, Small and Medium Enterprises, the Self-employed and Energy)	Completed questionnaire
Government of Belgium (Federal Agency for Medicines and Health Products)	Completed questionnaire
Nuclear Research Centre SCK-CEN – Belgium	Completed questionnaire
Institute for Radioelements (IRE) – Belgium	Completed questionnaire

1. In the first self-assessment, the same questionnaires were sent to governments. This time, targeted questionnaires were sent separately to government ministries responsible for research reactors and health. With regards to the responses, 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)*

Brazilian Commission of Nuclear Energy (CNEN) as a generator manufacturer	Completed questionnaire
Brazilian Society of Nuclear Medicine	Completed questionnaire
Government of Canada (Natural Resources Canada)	Completed questionnaire
Government of Canada (Health Canada)	**No response provided**
Atomic Energy of Canada Limited (AECL)	Completed questionnaire
Nordion – Canada	Completed questionnaire
Government of the Czech Republic (Ministry of Industry and Trade)	**No response provided**
Government of the Czech Republic (Ministry of Health)	Completed questionnaire
Research Centre Rez – Czech Republic	Completed questionnaire
Czech Society of Nuclear Medicine	Completed questionnaire
Euratom Supply Agency	Completed questionnaire
European Commission, Directorate-General for Health and Consumers	**No response provided**
Government of France (Ministry of Ecology, Sustainable Development and Energy) via the *Commissariat à l'énergie atomique et aux énergies alternatives* (CEA)	Completed questionnaire
Government of France (Ministry of Health)	**No response provided**
CEA – France	Completed questionnaire
IBA Group – France	Completed questionnaire
Government of Germany (Ministry of Economics and Energy)[2]	See footnote 2.
Government of Germany (Ministry of Health)	**No response provided**
Bavarian State Ministry of Education, Culture, Science and Art[3]	Completed questionnaire
Technical University of Munich – Germany	Completed questionnaire
Government of Japan via the Japan Radioisotope Association	Completed questionnaire
FUJIFILM RI Pharma Co. Ltd.	Completed questionnaire
Nihon Medi-Physics Co. Ltd.	Completed questionnaire
Korea Atomic Energy Research Institute (KAERI) (future irradiator)	Completed questionnaire
KAERI (future processor)	Completed questionnaire
Government of the Netherlands (Ministry of Economic Affairs)	Completed questionnaire
Government of the Netherlands (Ministry of Health, Welfare and Sport)	Completed questionnaire
Nuclear Research and consultancy Group (NRG) – Netherlands	Completed questionnaire
Mallinckrodt (processor) – Netherlands	**No response provided**
Mallinckrodt (generator manufacturer) – Netherlands	**No response provided**
Government of Poland (Ministry of Economy)	Completed questionnaire
Government of Poland (Ministry of Health)	Completed questionnaire
National Centre for Nuclear Research (NBCJ) – Poland	Completed questionnaire
Government of the Russian Federation (Federal Medical Biological Agency)	**No response provided**
Research Institute for Atomic Reactors (RIAR) (irradiator) – Russian Federation	Completed questionnaire
RIAR (processor) – Russian Federation	Completed questionnaire
Karpov Institute of Physical Chemistry (IPC) (irradiator) – Russian Federation	Completed questionnaire

2. The Bavarian State Ministry of Education, Culture and Sport responded instead.
3. The Ministry was not sent a questionnaire, but provided a response.

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

Karpov IPC (processor) – Russian Federation	Completed questionnaire
Karpov IPC (generator manufacturer) – Russian Federation	Completed questionnaire
South African Nuclear Energy Corporation (NECSA) – South Africa	Completed questionnaire
NTP Radioisotopes – South Africa	Completed questionnaire
Government of Spain (Spanish Agency for Medicines and Health Products)	Completed questionnaire
Spanish Society of Radiopharmacy	**No response provided**
Government of the United Kingdom (Department of Health)	Completed questionnaire
British Nuclear Medicine Society	Completed questionnaire
GE Healthcare – United Kingdom	Completed questionnaire
Government of the United States (National Nuclear Security Administration)	Completed questionnaire
Government of the United States (Centers for Medicare and Medicaid Services)	Completed questionnaire
Lantheus Medical Imaging – United States	Completed questionnaire
Association of Imaging Producers and Equipment Suppliers (AIPES)	**No response provided**
European Association of Nuclear Medicine (EANM)	Completed questionnaire
National Association of Nuclear Pharmacies (NANP) – United States	Completed questionnaire
Society of Nuclear Medicine and Molecular Imaging (SNMMI) – United States	Completed questionnaire

Of the 52 total responses, 18 came from governments or through their delegates from government-owned entities, 13 from reactor operators, 8 from processors, 7 from generator manufacturers, and 6 from nuclear medicine societies. Table 4.2 below shows a breakdown of questionnaire responses and response rates by supply chain participant group, including a comparison with the results in the first self-assessment in 2012.

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

	Number of responses (2014)	Number of responses (2012)	Response rate (in %, 2014)	Response rate (in %, 2012)
Governments[1]	18	15	75%	79%
Reactor operators	13	11	100%	92%
Processors	8	6	89%	86%
Generator manufacturers	7	2	88%	33%
Societies	6	3	75%	75%

1. Includes the regional government of the State of Bavaria.

The majority of participants at the four main levels of the ^{99}Mo/^{99m}Tc supply chain – reactor operators, processors, generator manufacturers, and nuclear medicine societies representing the end-users – completed the questionnaires. The response rates at each level were similar to those in the first self-assessment, with the exception of generator manufacturers, who significantly increased their participation. As a result, the conclusions drawn in this report (see Chapter 7) are broadly representative of each supply chain level and the global market overall.

Progress on implementing the HLG-MR policy approach

The process of implementing the HLG-MR policy principles continues albeit more slowly than desired. Most supply chain participants indicate moving towards full-cost recovery for ^{99}Mo production, although little progress has been made since the first self-assessment. Prices are reported to have increased significantly at all levels of the supply chain, and interestingly, many end-users have been able to adjust to these increases. At the same time, supply chain participants indicate a disconnection between ^{99}Mo prices upstream and ^{99m}Tc reimbursement rates downstream. This makes it difficult to determine if actions towards implementing full-cost recovery or appropriate isotope reimbursement are achieving their objectives.

Some countries have been producing ^{99}Mo on a commercial, full-cost recovery basis for a number of years now, while others have continued moving in that direction since 2012. More producers have achieved reactor operational cost recovery in the past two years, which is an important milestone. However, another important component of full costs, namely capital costs remains a serious barrier to full implementation, perpetuated by the existing below-full-cost-recovery prices. Decommissioning and waste management costs also continue to be largely excluded from full-cost recovery at the moment, as in most cases they are unknown, given the lack of definitive plans for final waste disposal and storage.

At the same time, there are also countries that do not intend to move towards full-cost recovery or do not plan to in the short term. For example, Canada is unable to implement full-cost recovery for ^{99}Mo production at the NRU given the contract terms between AECL and Nordion, prior to NRU's exit from the global supply chain in 2016. 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 major ^{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. Also of concern are the intentions of countries in South America and Asia to proceed with plans to build significant ^{99}Mo production capacity in the next few years with public funds and no clear plans for full-cost recovery.

Technical and economic challenges, coupled with the simultaneous implementation of full-cost recovery, are also slowing down the conversion to LEU targets for ^{99}Mo production. Higher costs of production without a clear benefit to the end-user (thus, inability to charge higher prices), makes it challenging for processors to convert. Despite being an externality in the production of isotopes, justifying government support, only the American and Belgian governments have so far provided financial support to producers for conversion. Partly as a result, producers have had to delay their timelines for full conversion to 2016-2017.

More effective reactor-processor-generator manufacturer co-ordination has maximised the use of available irradiator capacity at any time and contributed to more reliable supply. This was particularly evident during the recent major producer outages in late 2013 when ^{99}Mo supply to customers was strained but with very few (and isolated) reported shortages globally. Although improved producer co-ordination has increased supply reliability, it does not directly affect the fundamental economic situation in the supply chain. In the long term, should the market continue to be unsustainable, security of supply of ^{99}Mo/^{99}Tc will be at risk.

At the processor and generator manufacturer levels, most supply chain participants are commercial entities and recover their full costs (plus profit) related to ^{99}Mo production[4]. 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 the full associated costs. Admittedly, some processors have already signed or are in the process of negotiating contracts for outage reserve

4. There are exceptions, which are discussed later in the report.

capacity, with a corresponding payment, but this is still not a widespread practice in the market. Progress on sourcing and paying for outage reserve capacity since the first self-assessment has been painfully slow, which reduces supply reliability and impedes the implementation of full-cost recovery. Furthermore, there appears to be a misunderstanding by some supply chain participants of the purpose for outage reserve capacity and why it should be paid for. As a result, the price of ^{99}Mo does not fully reflect all production costs, including the costs of providing outage reserve capacity.

Governments

Eighteen government ministries/departments[5] responded to the self-assessment questionnaires. Of those, seven are responsible for reactors that currently irradiate targets for ^{99}Mo production. Governments have continued to reduce financial support for ^{99}Mo-related services at reactors since the first self-assessment, resulting in higher prices charged to processors, although there is some way to go until full-cost recovery is achieved. The withdrawal of public financial support, however, is still occurring at a different pace across reactors, as some reactors and processors are hesitant to significantly increase prices before others. For most reactors, capital, decommissioning and waste management costs remain largely unaccounted for in cost recovery. Moreover, governments continue to provide capital support to reactors, including for the construction of new ^{99}Mo production infrastructure. This is a major barrier to the implementation of full-cost recovery.

Further down the ^{99}Mo/^{99m}Tc supply chain, pressure on budgets in many countries has continued to affect nuclear medicine. Of the government responses to the second self-assessment, eight came from ministries or government agencies responsible for nuclear medicine. The responses indicate that governments are not planning to take action on radioisotope reimbursement in the short term. The report on the first self-assessment highlighted the supplementary payment by the US government, motivated by the desire to encourage conversion from HEU to LEU, and the Belgian government's plans to introduce a separate reimbursement for ^{99m}Tc, whose implementation has been delayed until 2015. No other significant steps have been taken since.

Reactors

Of the 12 reactor operators who responded (1 more than in the first self-assessment), 10 are existing ^{99}Mo irradiators and two are future (9 of them are part of the global supply chain). Only two of the existing irradiators have already implemented full-cost recovery for ^{99}Mo-related irradiation services, four are at various stages of implementation, three have not started the process yet, and one is unknown. One of the two future irradiators intends to implement full-cost recovery, while the other may not.

Full-cost recovery implementation at reactors has continued since the first self-assessment through price increases for irradiations, although it has been slower than desirable. Given the significant price increases by some reactor operators, this poses the question whether reactors are using the additional revenues to improve supply reliability by re-investing it in their ^{99}Mo-related operations. Participants at different levels of the supply chain report that the price increases by their suppliers (including from reactors) are partly due to moving towards full-cost recovery, but it is difficult to estimate that portion of the price increase.

Some reactors have stalled their progress towards full-cost recovery, as they are concerned about losing processor business if they increase their prices too high. Others are attempting to increase their market share and are willing to offer processors below-market irradiation prices (which are subsidised). In both cases, the lack of an

5. Includes the European Commission and the regional government of the State of Bavaria.

international, legally binding mechanism to ensure that all reactor operators implement full-cost recovery by the agreed time is a strong disincentive for full implementation. Furthermore, the intentions of some governments (in mostly future producing countries) to provide support to their reactors generate unfavourable market signals for other reactors, through a downward pressure on prices, to implement full-cost recovery. The simultaneously occurring process of LEU conversion has made it even more difficult to implement full-cost recovery for ^{99}Mo production.

Most new or replacement, multipurpose reactors intended for ^{99}Mo production, and alternative technologies for ^{99}Mo/^{99}Tc production, are planning to implement full-cost recovery, although it remains to be seen if all of them do. There have been indications that new production sources in Belgium, Canada, France and the United States will operate on a commercial basis. However, future ^{99}Mo-producing infrastructure in the Republic of Korea, Argentina, the People's Republic of China, and the Russian Federation is being financially supported by their governments without a clear plan for full-cost recovery. Brazil, where the government is also financing a new reactor and processing plant, plans to use its production only for the domestic market. However, after commissioning, at currently projected demand growth rates, it will be years before Brazilian ^{99}Tc demand catches up to the built capacity, which would leave the country with a surplus production and the possibility of exporting that surplus. Should it be part of the global supply chain, Brazil would need to ensure full-cost recovery for ^{99}Mo production.

Even if not all of the above-mentioned new/replacement projects come online, there is potential for over-capacity in the global market around 2020 and thereafter, as projected in *Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ^{99}Mo/^{99}Tc Market, 2015-2020* (NEA, 2014). If any of these projects do not implement full-cost recovery, existing ^{99}Mo producers at all levels of the supply chain could be under pressure to offer lower prices in order to stay in business. Such an undesirable scenario might conceivably force some market participants to exit.

Processors

The current processor market is comprised of four large companies – Nordion (Canada), Mallinckrodt (the United States (US)/Netherlands), NTP Radioisotopes (South Africa) and the Institute for Radioelements (IRE, Belgium). Together, they account for approximately 90% of the global supply of bulk ^{99}Mo and have significant influence over bulk ^{99}Mo prices. In addition, ANSTO (Australia), CNEA (Argentina) and JSC Isotope (Russian Federation)[6] already sell smaller amounts abroad. After the NRU's (and consequently, Nordion's) exit from the global supply chain in 2016, the processor market will likely become more concentrated in the short term post-2016.

The NEA received six responses to the self-assessment questionnaire from eight processors (three responses from the four major processors). The commercial entities among these organisations (most of them) have already implemented full-cost recovery in their pricing structures. However, where they purchase from reactors, which are not charging or not able to charge full-cost recovery prices, 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 global ^{99}Mo prices and acts as an impediment to needed investment in new or replacement capacity.

6. Markets bulk ^{99}Mo produced at the Research Institute of Atomic Reactors (RIAR) and the Karpov Institute of Physical Chemistry (IPC).

In addition to the current processor capacity, plans are underway in several countries to build new processing facilities. Some of the new projects (in North America) are intended to operate on full-cost recovery, but likely without the ability to provide ORC to the global market. Others (in South America and Asia) are being built with government funds and may be able to hold ORC, even if this ORC may only be used regionally.

Generator manufacturers

The majority of generator manufacturers responded to a self-assessment questionnaire, which was a significant improvement from the response rate in 2012, allowing the NEA to gather more usable information about this part of the ^{99}Mo/^{99m}Tc supply chain. A common theme in the received responses was the strong competition in the market, which makes it challenging to increase the prices of generators to radiopharmacies or hospitals. At the same time, long-term contracts with bulk ^{99}Mo producers provide some protection against regular and significant price increases. As commercial entities, generator manufacturers are expected to fully recover their costs of producing ^{99m}Tc generators plus a profit. However, to the extent that below-full-cost-recovery prices are passed down the supply chain from subsidised reactors, generator manufacturers do not pay the "true" cost of ^{99}Mo.

Nuclear medicine societies

The information provided by nuclear medicine societies was more comprehensive and detailed than in the first self-assessment, enabling a more thorough analysis. The pursued efficiencies in ^{99m}Tc use in response to the steep increases in ^{99}Mo prices in the wake of the 2009-2010 supply shortages have been largely achieved and carried through the subsequent fall in prices, which has resulted in reduced overall demand. It is doubtful whether further significant efficiencies can be achieved, meaning that higher generator prices would result in lower margins for radiopharmacies and hospitals unless isotope reimbursement levels increase. In this self-assessment, end-users report higher prices from their suppliers over the last two years without a corresponding increase in reimbursement, except for the additional payment of USD 10 in the United States for non-HEU ^{99}Mo. This has put pressure on hospitals' budgets and may lead to a substitution of ^{99m}Tc-based radiopharmaceuticals with others in the future.

Chapter 5. Country assessment

This chapter presents a brief profile of each country with major, current or future, irradiating or processing facilities. 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 overall and since the first self-assessment in 2012. The chapter also assesses the role of governments in helping the supply chain move towards long-term economic sustainability by withdrawing subsidies for ^{99}Mo production and 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 global demand for ^{99}Mo that this production is equivalent to. Global demand is estimated at approximately 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 per week, it is estimated to provide 20% of global demand in the week when it is operating, although **not** 20% of the average weekly global demand, because it does not irradiate targets every week of the year.

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.

Argentina

Argentina is a regional supplier of ^{99}Mo in South America with plans to become a major global supplier in the coming years. The country’s RA-3 reactor and processing plant produce 300-350 six-day curies in a normal week of operation, which accounts for approximately 3-3.5% of global demand. The RA-3 is one of only three reactors in the world, (the others being OPAL in Australia and SAFARI-I in South Africa), that use LEU for both fuel and targets. The reactor and associated processing plant are operated by the Argentine National Commission for Atomic Energy (CNEA). CNEA, a government-controlled entity, manages the supply of medical radioisotopes in the domestic and regional markets. It has responsibility for both the reactor and processor, thus vertically integrating target irradiation and bulk ^{99}Mo production. Argentina is also one of two manufacturers of targets for ^{99}Mo irradiations in the world (the other is France). Neither the reactor nor the processing plant provides outage reserve capacity to the global supply chain.

The RA-3 reactor and processing plant receive government support for ^{99}Mo production, most of which is directed to the CNEA Waste Management Division. The

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

government also provides capital funding for refurbishment and infrastructure needs. Notwithstanding the financial support, CNEA has been looking to apply full-cost recovery 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. Waste from ^{99}Mo production is managed by CNEA but funded by the Argentine government.

Argentina is planning to build a new reactor (RA-10) and processing plant, which is intended to irradiate targets for ^{99}Mo production, with a capacity of 2 000-3 000 six-day curies per week when operating. This would make the country a major global producer, once the new reactor and processing plant are commissioned. The new ^{99}Mo production infrastructure is being designed and built with government financial support.

Based on CNEA's responses, the organisation is taking steps to implement the HLG-MR policy principles; however, it appears to be at an early stage in the process. The government continues to play a prominent role in the ^{99}Mo/^{99m}Tc supply chain in Argentina, primarily through direct funding, which creates a disincentive to move to full-cost recovery. At the same time, it must be noted that Argentina is a special case in the global supply chain, as it 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 at present. However, the Argentine government providing direct support for the construction of the new RA-10 reactor and processing plant does not align with the HLG-MR policy principles and would be detrimental to full-cost recovery efforts in other countries.

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 addressing the issue of full-cost recovery for irradiation services and bulk ^{99}Mo production. It needs to design and implement an appropriate methodology or use the HLG-MR's agreed methodology. Direct government support is received by the reactor and processing plant, mainly for capital expenditures and waste management. The planned, new reactor (RA-10) and processing plant appear to be fully funded by the government.

No evidence of improvement since the first self-assessment in 2012.

Outage reserve capacity: Not started

Comments:

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

No change since 2012.

Australia

Australia is a major 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 Organization (ANSTO) operates the OPAL reactor and an associated processing plant, which produces up to 1 000 six-day curies EOP in a normal week of operation. Australia's ^{99}Mo production meets approximately 10% of global demand. OPAL is the newest and one of just two reactors worldwide (the other one is RA-3 in Argentina) that irradiate only LEU targets for ^{99}Mo production (SAFARI-I irradiates both HEU and LEU targets). 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, ANSTO is bound by Australian government policy to not create unfair competition in its domestic commercial operations, including for ^{99}Mo sales.

ANSTO has an agreement with NTP Radioisotopes in 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.

The Australian government is financing the construction of a new ^{99}Mo production plant and a waste processing plant, which would enable ANSTO to significantly increase bulk ^{99}Mo production and permanently and safely dispose of the final waste from processing. Apart from this capital support, which must be repaid over time, the government has largely not intervened in ^{99}Mo production activities.

Australia's progress report indicators are presented in the box below.

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 full-cost recovery 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 national long-term waste treatment and storage facility is built, as per the Australian government's commitment, ANSTO needs to include these costs as well in its full-cost recovery methodology.

No change since the first self-assessment in 2012.

Outage reserve capacity: Fully implemented

Comments:

ANSTO has made arrangements for the provision of outage reserve capacity and charges market rates for its availability and maintenance, based on its full-cost recovery methodology. 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.

No change since 2012.

Belgium

The BR-2 reactor in Belgium has the highest normal available capacity for ^{99}Mo irradiations and is one of the largest irradiators 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 more than 50% of global demand. Over its operational life to date, the reactor has undergone major refurbishments and is expected to remain online well into the 2020s. Another major refurbishment is planned for 2015-2016, which would take it out of production for an expected 16 months. The BR-2 is to be replaced at the end of its operating life by a new, multi-purpose reactor (MYRRHA), which is currently in the design stage.

The Belgian Nuclear Research Centre SCK-CEN operates BR-2 and irradiates HEU targets. The irradiated targets are sent for processing to the Institute for Radioelements (IRE) in Belgium and Mallinckrodt in the Netherlands. The reactor is currently in the process of converting to LEU targets, which is expected to be completed by 2016. Both SCK-CEN and IRE are taking steps to implement full-cost recovery despite price resistance from downstream supply chain participants. SCK-CEN already covers all of the reactor's operational costs related to ^{99}Mo production from its revenues. Costs related to reactor refurbishments and decommissioning are also included in SCK-CEN's cost methodology. However, SCK-CEN has indicated that they will not fully cost recover until market conditions improve, i.e. until other producers implement full-cost recovery as well, and prices increase.

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. The reactor has significantly increased its prices for ^{99}Mo-related services to processors in the two years to the end of 2013. SCK-CEN needs to continue its progress towards full-cost recovery, while also including refurbishment and decommissioning costs.

Progress continued to be made since the first self-assessment in 2012.

Outage reserve capacity: Fully implemented

Comments:

SCK-CEN is providing outage reserve capacity to processors and recovers the fixed and variable costs associated with this reserve capacity.

No change since 2012.

Company/organisation name: IRE – Belgium (processor)

Full-cost recovery: Significant progress made

Comments:

IRE has experienced significant price increases for irradiation services from reactors and increased its own prices for bulk ^{99}Mo despite resistance from the supply chain further downstream. 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 the full waste management and capital costs.

Some progress made since the first self-assessment in 2012.

Outage reserve capacity: Fully implemented

Comments:

IRE is maintaining outage reserve capacity at several reactors and paying its reactor suppliers for it. IRE also has a backup agreement with other processors to provide/receive production capacity in the event of an unexpected or extended reactor shutdown.

Significant progress made since 2012.

At present, the Belgian government provides limited financial support for capital, decommissioning and waste management costs. In addition to the higher irradiation costs from moving towards full-cost recovery, IRE has also faced still higher costs from converting to LEU targets. Belgium's commitment to nuclear security and non-proliferation necessitates such a move, which is underway, although the government has not provided financial support for conversion. IRE expects to fully convert to LEU by 2016.

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). SCK-CEN's and IRE's progress indicators are shown in the boxes above.

At the end-user level, Belgium is working to separate reimbursement for ^{99m}Tc from the radiopharmaceutical to increase transparency of costs. This new policy is planned to enter into force in June 2015. There is already a complete separation of reimbursement for the isotope from the medical diagnostic procedure.

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. The country is already applying a full-cost recovery methodology at the generator manufacturer level despite upward pressure on bulk ^{99}Mo prices and uncertainty on corresponding increases in ^{99m}Tc reimbursement rates.

The Brazilian government is heavily involved in the manufacture of ^{99m}Tc generators as well as the reimbursement of isotopes. The strong regulation of the country's health care systems (public and private), including reimbursement policies, creates a barrier to timely reviews and adjustments of isotope reimbursement rates when ^{99m}Tc generator prices must increase in response to more expensive bulk ^{99}Mo.

To increase control over its domestic supply of ^{99}Mo/^{99m}Tc, Brazil is working on the project to build new reactor and processing capacity by the end of the decade, to ensure that the country meets its own demand. The new ^{99}Mo production capacity of 1 000 six-day curies would meet domestic demand. Although Brazil does not plan to export bulk ^{99}Mo to other countries, meeting its own demand for ^{99m}Tc, which is projected to grow over time, would free up production capacity elsewhere in the world to cover potential unexpected or extended reactor outages.

Canada

Canada's National Research Universal (NRU) is one of the largest (and oldest) reactors in the world for irradiation of (HEU) targets for ^{99}Mo production. In a normal week of operation, the reactor can supply almost half of the global demand for ^{99}Mo, making it a significant participant in the global supply chain. This significance 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. Since its return to service, the NRU has been operating below its historical level of production.

Canada's 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 its only customer – Nordion, a private company. Nordion then sells the purified bulk ^{99}Mo to generator manufacturers. Waste from ^{99}Mo production generated by both AECL and Nordion is managed by AECL on behalf of the Canadian government. Costs are partially covered by revenues from Nordion, with the shortfall covered by the government.

The AECL-Nordion relationship is governed by a commercial supply contract, which was re-negotiated in 2013 to enable AECL to recover more of its ^{99}Mo-related costs. However, the contract still does not allow for full-cost recovery, so AECL receives direct financial support from the Canadian government. Nordion, on the other hand, as a commercial entity, applies full-cost recovery for its ^{99}Mo production. This said, the Canadian government supports the policy objective of full-cost recovery and intends to apply it in non-reactor-based isotope production post-2016.

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

Company/organisation name: AECL – Canada (irradiator)

Full-cost recovery: Some progress made

Comments:

AECL signed a revised supply contract with Nordion in 2013. This new contract has stepped up cost recovery at the reactor and is allowing AECL to move towards full-cost recovery. However, government funding is received to cover shortfalls of revenues from irradiations. The decision by the Canadian government to cease ^{99}Mo irradiations at the NRU reactor precludes the latter from converting to LEU targets. The government is supporting the development of alternative technologies for medical radioisotope production, which are expected to operate on a full-cost recovery basis post-2016.

Some progress since the first self-assessment in 2012.

Outage reserve capacity: Not started

Comments:

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

No change since 2012.

Company/organisation name: Nordion – Canada (processor)

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

Comments:

As a commercial entity, Nordion is fully recovering its costs of bulk ^{99}Mo production. Nordion's unique revenue-sharing agreement AECL, however, makes it difficult for other supply chain participants to implement full-cost recovery. Waste management costs are also covered by the agreement with AECL – a portion is covered by revenues from ^{99}Mo sales and the rest by the government.

No change since the first self-assessment in 2012.

Outage reserve capacity: Not started

Comments:

Given the unique relationship between AECL and Nordion, where AECL supplies more than just irradiation services to Nordion, the latter does not source outage reserve capacity, although it is available at the reactor. Consequently, there is no payment made for this capacity.

No change since 2012.

The Canadian government has confirmed its decision to discontinue reactor-based ^{99}Mo production after the current NRU licence expires in 2016. Instead, it is investing in non-reactor-based technologies to supply the domestic market. The government intends to apply the principles of full-cost recovery in non-reactor-based isotope production post-2016. The exit of Canadian irradiation and, in particular, processing capacity would make the global supply chain vulnerable to disruptions unless new infrastructure became operational by the time the NRU ceased to irradiate targets.

To prepare for this, the Canadian government is investing in alternative technologies specifically, linear accelerators and cyclotrons for the production of ^{99}Mo and ^{99m}Tc. The investment will provide for a more distributed supply chain. In the case of cyclotrons, ^{99m}Tc is produced directly, which, given its short half-life, would only be available domestically to locations close to the cyclotron. The linear accelerator option will produce ^{99}Mo to meet the needs of remote locations, providing for diversity and redundancy in the supply chain. The Canadian government intends for non-reactor-based isotope production post-2016 to be fully commercial, with no government participation in production.

Given the unique position of AECL and Nordion in the ^{99}Mo supply chain, there are no explicit provisions for outage reserve capacity between them. AECL has reserve capacity, although it is not paid for by Nordion and not specifically designated as outage reserve capacity. AECL's and Nordion's progress indicators on full-cost recovery and outage reserve capacity are presented in the boxes above.

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 Nuclear Research Institute REZ, began irradiating (HEU) 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 has been typically producing only about 600-700 six-day curies when in operation, accounting for 6-7% of global demand. Given its current low utilisation for target irradiation, the reactor provides significant outage reserve capacity, which is paid for by the processor.

REZ, the LVR-15 reactor operator and a private company, has made progress in implementing full-cost recovery, although it seems that much remains to be done to recover the full costs associated with ^{99}Mo irradiations. For example, capital, overhead and decommissioning costs are not currently covered by revenues from ^{99}Mo irradiation services at LVR-15. As REZ states that it does not receive financial support from the Czech government, it is unclear how it accounts for the full costs of ^{99}Mo irradiations in LVR-15. 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: REZ – Czech Republic

Full-cost recovery: Some progress made

Comments:

REZ has implemented its own full-cost recovery methodology for ^{99}Mo irradiations and it currently recovers operational and maintenance costs from ^{99}Mo revenues. However, these costs represent only a portion of the full costs of ^{99}Mo irradiations. REZ also needs to recover capital, overhead and decommissioning costs. Waste management is a responsibility of IRE, who processes the irradiated targets.

Some progress since the first self-assessment in 2012.

Outage reserve capacity: Significant progress made

Comments:

REZ states that it provides outage reserve capacity, which is fully paid for – both its fixed and variable costs. However, this reserve capacity appears to be due to operational flexibility of the reactor and not "true" outage reserve capacity.

Some progress since 2012.

European Union

Following the global shortage of $^{99}Mo/^{99m}Tc$ in 2009-2010, the European Council concluded that the medium- and long-term security of supply of medical radioisotopes in the European Union (EU) was at risk, given 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 issues related to the proper functioning of the $^{99}Mo/^{99m}Tc$ market in the EU with a focus on:

- effective scheduling of nuclear reactor operations for irradiating targets for ^{99}Mo production;
- provision of adequate reserve capacity at reactors for periods of unexpected and/or extended reactor shutdowns;
- communication to governments in case of ^{99}Mo supply disruptions;
- market economics, including adequate supply of ^{99}Mo – based on the full recovery of costs for its production – and accurate projections of ^{99m}Tc demand; and,
- timely and economically viable transition to the use of LEU targets for ^{99}Mo production.

The European Observatory's four working groups have contributed significantly to addressing the issues related to the security of supply of $^{99}Mo/^{99m}Tc$ in the EU. Working Group One and its Emergency Response Team has been very effective in minimising supply disruptions during unexpected major producer outages in November 2012, April – June 2013 and November 2013. Working Group Two has reached out to European stakeholders on full-cost recovery and isotope reimbursement, and supported a process by the six large European ^{99}Mo-producing countries to arrive at an agreement on the implementation of full-cost recovery. Working Group Three has identified issues associated with LEU conversion and recommended a number of potential policy options to address these issues and ensure that the conversion process does not have an adverse impact on reliable supply. In this context, the European Commission has announced funding of 4-6 million euros for research and development of high-density LEU fuel and targets for medical radioisotope production, as part of its 2014-2015 Euratom Work Programme for nuclear research. Finally, Working Group Four has examined the capacity/demand situation in Europe and analysed the potential impact on supply from permanent reactor shutdowns and new/replacement capacity coming online.

The European Observatory is also working to encourage EU health care funding systems to ensure appropriate reimbursement rates for isotopes in medical procedures to help in the move towards full-cost recovery and economic sustainability in the EU $^{99}Mo/^{99m}Tc$ market.

France

France is a major supplier of irradiated (HEU) targets for ^{99}Mo production through its OSIRIS reactor, which produces 1 200 six-day curies EOP per week when operating. This accounts for 12% of global demand. However, OSIRIS has been in service for 48 years and is approaching its retirement, currently anticipated at the end of 2015. The *Commissariat à l'énergie atomique et aux énergies alternatives* (CEA), the reactor operator, is planning to replace OSIRIS. It has begun the construction of a new, multi-purpose reactor (Jules Horowitz – JHR) that will irradiate (LEU) 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 CEA is now fully recovering its ^{99}Mo irradiation costs, except capital costs. Given the fact that OSIRIS' capital costs are fully amortised, CEA does not plan to recover them in existing commercial contracts before OSIRIS' permanent shutdown at the end of 2015. However, capital costs will be included in CEA's full-cost recovery methodology applied at JHR, when it enters into service in the next few years.

As OSIRIS is primarily used for nuclear research, it does not maintain permanent outage reserve capacity and consequently, is not paid for such. Some irradiation capacity though, becomes available occasionally, depending on experimental research missions, for ^{99}Mo production. This capacity is only partially paid for by users. 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 implemented a full-cost recovery methodology for the OSIRIS reactor, excluding capital costs. CEA intends to fully cost recover for irradiations (including capital costs) at the new JHR reactor, which is currently under construction.

Some progress since the first self-assessment in 2012.

Outage reserve capacity: Not started

Comments:

CEA has not dedicated outage reserve capacity at the OSIRIS reactor, although such capacity is available occasionally depending on the schedule of other reactor missions. As such, CEA does not require a payment for using this capacity. CEA plans to make outage reserve capacity available at JHR to processors on a commercial basis.

No change since 2012.

Germany

Germany is not currently producing ^{99}Mo, but expects to join the global supply chain in 2017-18, 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) is being modified to accommodate target irradiation and is estimated to produce up to 2 100 six-day curies EOP in a normal week of operation, which would account for 21% of global demand.

Financial support for research and development activities related to future ^{99}Mo production is provided by German federal government. In addition, part of the costs for personnel has been taken over by the Government of the State of Bavaria. The latter has directed the reactor operator, TUM, to implement full-cost recovery for future ^{99}Mo production, including also the provision of outage reserve capacity.

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.

This report assumes that Japanese generator manufacturers have implemented full-cost recovery in their operations given their commercial status in the market. Although, it should be noted that, given its geographical location far from major ^{99}Mo producers and being a price-taker in the market, Japan is more vulnerable than most countries to unplanned producer outages affecting supply. Similar to other countries, there is a disconnection between price changes upstream and ^{99m}Tc reimbursement. This puts pressure on generator manufacturers in Japan faced with price increases for bulk ^{99}Mo they source abroad, while having to keep stable prices of their generators. Higher prices and insecure supply has resulted in a declining ^{99}Mo/^{99}Tc demand in Japan over the last few years.

Republic of Korea

The Republic of Korea, like Japan, does not have its own ^{99}Mo production capabilities and is dependent on the global market for supply as a price-taker. The country even imports ^{99m}Tc generators. This almost complete dependency on outside sources and a rising domestic ^{99}Mo demand has persuaded the Korean government to build new ^{99}Mo production infrastructure – a reactor and a processing plant. The Republic of Korea is included in this self-assessment report because of its intention to become a major global ^{99}Mo producer once its new infrastructure is commissioned, likely around or after 2020. Current plans are to produce 2 000 six-day Ci/week in a normal week of operation, which is approximately 20% of global demand.

The Korean government is providing financial support for the construction of the new reactor and processing plant, and has indicated that it will operate the reactor. A decision on whether the government or a private company will operate the processing plant has not yet been made. Despite the government's support of the six HLG-MR policy principles and its interest in implementing them in the Republic of Korea, it is doubtful whether this will be done, at least for irradiations. Full-cost recovery would require that the government investment be repaid, which may not happen if the government is also operating the reactor. At the processing stage, should a private company be chosen to operate the ^{99}Mo plant, it would be expected to fully recover its costs. However, with the government operating (and subsidising) the reactor, this would be a very similar situation to the one currently in Canada with AECL and Nordion. Experience with the latter has shown that full-cost recovery and sustainable pricing are not attainable in such a situation.

The Korean government has indicated that it intends to provide outage reserve capacity to the global supply chain, although given the Republic of Korea's geographical location away from most large markets, a realistic approach could be an agreement with another processor(s).

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, operated by the Nuclear Research and consultancy Group (NRG), has normal available capacity to produce 4 680 six-day curies EOP in a normal week of operation, accounting for 47% of global demand. The HFR uses LEU fuel but irradiates HEU targets, which it supplies to two processors, Mallinckrodt and IRE, for the production of bulk ^{99}Mo. Mallinckrodt also manufactures ^{99m}Tc generators. The HFR reactor, along with both IRE and Mallinckrodt, is in the process of converting to use LEU targets, with an expectation of full conversion by 2017.

In the wake of two major outages in 2013, NRG has conducted a thorough cost review of reactor operations. The full costs of ^{99}Mo production are being identified and will be taken into consideration in future contract negotiations with customers, once all ^{99}Mo-related costs are known. NRG expects to implement its full-cost recovery methodology for ^{99}Mo production by early 2015 and eventually recover all costs by 2016 through new/updated contracts with processors. This timeline of implementation is more precise than indicated by NRG in the first self-assessment in 2012, which is an encouraging sign towards the implementation of full cost recovery.

NRG is also responsible for waste management from the extraction and purification of ^{99}Mo that takes place in the Netherlands. It handles short-term storage, monitoring and transportation to the Dutch national organisation that manages radioactive waste – COVRA. For these services, NRG receives compensation, however, does not fully recover its costs. For example, certain waste management support services are not paid for.

Even though the HFR has reserve capacity available, albeit a small amount relative to its total available irradiation capacity, only a portion of the costs are recovered. Much of this reserve capacity is not "true" outage reserve capacity, but results from operational flexibility, i.e. spare capacity when the facility is not used to its full capacity. NRG also receives payments for reserve capacity activation (the variable costs of providing this service). It is negotiating with processors to price reserve capacity, but it is not clear what the outcome will be. The continuing downward pressure on market prices makes it a challenge to convince customers to pay for a service that they do not always see as essential to their operations, even though this service increases supply reliability.

In the long term the HFR is planned to be replaced by a new reactor, PALLAS, which will start irradiating targets for ^{99}Mo production sometime in the 2020s. It is the Dutch government's and NRG's intention that irradiation for ^{99}Mo production at PALLAS is undertaken on a commercial basis. The progress indicators for the two Dutch ^{99}Mo producers, NRG and Mallinckrodt, are presented in the boxes 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 (improvement since 2012)

Comments:

NRG has identified its full ^{99}Mo-specific costs at the HFR reactor and is working on identifying the common costs to be allocated to ^{99}Mo irradiations. NRG plans to implement its full-cost recovery methodology by early 2015 and start recovering its full costs of ^{99}Mo irradiations by 2016. It has been increasing its prices and is communicating the reasons to its customers.

Significant progress has been made since the first self-assessment in 2012.

Outage reserve capacity: Some progress made

Comments:

NRG holds reserve capacity when irradiation positions are not fully utilised by processors (not "true" outage reserve capacity, but operational flexibility). However, this capacity is only partially paid for. To ensure the reliability of supply and comply with the principle of full-cost recovery, NRG needs to negotiate a pricing mechanism for its outage reserve capacity.

No change since 2012.

Further downstream, the Dutch government is not directly involved in setting reimbursement for medical diagnostics and has not taken action to date to examine ^{99m}Tc funding. Reimbursement in the Dutch health care system is on a "per procedure" basis and is done between medical insurance companies and hospitals. This makes it difficult to identify the value of the isotope. Hospitals have some freedom to allocate resources to the different components of a medical diagnostic procedure, including the isotope, based on their negotiated prices with medical insurance companies. These negotiated prices would, in turn, influence hospitals' negotiations with ^{99m}Tc generator manufacturers on prices.

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

Company/organisation name: Mallinckrodt – Netherlands (processor and generator manufacturer)

Full-cost recovery: NO RESPONSE – unable to assess the implementation status of full-cost recovery

Outage reserve capacity: NO RESPONSE – unable to assess 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 of full-cost recovery and outage reserve capacity.

Poland

Poland is a relatively new ^{99}Mo/^{99m}Tc supply chain participant, providing irradiation services since 2010 in its MARIA reactor to Mallinckrodt in the Netherlands. The reactor has been recently converted to LEU fuel. It uses HEU targets to produce approximately 1 500 six-day curies EOP in a normal week of operation, which is 15% of global demand. The reactor operator, the National Centre for Nuclear Research (NBCJ), is working to increase the reactor capacity for ^{99}Mo irradiations to 2 200 six-day Ci/week from January 2015 (22% of global demand).

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 has considered applying full-cost recovery for irradiation services at the MARIA reactor, however, no concrete action has been taken yet. Some government funding is received for target irradiations. 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.

Some progress since the first self-assessment in 2012 - more discussion about full-cost recovery, but no actions yet. However, NCBJ is taking actions to increase its commercial orientation for ^{99}Mo production, such as seeking private funds for a new processing plant.

Outage reserve capacity: Not started

Comments:

The MARIA reactor has significant capacity to hold as outage reserve capacity, however, it receives no payment for it.

No change since 2012.

Although the Polish government does not provide specific financial support to NBCJ for ^{99}Mo irradiation services, it provides funds covering part of the spending related to reactor safety and supporting infrastructure. In general, more than one-half of NCBJ's income is derived from commercial activities (including radioisotope production), and the profits are partially used to support research activities. NCBJ has discussed applying full-cost recovery with the Polish government, but no concrete action has been taken so far.

MARIA has the ability to hold outage reserve capacity, however, it is not being contractually provided or paid for at the moment.

There are plans to build a new processing plant for bulk ^{99}Mo in Poland, with a capacity of 1 000 six-day Ci/week, and commission it before the end of the decade. NCBJ is currently working to secure a commercial loan for the new facility, which shows its efforts to increase ^{99}Mo production on commercial terms. NCBJ's progress indicators on full-cost recovery and outage reserve capacity are shown in the box above.

Reimbursement for nuclear medicine procedures in Poland is negotiated annually between hospitals and the National Health Fund. For ^{99m}Tc-related diagnostics, reimbursement covers the entire procedure without a separation of the isotope or radiopharmaceutical. The Polish government indicates that it is possible to implement full-cost recovery at the end-user level in the country, but it is unlikely to happen before 2016, assuming appropriate adjustment to reimbursement amounts as estimated in *An Economic Study of the Molybdenum-99 Supply Chain* (NEA, 2010).

Russian Federation

The Russian Federation is aiming to become a major global ^{99}Mo/^{99m}Tc supplier at all levels. Although it produces only small amounts of ^{99}Mo at present (in three reactors), it is aiming to achieve production of up to 1 300 six-day curies EOP in the next few years. This would be equivalent to 13% of 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 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.

Target irradiation and processing takes places at two production sites – the Research Institute of Atomic Reactors (RIAR) and the Karpov Institute of Physical Chemistry (IPC). The latter also manufactures ^{99m}Tc generators. Current Russian ^{99}Mo production is directed at the domestic market, with small amounts also exported.

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

Company/organisation names: RIAR – Russian Federation (irradiator and processor) and Karpov IPC – Russian Federation (irradiator, processor and generator manufacturer)

Full-cost recovery: Unable to determine progress

Comments:

RIAR is in the process of ramping up production to full capacity and is developing a cost recovery methodology. However, it is not clear what costs will be included in this methodology. RIAR indicates that it does not receive government support for ^{99}Mo production. Karpov IPC applies its own full-cost recovery methodology for irradiations, processing and generator manufacturing. It is unclear, however, to what extent it is similar to the agreed HLG-MR methodology. Hence, the NEA is unable to determine at this time the progress made by Karpov IPC in implementing full-cost recovery.

Outage reserve capacity: Not started at RIAR and partially implemented at Karpov IPC

Comments:

The reactor at Karpov IPC does not hold outage reserve capacity for other ^{99}Mo producers. In case of an unplanned outage, its lost ^{99}Mo production is compensated by production at RIAR. However, it is unclear whether RIAR receives payment for the ^{99}Mo provided to Karpov IPC. RIAR itself does not hold ORC in its two reactors.

Russian ^{99}Mo producers are mostly funded 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.

South Africa

South Africa is a significant participant in the global ^{99}Mo/^{99m}Tc supply chain as an irradiator and processor. The South African Nuclear Energy Corporation (NECSA) operates the SAFARI reactor and NTP Radioisotopes (NTP), a subsidiary of NECSA, produces bulk ^{99}Mo from targets irradiated at SAFARI. The reactor uses LEU fuel and is advanced in the process of converting to the use of LEU targets (expected by the end of 2014, pending health approvals for its customers) for ^{99}Mo production. In a typical week of operation, it produces 2 500 six-day curies, which accounts for 25% of global demand.

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

Comments:

NECSA has implemented a full-cost methodology and applied it to the price they charge for irradiation services, resulting in the price increasing when costs increase. NTP has implemented full-cost recovery itself, including capital and waste management costs. NECSA also includes decommissioning and decontamination costs in its full-cost methodology.

No change since the first self-assessment in 2012.

Outage reserve capacity: Partially implemented

Comments:

NECSA provides outage reserve capacity and charges normal irradiation rates for its availability, based on its full-cost recovery methodology. However, it appears that NECSA charges its customer only when outage reserve capacity is activated and not for maintaining it during normal reactor operational times.

No change since 2012.

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

Full-cost recovery: Fully implemented

Comments:

NTP's supplier of irradiation services has implemented a full-cost methodology and applied it to the price they charge. NTP has accepted this action and applied full-cost recovery itself, including capital and waste management costs. However, it faces strong price competition for its bulk ^{99}Mo from other processors who have not implemented full-cost recovery yet. This has led to lower prices creating the need to absorb some of the additional costs internally.

No change since the first self-assessment in 2012.

Outage reserve capacity: Fully implemented

Comments:

NTP has back-up 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.

No change since 2012.

Both NECSA and NTP have implemented a full-cost recovery methodology and operate the reactor and processing plant on a commercial basis. They receive no financial support from the South African government for ^{99}Mo-related activities. In addition, NTP has agreements with other processors in the global supply chain to provide outage reserve capacity (giving it access to other reactors), which is paid for on commercial terms, while SAFARI-I also maintains such capacity.

Spain

Spain is a downstream participant in the ^{99}Mo/^{99m}Tc supply chain, primarily as a consumer of ^{99m}Tc. Following the 2009-2010 global supply shortage, the Spanish commission in charge of pricing decisions regarding ^{99m}Tc use agreed to allow a significant increase in the price of generators marketed in the country. Another similar increase has been approved since, reflecting Spain's commitment to a reliable supply by contributing to the implementation of full-cost recovery in the global supply chain. At the end-user level, no actions have been taken to date to examine the sufficiency of ^{99m}Tc-related reimbursement or to separate the price of the isotope from that of the radiopharmaceutical or the medical diagnostic procedure.

United Kingdom

The United Kingdom 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 the generator manufacturers operating in the United Kingdom are all commercial entities, this report assumes that they are already operating on the basis of full-cost recovery with a profit margin. There is a concern, however, that isotope reimbursement needs to be revisited by the government and that it may not be sufficient if bulk ^{99}Mo prices increase in the future.

In the United Kingdom, health care funding (including for radioisotope reimbursement) is managed through local Health Trusts. Hospital nuclear medicine departments are responsible for purchasing radiopharmaceuticals from in-house or central radiopharmacies. Hospitals or regional procurement hubs manage the purchasing of ^{99m}Tc generators. The isotope is not separately reimbursed from the radiopharmaceutical.

Compared to the first self-assessment in 2012, there is a greater awareness in the United Kingdom of ^{99}Mo/^{99m}Tc security of supply issues, including the need for price increases throughout the supply chain for long-term market sustainability. In response to uncertainty about reliable supply, end-users in the United Kingdom have implemented a number of measures to increase the efficiency of ^{99m}Tc use, such as more ^{99m}Tc elutions per generator, procurement of smaller generators, higher use of alternative modalities, and others.

United States

The United States is the largest consumer of ^{99m}Tc, accounting for approximately one-half of global demand, but without domestic ^{99}Mo production capacity. The United States is currently involved in 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 United States is developing its own domestic capacity for ^{99}Mo production using non-HEU, both reactor- and non-reactor-based technologies. The US government has supported four potential new ^{99}Mo producers, on a cost-share basis, two of whom continue to advance their projects. Should these two projects come to fruition, their combined production capacity could meet the entire US demand for ^{99}Mo. There are also other ventures that may develop the capability to produce ^{99}Mo in the United States without government support.

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, including providing financial support to existing ^{99}Mo/^{99m}Tc producers to convert from the use of HEU targets to LEU targets. With no direct influence on the supply side (as there is currently no 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 to domestic projects. The US government has examined the feasibility of a separate payment for the isotope from the radiopharmaceutical and the diagnostic procedure, but has determined that a single payment mechanism is not feasible across the hundreds of payer systems and that an interim differential payment partially tied to full-cost recovery is the appropriate payment policy change to promote a sustainable supply within the US system at this time. To this effect, the Center for Medicare and Medicaid Services (CMS), the public agency that is responsible for reimbursement under the Medicare and Medicaid programmes, has implemented a separate payment to hospitals that utilise at least 95% non-HEU ^{99m}Tc in nuclear medicine procedures.

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 and outage reserve capacity, and the degree of support by governments for ^{99}Mo production since the first self-assessment in 2012. 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. This 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". "No subsidy" includes cases where a government provides support (e.g. through a loan) that is required to be repaid over time.

Figures 6.1 and 6.2 present the progress made by reactors on full-cost recovery and outage reserve capacity in the two-year period since the first self-assessment. Twelve reactor operators (including all nine currently producing reactors in the global supply chain) participated in the self-assessment, but the FRM-II reactor in Germany and the reactors at the Research Institute for Atmoic Reactors (RIAR) and the Karpov Institute of Physical Chemistry (IPC) 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 2017-18. The reactors at RIAR and the Karpov IPC irradiates primarily for the domestic market.

Figure 6.1. Full-cost recovery implementation, producing reactors, 2012 and 2014

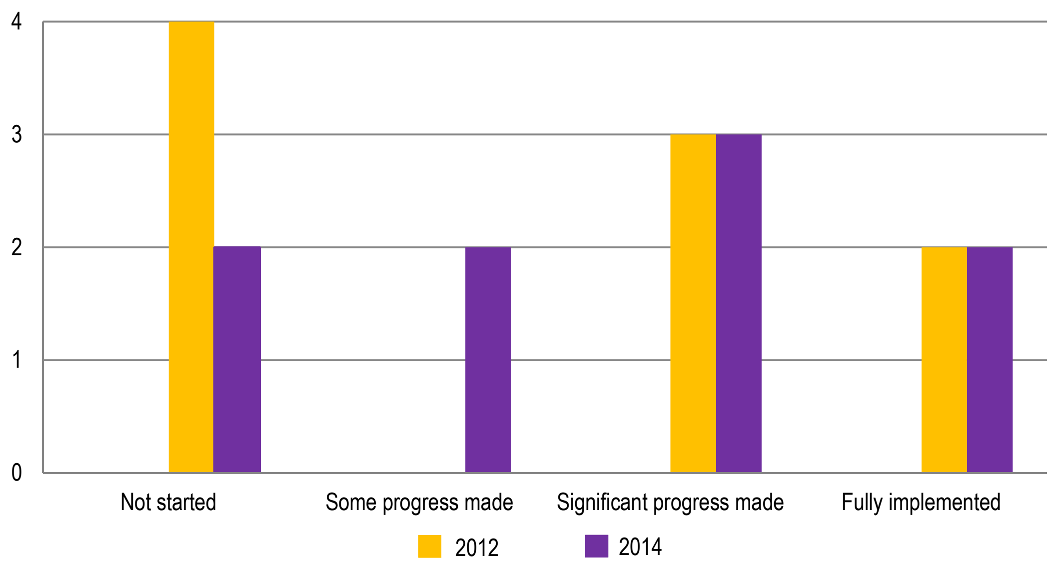
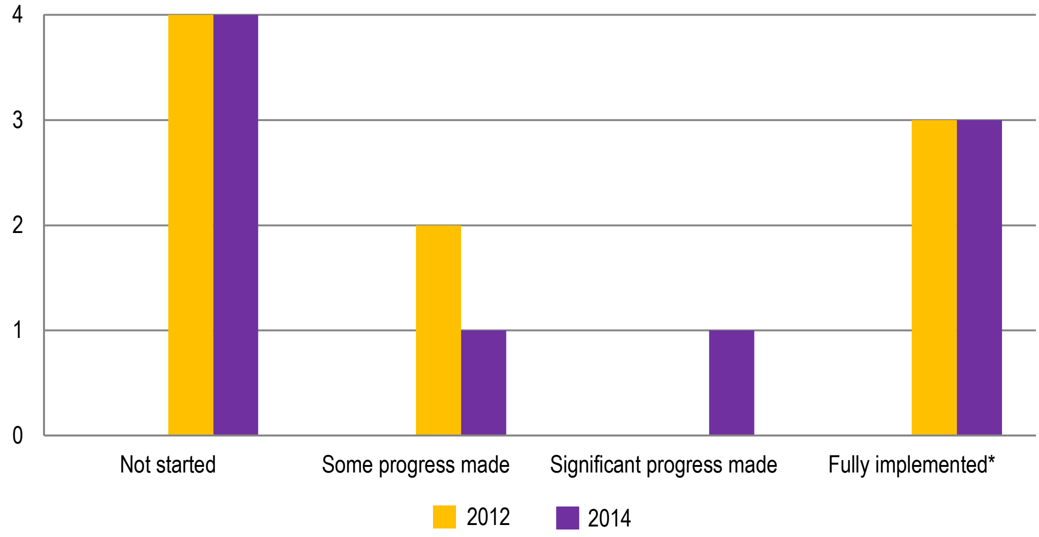


Figure 6.2. Outage reserve capacity implementation, producing reactors, 2012 and 2014



* "Fully implemented" means that these reactors have indicated that they hold outage reserve capacity and receive 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, compared with the first self-assessment. Russian production is not included, as it is intended primarily for the domestic market and does not significantly impact the global supply chain at present.

Figure 6.3. Full-cost recovery implementation, processors, 2012 and 2014

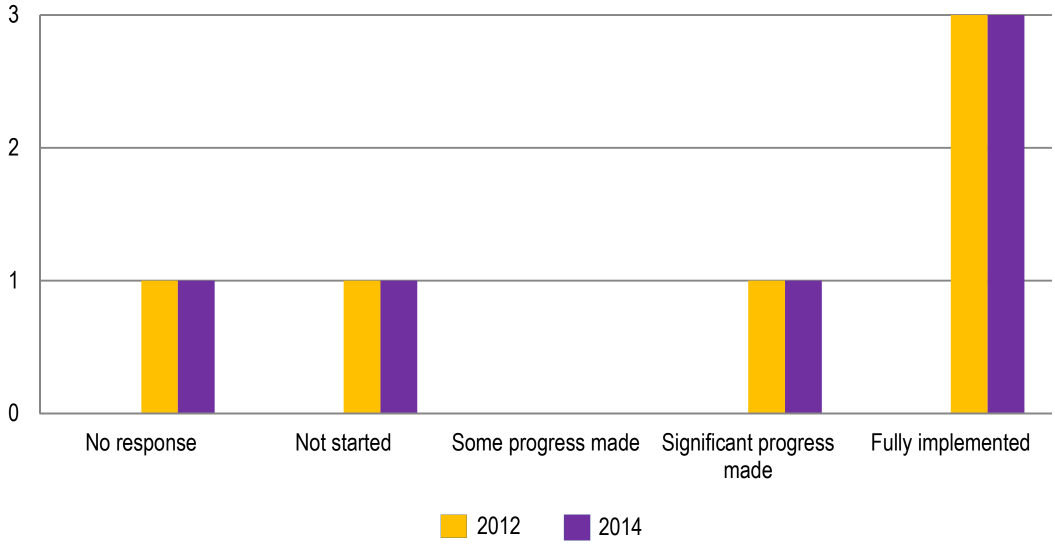
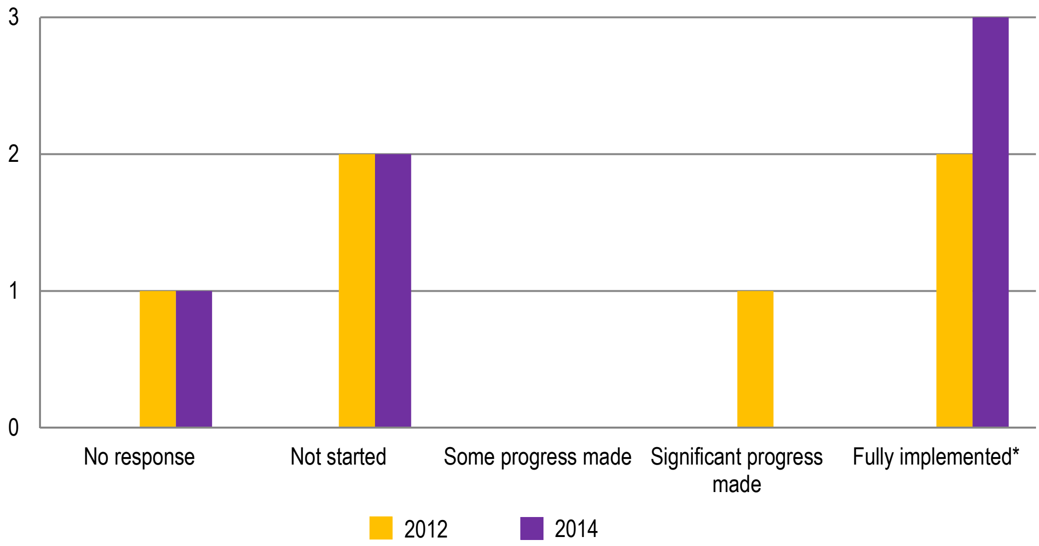


Figure 6.4. Outage reserve capacity implementation, processors



* "Fully implemented" means that these processors have indicated that they hold outage reserve capacity and make adequate payment for it.

Figure 6.5 depicts the 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. As both figures show, there has been no change in government commitment for reactor-based ^{99}Mo production between 2012 and 2014.

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

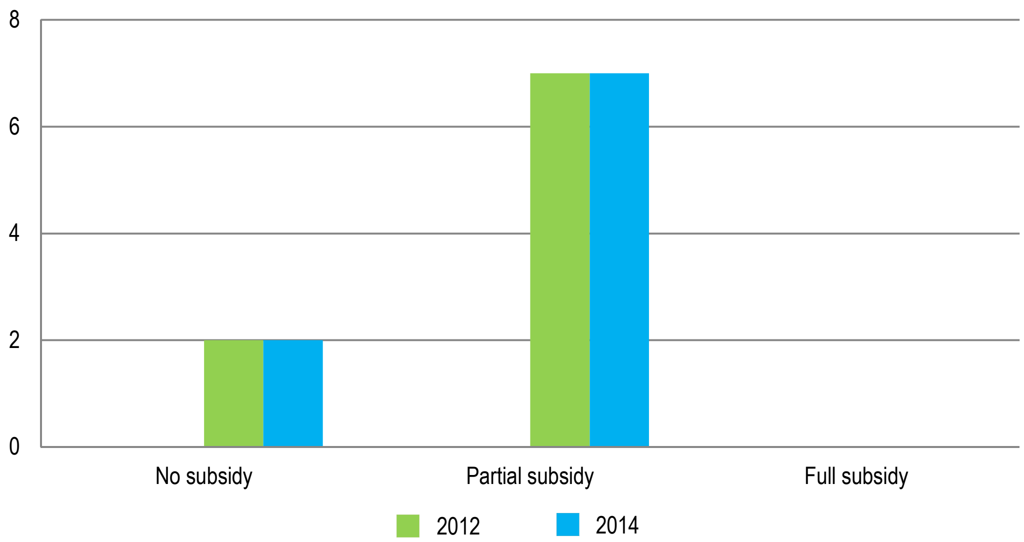
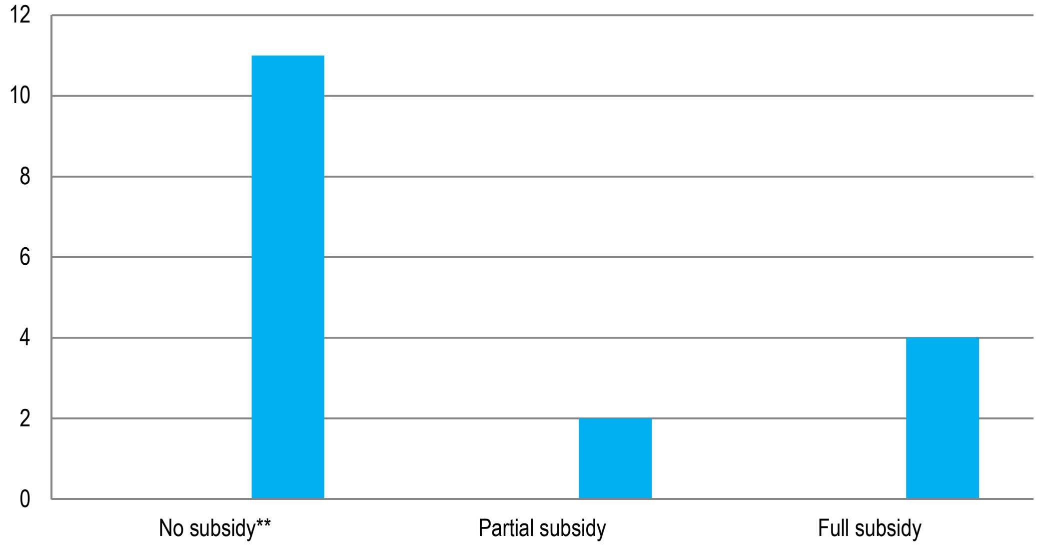


Figure 6.6. Intended government support for ^{99}Mo/^{99m}Tc production, projects under development, 2014*



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

** May include government loans or other support to be paid back by the reactor operator.

Chapter 7. Conclusions

This self-assessment is the second 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 are similar to those from the first self-assessment, showing slower-than-desired progress towards implementing the six HLG-MR policy principles, which has led to missing the deadline of June 2014 for full implementation, agreed by the governments represented on the HLG-MR. With the exception of Principles 5 and 6, governments and supply chain participants have not taken sufficient action and the ^{99}Mo/^{99m}Tc market continues to be unsustainable. At the same time, producers report increasing prices at each level of the supply chain, while many end-users have been able to absorb these increases. This suggests a move in the right direction by supply chain participants. Issues remain, however. For example, despite higher irradiation prices, it is not clear whether reactor operators are using the additional revenues to re-invest in their ^{99}Mo-related operations, which would increase global supply reliability. Some supply chain participants report that the price increases by their suppliers are partly due to moving towards full-cost recovery, but it is difficult to estimate that portion of the price increase.

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. The work of the HLG-MR and its stakeholders has contributed much 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. To date, voluntary commitments have not resulted in sufficiently effective actions towards implementing the HLG-MR policy approach and there is a need for governments to take more direct action. This conclusion was also made in the first self-assessment report, which underlines that work remains to be done to help the market become sustainable.

A repeated argument by supply chain participants is that the market cannot absorb the necessary price increases for full-cost recovery and outage reserve capacity. Despite ^{99}Mo producers' best intentions, many of them are deterred in implementing the policy principles by below-full-cost-recovery prices prevailing in the market, which perpetuates the current situation and does not bode well for the future. From an economic point of view, one of two things must happen to achieve market sustainability and ensure secure supply of ^{99}Mo/^{99m}Tc – a collective, voluntary move by industry to adopt the principles agreed by the HLG-MR or direct action by governments to move the market in the desired direction. The former is preferable, as articulated in Principle 3, but has clearly not happened to a sufficient degree since the 2009-2010 supply crisis.

The supply shortages in late 2013 that occurred as a result of the simultaneous outage of the HFR reactor, the Petten processing plant, and NTP's processing plant, albeit small and isolated, demonstrated again the continued fragility of the supply chain. Only the effective, co-operative action taken by producers within AIPES and additional outage reserve capacity in the market prevented more widespread and longer shortages.

However, the short-term outlook for supply is not favourable. The planned permanent shutdown of OSIRIS at the end of 2015 and the NRU (for ^{99}Mo production) in 2016 will make the global supply situation more uncertain, with less available production capacity. There is an elevated risk of shortages in the 2015-2017 period, as shown in *Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ^{99}Mo/^{99}Tc Market, 2015-2020* (NEA, 2014), although timely and coordinated actions by the supply chain could minimise this risk.

A sustainable ^{99}Mo/^{99m}Tc market will likely be based on a network of research reactors in the foreseeable future. Despite the promise of alternative ^{99}Mo/^{99m}Tc production technologies, such as linear accelerators and cyclotrons, whether they will be widely deployed on a commercial basis remains to be seen. Given the current reliance on ageing reactors for most of the global ^{99}Mo supply, plans for their replacement or building new reactors are important developments for ensuring the security of supply. However, this new/replacement capacity must be based on full-cost recovery to avoid over-capacity in the market, which can only act to drive down prices to levels at which some producers may be forced to exit the market. Furthermore, governments should refrain from taking actions such as using reserve auctions to push down the price of ^{99}Mo, favouring producers who can use subsidised reactors. This exacerbates the problem of below-full-cost-recovery prices and diminishes confidence in the future sustainability of the market.

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, forcing them to extend their timelines for full conversion. As the LEU conversion process is an externality, government support for these supply chain participants (e.g. through financial incentives) would be consistent with the HLG-MR principles. However, the American and Belgian governments are the only governments that have taken concrete action to date, recognising the importance of LEU conversion. The lack of government financial support for LEU conversion has resulted in higher costs for some ^{99}Mo producers and may have contributed, along with technical challenges, to their delay in not only converting but also implementing full-cost recovery, given the existing downward price pressures in the market.

Much of the experience since the 2009-2010 supply crisis has shown that short-term commercial considerations (e.g. increasing or retaining market share) continue to trump long-term sustainability, resulting in unhealthy competition and inefficient market outcomes. Furthermore, some governments are still subsidising ^{99}Mo production, despite their commitment to the HLG-MR principles. This sends negative signals to potential investors in future commercially based production and jeopardises the long-term security of supply by potentially perpetuating below-full-cost-recovery prices and creating undesirable additional capacity. More broadly, governments should redefine the "social contract" with the medical isotope industry and help it move to sustainability, through appropriate incentives and effective regulation. Clearly, voluntary actions to date by HLG-MR supply chain participants have been insufficient to secure ^{99}Mo/^{99m}Tc supply and it may be time for more direct action by HLG-MR governments.

References

NEA (2014) "Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ^{99}Mo/^{99}Tc Market, 2015-2020", OECD, Paris.

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

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

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

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

NEA (2010), *An Economic Study of the Molybdenum-99 Supply Chain*, OECD, Paris.

Annex 1. 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 downward pressure on prices and a slowing down of full-cost recovery implementation.

Economic loss and reduced competitiveness due to delays in the implementation of full-cost recovery

There is concern about some producers delaying full-cost recovery implementation, while the lack of a legally binding mechanism to ensure that everybody participates in this process is a reason given for these delays. A related concern is the opacity of ^{99}Mo production costs in the supply chain, which makes it challenging to ensure that producers are indeed working towards full-cost recovery implementation. Furthermore, it is asserted that the success of the full-cost recovery and the other principles depends on their timely and consistent implementation by the entire supply chain to minimise the economic loss to early implementers.

Concern that higher revenues at reactors are not re-invested to support more reliable ^{99}Mo supply

Most reactor operators have significantly increased their prices for ^{99}Mo irradiations in the last few years, yet it is not clear that the resulting higher revenues are earmarked for capital or operational improvements. Reactor operators need to be more transparent on how they use their ^{99}Mo revenues to increase confidence in the rest of the supply chain that they are making their operations more reliable. Improving ^{99}Mo/^{99m}Tc supply reliability clearly involves supporting future new/replacement production infrastructure or refurbishments from current ^{99}Mo sales.

Little progress on outage reserve capacity

Although the process of implementing outage reserve capacity is underway, it is far from complete. There are reactors and processors that continue to under-value and under-pay for this capacity (in some cases, not pay at all for it), which helps keep ^{99}Mo prices artificially low. In addition, outage reserve capacity is sometimes used as normal available capacity at reactors, which reduces supply reliability in cases of unplanned outages, as there is less remaining 'true' outage reserve capacity.

Full-cost recovery and reduced demand for ^{99m}Tc

Higher prices throughout the supply chain, as a result of implementing full-cost recovery, may cause a shift towards non-^{99m}Tc-based radiopharmaceuticals by hospitals and physicians. Non-increasing reimbursement rates for ^{99m}Tc compared to increasing reimbursement rates for other radiopharmaceuticals may also contribute to the same outcome. A related concern is the disconnection between price changes upstream and ^{99m}Tc reimbursement policies, which makes it difficult to achieve full-cost recovery at the end-user level.

Concerns that non-full-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 2. Self-assessment questionnaire – governments (ministries/departments responsible for reactors)

1. Do you provide financial support (directly or indirectly) to a reactor or alternative technology operator that is part of the global ^{99}Mo/^{99m}Tc supply chain? If so, what is that support used for?
2. Are you taking actions to phase out this support? If so, when do you anticipate to completely phase out this support? Please, indicate a year if possible.
3. Do you provide financial support (directly or indirectly) to a processor that is part of the global ^{99}Mo/^{99m}Tc supply chain? If so, what is that support used for?
4. Are you taking actions to phase out this support? If so, when do you anticipate to completely phase out this support? Please, indicate a year if possible.
5. Who is responsible for managing ^{99}Mo-related waste in your jurisdiction?
6. Do you provide funding for any or all stages of the ^{99}Mo-related waste management process? Are there other organisations that provide funding? Please, describe.
7. 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.
8. Are there any barriers to the implementation of full-cost recovery for ^{99}Mo irradiation and/or processing in your jurisdiction? If so, please describe.
9. If there are ^{99}Mo irradiation and/or processing facilities in your jurisdiction that use HEU targets, are these facilities taking actions to fully convert to LEU targets? If so, please indicate the anticipated year of full conversion.
10. Are there any barriers to conversion to the use of low-enriched uranium (LEU targets)? If so, please describe.
11. Do you provide any financial support (directly or indirectly) to a ^{99}Mo irradiation and/or processing facility to convert to LEU targets? If so, what is that support used for? Please, describe.
12. With your experience and your observations of the supply chain, are there any aspects of the HLG-MR 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 as to why the aspect should be revisited, and your suggested reform, if possible.
13. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy principles?
14. Would you like the NEA to call you to discuss any of your responses in more detail?

Annex 3. Self-assessment questionnaire – governments (ministries/departments responsible for health)

1. Please, describe your policy/guidelines for funding of ^{99m}Tc-related medical procedures.
2. Have you undertaken any actions to examine the sufficiency of ^{99m}Tc-related health care funding (e.g. reimbursement rates or isotope budgets) in your jurisdiction, recognising the need for ^{99}Mo irradiation service providers to move to full-cost recovery? If so, please describe.
3. Have you taken any actions to identify methods to provide transparency in relation to the various component prices of ^{99m}Tc-related medical procedures (e.g. the price of the isotope, the radiopharmaceutical product, and the diagnostic imaging procedure)? If so, please describe.
4. With your experience and your observations of the supply chain, are there any aspects of the HLG-MR 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.
5. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy principles?
6. Would you like the NEA to call you to discuss any of your responses in more detail?

Annex 4. Self-assessment questionnaire – irradiators

1. 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.
2. 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(s) for all services? What is the range of waste management services provided (e.g. local short-term storage, interim storage, or final disposition)?
3. 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?
4. Capital Investments
   a. Have you incurred any capital costs over the last two years (ending December 2013)?
   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?
5. Have you increased your prices for providing ^{99}Mo-related services over the last two years (ending December 2013)? 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?
6. 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?
7. If you have faced barriers to implementing full-cost recovery, could you please describe those barriers?
8. 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.
9. Do you provide outage reserve capacity (ORC) to the supply chain? Please describe.
10. Does your pricing of ORC cover the full costs (fixed and variable) of provision of that service? Are your costs covered when required to use that ORC?
11. What has been the response of processors to paying for ORC?

12. With your experience and your observations of the supply chain, are there any aspects of the HLG-MR 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.
13. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy approach?
14. Would you like the NEA to call you to discuss any of your responses in more detail?

Annex 5. Self-assessment questionnaire – processors

1. Price increases:
   a. Have your suppliers of irradiation services increased their prices over the last two years (ending December 2013)?
   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 major or minor? A major price increase is considered to be an increase by at least 20% 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 these increases? If so, can you please describe the reasons?
   b. 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 price increases internally?
   c. If you have not been able to pass through the price increases, what has been the barrier(s)?
   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 December 2013)?
4. Additional sources of funding:
   a. Could you, please describe your financial obligations for the management of waste 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 organisation(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. 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.
6. Please describe how you source outage reserve capacity (ORC)? 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? Do they charge you for their fixed costs of holding ORC and/or the variable costs of using this capacity?
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. With your experience and your observations of the supply chain, are there any aspects of the HLG-MR 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.
13. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy approach?
14. Would you like the NEA to call you to discuss any of your responses in more detail?

Annex 6. Self-assessment questionnaire – generator manufacturers

1. Price increases:
   a. Have your suppliers of bulk ^{99}Mo increased their prices over the last two years (ending December 2013)?
   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 major or minor? A major price increase is considered to be an increase by at least 30% 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 expire?
2. Reasons for price increases:
   a. If you have seen price increases, have you received appropriate information on the reasons for them?
   b. If so, can you please describe these 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? If so, please describe.
3. Barriers to accommodation:
   a. If you have been faced with price increases, have you been able to pass these increases through to your customers?
   b. Have you had to absorb some of the bulk ^{99}Mo price increases internally?
   c. If you have not been able to pass through your cost increases, what has been the barrier(s)?
   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 December 2013)? In this context a significant price increase is considered to be an increase by 25% or more to be in line with what is required for full cost recovery.
4. Do you have confidence that the processors in your supply chain source outage reserve capacity (ORC)? Please provide any details on why you have that confidence. For example, have you been provided information on the back-up capacity that your providers have sourced?
5. Are you required to pay a separate fee or premium related to supporting ORC? Please describe.
6. Is your company routinely providing the market with an advance notice of anticipated availability of generator supply? If so, how far in advance is this notice?

7. 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)?
8. With your experience and your observations of the supply chain, are there any aspects of the HLG-MR 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.
9. Is there any additional information that you would like to add regarding your own actions to implement the HLG-MR policy approach?
10. Would you like the NEA to call you to discuss any of your responses in more detail?