Nuclear Development
NEA/SEN/HLGMR(2017)5
December 2017
www.oecd-nea.org

The Supply of Medical Radioisotopes

Results from the Third Self-assessment of the Global Mo-99/Tc-99m Supply Chain

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Acknowledgements

This report would not have been possible without the contributions of a significant number of supply chain participants, including major irradiators, major processors, generator manufacturers and government stakeholders.

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

The report was written by Mr Kevin Charlton of the NEA Division of Nuclear Development. The High-level Group on the security of supply of Medical Radioisotopes (HLG-MR) provided detailed review, comments and advice.

Disclaimer:

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

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^{99}Mo	Molybdenum-99
^{99m}Tc	Technetium-99m
EOP	End of processing
FCR	Full-cost recovery
HEU	High-enriched uranium
LEU	Low-enriched uranium
ORC	Outage reserve capacity

Executive summary

This self-assessment is the third review of the implementation of the Nuclear Energy Agency (NEA) High-level Group on the security of supply of Medical Radioisotopes (HLG-MR) policy principles by the supply chain and governments. It is based on information supplied by a wide variety of stakeholders and the NEA appreciates the willingness of the majority of stakeholders to provide useful information.

The overall results are similar to those from the first and second self-assessments, showing continued but slow progress towards implementing the six HLG-MR policy principles and in particular, principles 1 and 2 – full-cost recovery (FCR) and outage reserve capacity (ORC). Much of the experience since the medical isotope supply crisis period of 2009-2010 has shown that short-term commercial considerations (e.g. increasing or retaining market share) continue to be valued above long-term sustainability, resulting in unhealthy competition and inefficient market outcomes.

The governments represented on the HLG-MR originally agreed to a deadline of June 2014 for full implementation of the policy principles, and that deadline was missed. Following the second self-assessment report made in 2014, it was agreed that voluntary commitments had not resulted in sufficiently effective actions being taken towards implementing the policy approach and it was proposed that governments take more direct action.

The action chosen was to prepare a Joint Declaration recognising that an unsustainable economic structure threatened the reliability of the ^{99}Mo/^{99m}Tc supply chain, and that global action to move to FCR was necessary to ensure the economic sustainability necessary for the long-term secure supply of medical isotopes. The Joint Declaration provided a co-ordinated political commitment by countries involved in the production and use of medical radioisotopes to help bring about the necessary changes across the whole supply chain in a timely and effective manner. The Joint Declaration was made on 17 December 2014 with the formal adherence of 11 countries and with the adherence of a further three countries during early 2015. The Joint Declaration signatories are Australia, Belgium, Canada, France, Germany, Japan, Korea, the Netherlands, Poland, the Russian Federation, South Africa, Spain, the United Kingdom and the United States.

In the period since the second self-assessment, the supply chain has faced a number of important challenges to irradiation and processing capacity. The OSIRIS reactor, which had a weekly irradiation capacity equivalent to 27% of weekly world demand, ended operation in late 2015; the irradiation and processing capacity equivalent to 52% of weekly world demand derived from the National Research Universal (NRU) reactor in Canada moved to a "hot standby" mode from October 2016; the BR-2 reactor which has the highest weekly irradiation capacity of any reactor, had an extended planned maintenance period from mid-2015 until mid-2016.

Despite these challenges, supply was successfully maintained during the whole period. This was achieved by combining stepwise increases in baseload capacity at a number of points in the existing supply chain and with detailed planning of operating schedules and outage periods at individual facilities. This planning was successfully co-ordinated through the Association of Isotope Producers and Equipment Suppliers (AIPES) Reactor and Isotope Working Group. Successful supply performance, during an extended period of identified challenges, demonstrates some of the progress that has been made by the supply chain. The third self-assessment has demonstrated that supply chain participants recognise the need to fully implement FCR and also to hold sufficient ORC in order to ensure security of supply. They also recognise that this ORC must be paid for by the whole supply chain to ensure its availability and readiness.

However, progress towards full implementation of FCR has been hampered in a number of ways. In the third self-assessment, all steps in the supply chain reported a substantial increase in base costs associated with operating their businesses; these were at levels well above inflation. Some increases came from the direct effect of FCR implementation higher up the supply chain. There were also important increases to costs for other reasons; in particular, improvements to the resilience of facilities to natural events (post Fukushima) and increases in physical and other security measures (in response to terrorist risks). These together with the continued move towards the use of low-enriched uranium (LEU) targets for production, an externality that adds costs, reduces process efficiency and increases waste, have increased the total cost burden on the supply chain.

Most supply chain participants have reported that important price increases have been achieved for their final products, but that the substantial cost increases experienced reduced the effective rate of progress made towards achieving FCR. An exception has been reported at the generator manufacturer step of the supply chain, where a number of manufactures have been able to make only limited, or in some cases, no price increases during the whole period from 2012 to end 2015. Most generator manufacturers reported substantial cost increases, but clear divergence was seen between generator manufacturers that could achieve important price increases and those that could not. The inability of some generator manufacturers to increase price in some markets reflects the continued high level of competition in some markets; but perhaps more importantly, it reflects important markets where there has been little or no change in the levels of reimbursement for multiple years for the medical isotope component of nuclear imaging procedures.

The development of this report has been long and painstaking and was hampered by a slow response rate to the self-assessment questionnaires. The NEA advised that a self-assessment report would only be worthwhile if there was a substantial level of response from stakeholders. This was discussed in detail with HLG-MR participants during both HLG-MR meetings held in 2016 and commitment was finally made to provide the level of information requested. Some targets were agreed for minimum acceptable response levels and eventually those targets were met for all self-assessment categories, with the exception of government healthcare responses, which remained below the agreed threshold. The slow and limited response from government healthcare is a clear indication of insufficient engagement from that group of stakeholders. The responses that were received from government healthcare frequently identified that the sufficiency of reimbursement for medical isotopes in their country had not, or could not be assessed. Only a limited number of countries were able to report that they had made positive steps towards analysing and then providing support to the market through adjusting healthcare policy and reimbursement arrangements, suggesting that lessons can be learnt from best practice in this area.

The supply chain has worked well to successfully manage supply despite a net reduction in total production capacity at both the irradiator level and the processor level. FCR has not yet been fully implemented because backpressure (e.g. a refusal to accept higher prices) within the supply chain continues to block the level of price increase needed to achieve FCR. At this time, the backpressure effect is particularly focused at the generator manufacturer level of the supply chain, where input costs are increasing, but the ability to pass on those costs is often blocked by a combination of competitive pressure and intransigence towards reimbursement policy. The generator manufacturers naturally transfer the effect of that blockage back up the supply chain by resisting price change.

The coverage and level of paid ORC in the supply chain has increased, but some participants still do not receive full, or in cases, any ORC payments; this is despite those same participants being called upon to provide back-up services. The need for fully paid ORC is nearly universally recognised by the market participants, but application is neither consistent nor universal. When the need and value of ORC is not correctly recognised, then that holding of reserve capacity is unrewarded. When holding reserve capacity is unrewarded, it is at risk of being viewed as being excess capacity with resulting negative market feedback effects.

It seems remarkable that unpaid excess capacity can exist within a market that is viewed by many stakeholders as being at risk of supply default and where the whole industry is expected by stakeholders to collaborate on detailed planning and scheduling efforts. Stakeholders also expect the market participants to quickly take emergency response actions to mitigate anticipated supply risks at their own cost. There is a reasonable expectation from the healthcare community and their patients for the continuous availability of medical imaging agents. However, this can only be assured by reaching an economically sustainable market structure that holds adequate levels of paid ORC that is being fully funded by reimbursement.

As FCR has not yet been achieved, it remains necessary for some individual governments to continue to provide support to supply chain organisations that are essentially underfunded. Some governments continue to take this burden of support from a perceived obligation to maintain security of supply and to ensure that it is done in a safe and secure way. It is not done from a desire to subsidise healthcare in other countries, which is the unintended outcome. The market remains economically unsustainable; progress towards FCR implementation continues and governments are reducing and removing direct support to the supply chain where possible, but implementation of a hard time point for ending that support has not been a practical option, as it would have led directly to organisational failures and supply disruption. It is essential that all supply chain participants continue to press on towards achieving FCR implementation as quickly as possible, but this will only be achievable when some of the backpressure present in the commercial supply chain is reduced by governments taking steps to adjust healthcare policy.

The data collected in this self-assessment indicates that there is still some way to go to achieve FCR implementation. However, the data also identifies that the total increase necessary to stabilise supply is low compared to the total cost and the value of the medical procedures that depend upon them. While the HLG-MR six policy principles remain unfulfilled, particularly while FCR is not fully implemented and some ORC provision remains unpaid, the world supply of $^{99}Mo/^{99m}Tc$ will remain economically unsustainable. In the short term, supply remains dependent upon the goodwill of a limited number of governments that feel obliged to support the financial shortfall. This is risky for all stakeholders, as that goodwill may be lost at any time and many of the present production facilities are quite old, requiring regular investment in maintenance.

Supply has been stabilised by the actions of existing supply chain participants and the continued support of some governments. Many of the technical problems that led to the 2009-2010 supply crisis period have been solved and alternative technologies have demonstrated their ability to successfully produce $^{99}Mo/^{99m}Tc$. However, those technologies have yet to be successfully brought to market and project delays have been frequent. The market remains economically unsustainable, so new supply projects, whether conventional or using alternative technologies, risk further delay or cancellation due to the prevailing negative economic conditions.

In a normal functioning market, there is a critical price level beneath which no commercially operating organisation would normally go. The market for the supply of $^{99}Mo/^{99m}Tc$ continues to operate substantially below such a critical price level. Indeed, the market has never experienced a sustained period when it has operated above it. For the

^{99}Mo/^{99m}Tc market to become sustainable, market pricing must rise above this critical price level at all points in the supply chain and be able to stay above it. Once that situation has been reached and stabilised, the market will have the opportunity to then function properly under normal market constraints.

Despite delays and some project cancellations, there remains a substantial list of potential new supply projects. It is arguable that the successful deployment of all the known projects would result in a significant level of overcapacity, a level well above the likely medium-term market demand. The successful deployment of some additional capacity is essential to replace aging infrastructure, but the market remains economically unsustainable and on some "life support". The market must complete the transition to an economically sustainable model, either by achieving FCR implementation, or by the successful introduction of new capacity that has a substantially lower unit cost base.

The work of the HLG-MR, its stakeholders and the supply chain has contributed much towards addressing and overcoming the challenges. However, much still remains to be done globally to secure the supply of medical radioisotopes in the long term. The remaining government support for ^{99}Mo production must end and appropriate reimbursement rates for medical isotopes must be ensured. Voluntary commitments even following the Joint Declaration have not resulted in sufficiently effective actions towards implementing the HLG-MR policy approach and there is a need for governments to take further direct action. More broadly, governments should redefine the "social contract" with the medical isotope industry and help it move to economic sustainability, through appropriate incentives and effective regulation.

The same general conclusion was made in both the first and second self-assessment reports, which underlines the slow rate of progress being made and the intransigence of some market players and some stakeholders towards helping ensure that the market become sustainable. This intransigence risks sending negative signals to potential investors in future commercially-based production and therefore jeopardises the long-term security of supply by potentially perpetuating below-full-cost-recovery prices in the market.

Chapter 1. Introduction

At the request of its member countries, the 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, however this initial target was not achieved due to slow implementation of full-cost recovery (FCR), continuing high levels of market competition, back pressure against price increases in the supply chain and only limited progress with implementing change to reimbursement policy.

In the second and the third mandate of the HLG-MR (2011-2013 and 2013-2015), the NEA Secretariat undertook two reviews 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 (ORC) and governments' role in the market. The results from those self-assessments were published as reports in 2012 and 2014, respectively. In its fourth mandate (2015-2017), the HLG-MR has continued to evaluate progress towards the implementation of the six policy principles and encouraged governments and supply chain participants to take actions for ensuring secure supply of $^{99}Mo/^{99m}Tc$ through developing an economically sustainable market structure.

This report provides analysis of information from the third self-assessment by supply chain participants and governments about the progress made towards the implementation of the HLG-MR policy approach, with comparisons with the earlier self-assessments and discussion about the present market condition.

Chapter 2. Objectives and methodology

Objectives

In June 2011, the High-level Group on the security of supply of Medical Radioisotopes (HLG-MR) released a six-principle policy approach to move the molybdenum-99 (^{99}Mo) and technetium-99m (^{99m}Tc) supply chain to a sustainable economic basis and to help ensure the security of supply.

As a direct action to implement Principle 6, in 2015-2016, the NEA has conducted a third self-assessment of the ^{99}Mo/^{99m}Tc supply chain. The main objective of the third self-assessment is to evaluate progress made by supply chain participants with the implementation of HLG-MR policy principles. There is comparison with the first and second self-assessments made in 2012 and 2014 respectively and it reports on the functioning of the ^{99}Mo/^{99m}Tc supply chain and the progress made towards establishing an economically sustainable market. The self-assessment report is essential to determine if and to what extent the HLG-MR policy approach is being implemented, the main focus is on full-cost recovery (FCR), outage reserve capacity (ORC) and governments' role in the market.

The report serves as a "monitoring mechanism" to help ensure that the HLG-MR policy approach succeeds; all stakeholders need to have confidence that the actions they are taking are being matched by all other players. This report identifies supply chain participants who have implemented or are making good progress towards full implementation of the policy approach, compared to the earlier self-assessments. It also notes those who are not making significant progress, any that have yet to start and those who are not engaging with the process. Where the report identifies that the HLG-MR policy approach is not being implemented as agreed, the HLG-MR member countries should examine the issues and agree on appropriate steps to address the issues.

Methodology

The NEA Secretariat obtained information from key supply chain participants and governments 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 from the second self-assessment were modified to gain some semi-quantitative information about the degree of progress made in the period from 2012 to 2015 and also to assess the confidence that generator manufacturers had about the level of ORC held in the supply chain. The blank questionnaire formats, which are available from the NEA Secretariat upon request, 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 soliciting potentially 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 to clarify submitted information.

The self-assessment questionnaires also provided an opportunity for supply chain participants and governments to share their views and observations concerning general performance aspects of the ^{99}Mo/^{99m}Tc market and the progress (or not) of the market in the implementation of the six policy principles. Some individual observations and recommendations from that exercise are reported in an anonymised fashion (see Annex 2 of the report).

Reporting of results

Similar to the earlier self-assessments, the third self-assessment report shows results for each key individual supply chain step using progress indicators for FCR and ORC. This enables individual data confidentiality to be maintained, while providing important information and maintaining consistency for comparison with the earlier self-assessments. The progress indicators used had the following classifications:

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

The NEA Secretariat was concerned that the use of the classification group “Significant progress made” used in the first two self-assessment reports did not leave enough scope for assessing further important progress that had been made by market participants, but still fell short of that HLG-MR principle being “Fully implemented”. The NEA Secretariat investigated the possible adjustment of the classifications but concluded that the introduction of additional categories made the clear reporting of change more difficult. In this regard, this self-assessment report considers that the classification group “Significant progress made”, as used in the previous self-assessment reports, contained a relatively wide bandwidth of actual progress made towards full implementation.

An example of the progress indicators is presented in Figure 2.1 below.

Figure 2.1. 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 FCR 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 FCR 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 ORC 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. The NEA has not made any independent evaluation of the assessments reflected in the progress indicators except through follow-up conversations for clarification.

Like the second self-assessment, this report includes waste management costs in assessing progress towards FCR, 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.

Chapter 3. Questionnaire responses

In November 2015, the NEA started the process of sending self-assessment questionnaires to all major supply chain participants – nuclear research reactor operators (irradiators), processors, generator manufacturers and governments.

During the initial phases of the third self-assessment process, questionnaires were also sent to the final end-user steps of the supply chain, these included nuclear pharmacies, societies representing nuclear medicine professionals and industry associations representing organisations active in the fields of nuclear medicine and/or medical imaging. Unfortunately, adequate response rates could not be achieved in the end-user steps by the time of the publication of this report, so they are not included, but may be reported separately at a later date.

By place/role in the global supply chain, the NEA surveyed:

- 32 ministries/departments in 17 governments[1]
- 11 reactor operators (irradiators)
- 7 processors
- 10 generator manufacturers

Of the 51 total responses, 24 came from governments or through their delegates from government-owned entities, 1 from the ESA, 11 from irradiators, 6 from processors and 9 from generator manufacturers.

Table 3.2 below shows a breakdown of questionnaire responses and response rates by supply chain participant group, including a comparison with the results in the second self-assessment in 2014. Annex 1 shows a list of all the entities that were sent self-assessment questionnaires, indicating the ones who responded and the ones who did not.

In total, for the steps in the supply chain from irradiator to generator manufacturer, 28 questionnaires were sent and 25 were completed and returned, for an overall response rate of 89%; there was also one partial response.

Table 3.2. Responses and response rates by supply chain participant group

	Number of responses (2016)	Number of responses (2014)	Response rate (in %, 2016)	Response rate (in %, 2014)
Governments (Economics)	13	10	81%	91%
Governments (Health Policy)	11	8	69%	62%
Reactor operators	11	12	100%	100%
Processors	6	7	86%	88%
Generator manufacturers	9	7	90%	88%

1. In the first self-assessment, only one questionnaire was sent to governments. This time, as for the second self-assessment, targeted questionnaires were sent separately to government ministries responsible for economics/research reactors and for health policy.

The final response rates at each level were similar to those in the second self-assessment. The conclusions drawn in this report are broadly representative of each supply chain level and the global market overall and are therefore broadly comparable with the second self-assessment.

Chapter 4. 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. The main findings of this report are given in the following subsections.

Full-cost recovery – Irradiators

Progress towards implementing full-cost recovery (FCR) by irradiators has continued at a slow pace since the second self-assessment, but only the irradiators that are wholly integrated with a processor (e.g. Australia and South Africa) have fully implemented FCR. The percentage of irradiator capacity classified as "Fully implemented" has increased to 19% in 2016 from 14% in 2014; this is due to an increase in services available from irradiators already fully implementing FCR and partly due to a reduction in total irradiation capacity. Progress has been made in other classifications, with "Significant progress made" now reported at 74% of the total world irradiator capacity, up from 53% in 2014. In total, 93% (up from 67% in 2014) of all existing irradiator capacity has made significant progress or has fully implemented FCR by 2016. The remaining 7% of irradiator capacity has made some progress and no irradiators remain classified as having not started the process.

During the past two years increased recovery for operational costs related to ^{99}Mo production has been reported by all irradiators through higher prices, but all have also reported substantial cost increases well above inflation levels during the same period. The increase in their cost base has been associated with essential maintenance, safety related activities and low-enriched uranium (LEU) conversion. These increased costs have played an important role in partially offsetting the progress made towards achieving FCR.

In some cases capital, decommissioning and waste management costs are still being subsidised by governments. However, in most cases the subsidy is due to a perceived obligation by the government to keep facilities safe and operational and is not being made from a direct desire to subsidise the actual production of medical isotopes. Government subsidies are being reduced and in all cases, irradiators are instructed to achieve FCR from the market, but there continue to be economic barriers to implement FCR in all cases.

It should be noted that the total normal available weekly irradiator capacity reported for 2016 at 26 600 six-day Ci ^{99}Mo per week EOP is slightly lower (5.9%) than the level reported in 2014. This is due to the end of operation of the OSIRIS reactor (France) and the end of routine supply from the National Research Universal (NRU) reactor (Canada). The relatively low level of total reduction reflects a counterbalancing increase in capacity introduced by some of the remaining irradiators and the addition of some irradiation capacity from the Russian Federation.

The irradiators were each asked to estimate their progress made towards achieving FCR in terms of the percentage of FCR pricing achieved at the end of 2015. The irradiators that reported represent more than 70% of the irradiation capacity used by the market in normal operating periods and could be split into two groups, those that were already achieving FCR and the others that reported a level of FCR achievement ranging between only 45% and 70%. When the data was weight-averaged based on known typical levels of facility utilisation, the two groups combined showed an overall average FCR achievement of around 70%. This data indicates that there is still a substantial way to go before 100% FCR pricing can be achieved at the irradiator level of the supply chain, but also indicates that the level of change needed to achieve that should not be insurmountable.

Table 4.1. shows the progress by irradiators in implementing FCR expressed in terms of their normal available weekly capacity, as shown in the latest NEA report: *2017 Medical Isotopes Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2017-2022* (NEA, 2017). The values are compared to those from the earlier self-assessments in 2014 and 2012 (respective figures shown in brackets). Capacity that has been lost since the 2014 self-assessment report is shown in the bottom row of the table.

Table 4.1. FCR implementation at irradiators by normal available weekly capacity

Progress indicator	Number of irradiators, 2016 (2014/2012)	Normal available capacity in 6-day Ci ^{99}Mo/week EOP, 2016 (2014/2012)	Share of total normal available capacity in %, 2016 (2014/2012)[1]
Fully implemented	2 (2/2)	5 150 (4 000/4 000)	19% (14%/15%)
Significant progress made	4 (3/3)	19 700 (14 880/13 680)	74% (53%/50%)
Some progress made	3 (2/0)	1 750 (7 480/0)	7 % (26%/0%)
Not started	0 (2/4)	0 (1 900/9 800)	0% (7%/36%)
Total	9 (9/9)	26 600 (28 260/27 480)	
~~*Stopped Operation*~~	~~*2*~~	~~*7 080*~~	

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

Full-cost recovery – Processors

At the processor level in the supply chain, there is a mixed picture. As is the case with irradiators, it is only the processors that are wholly integrated with an irradiator (e.g. Australia and South Africa) that have fully implemented FCR. The percentage of total processing capacity available that is classified as "Fully implemented" has actually reduced to 33% in 2016 from 52% in 2014. This is due to the exit from routine supply of the Canadian processing capacity that was associated with the NRU reactor and that had claimed FCR implementation. While this was technically correct, the NRU reactor that supported that processing capacity was itself not FCR compliant, so this could be considered as being "phantom" full implementation. Another important factor is the processor in the "No response" classification which substantially increased its capacity; as a result, the "No response" classification has increased to 32% in 2016 from 21% of all capacity in 2014.

As a result, the change in total processing capacity that is reported as "Fully implemented" in 2016 compared to 2014 is perturbed. It would be very useful if the significant level of capacity that has not responded could be correctly attributed. However, it should be noted that the irradiators that supply that processor have reported that they are not achieving FCR, so if the processor did report full implementation of FCR pricing, then it would be a "phantom" claim for the total supply chain to that point.

Like irradiators, the processor step in the chain also saw a loss of important processing capacity since 2014 (Atomic Energy of Canada Limited/Nordion capacity – on hot standby since end October 2016). This has been partially compensated by increases in capacity by some remaining supply chain participants and by the addition of some processing capacity in the Russian Federation. As a result, the total normally available weekly processing capacity reported for 2016 at 15 400 six-day Ci ^{99}Mo per week EOP is 7.1% lower than the equivalent level reported in 2014. Overall, it can be concluded that there has been some change in balance at the processor level, but the degree of FCR implementation has not changed substantially, with the growth of the "No response" classification having a confounding effect upon the numbers.

The processors that did respond, all indicated that they had experienced important cost increases within their operations, some directly related to the increase in prices received from irradiators associated with attempts to achieve FCR, but there were also important and substantial additional costs reported with regard to LEU conversion activities, investments, maintenance and increased physical security. The processors that responded all reported important increases to price levels for their products, but those increases were often lower in magnitude than the level of increase in costs that they had experienced. This suggests that many processors may have been margin squeezed during the period. They reported substantial resistance to price increases from the generator manufactures and from the downstream market in general.

Table 4.2 presents the progress made by processors in implementing FCR, expressed in terms of their stated operational capacity, as reported in the latest NEA: *2017 Medical Isotopes Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2017-2022* (NEA, 2017) report. The values are compared to those from the earlier self-assessments. Capacity that has become unavailable since the 2014 self-assessment report is shown in the bottom row of the table.

Table 4.2. FCR implementation at processors by normal available weekly capacity

Progress indicator	Number of processors, 2016 (2014/2012)	Normal available capacity in 6-day Ci ^{99}Mo/week EOP, 2016 (2014/2012)	Share of total normal available capacity in %, 2016 (2014/2012)[1]
Fully implemented	2 (3/3)	5 150 (8 680/11 200)	33% (52%/62%)
Significant progress made	1 (1/1)	3 500 (3 500/2 500)	23% (21%/14%)
Some progress made	3 (0/0)	1 750 (0/0)	11% (0%/0%)
Not started	0 (1/1)	0 (900/900)	0% (5%/5%)
No response	1(1/1)	5 000 (3 500/3 500)	32% (21%/19%)
Total	7 (6/6)	15 400 (16 580/18 100)	
~~*Stopped Operation*~~	~~1~~	~~4 680~~	

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

Outage reserve capacity – Irradiators

Progress towards implementing outage reserve capacity (ORC) by irradiators has improved since the second self-assessment. The percentage of irradiator capacity classified as "Fully implemented" for paid ORC has increased to 60% from 42% in 2014. However, only a limited amount of capacity now remains in the "Significant progress made" category; this is reported at only 5% of the total irradiator capacity, down from 10% in 2014. In total, 65% of all existing irradiator capacity (up from 52% in 2014) has made significant progress or has fully implemented ORC.

Although there has been some progress, it is a concern that one major irradiator remains in the category "Some progress made" and two irradiators still have made no progress, although for different reasons. One irradiator holds the capability of providing

ORC services, but is still not paid for holding the service; while the other is geographically isolated and unable to offer ORC services.

The progress with the provision of paid ORC services at the irradiator level reflects an increased recognition by the industry of the need to pay for ORC services, in particular at the irradiator level of the supply chain. This move has been supported by increases in overall irradiation capacity from those historically providing ORC services and the exit from the supply chain of two irradiators that were historically not providing paid ORC services.

Table 4.3 shows the progress by irradiators, expressed in terms of their normal available capacity, as reported in the latest NEA: *2017 Medical Isotopes Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2017-2022* (NEA, 2017) report.

Table 4.3. ORC implementation at producing irradiators by normal available weekly capacity

Progress indicator	Number of irradiators, 2016 (2014/2012)	Normal available capacity in 6-day Ci ^{99}Mo/week EOP, 2016 (2014/2012)	Share of total normal available capacity in %, 2016 (2014/2012)[1]
Fully implemented	4 (3/3)	15 950 (11 800/11 800)	60% (42%/43%)
Significant progress made	2 (1/0)	1 350 (2 800/ 0)	5% (10%/0%)
Some progress made	1 (1/2)	6 200 (4 680/7 480)	23% (17%/27%)
Not started	2 (4/4)	3 100 (8 980/8 200)	12% (32%/30%)
Total	9 (9/9)	26 600 (28 260/27 480)	
~~*Stopped Operation*~~	~~*2*~~	~~*7 080*~~	

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

Outage reserve capacity – Processors

Some progress can also be reported with regard to holding paid ORC at the processor level of the supply chain. In 2016, 65% of the processing capacity is reported as having made significant progress or having fully implemented ORC, up from 45% in 2014. However, the improvement is substantially due to the increase in capacity of existing processors that were already holding paid ORC and from the exit from service of processors who were not holding paid ORC.

As with FCR implementation, a substantial quantity and an increased percentage of overall processing capacity (32%) is now classified as "No response" concerning ORC implementation. This increases the uncertainty of the overall progress towards ORC implementation. It would be very useful if this significant level of capacity be correctly attributed, as it is understood that the processor does hold some paid ORC. On the positive side, only one small processor has not started with paid ORC implementation, and this is due to geographic location.

Table 4.4 presents the progress made by processors in implementing ORC, expressed in terms of their stated weekly capacity, as reported in the latest NEA: 2017 Medical Isotopes Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2017-2022 (NEA, 2017) report.

Table 4.4. ORC implementation at producing processors by normal available weekly capacity

Progress indicator	Number of processors 2016 (2014/2012)	Normal available capacity in 6-day Ci ^{99}Mo/week EOP 2016 (2014/2012)	Share of total normal available capacity in %, 2016 (2014/2012)
Fully implemented	3 (3/2)	8 650 (7 500/4 000)	56% (45%/22%)
Significant progress made	2 (0/1)	1 350 (0/2 500)	9% (0%/14%)
Some progress made	0 (0/0)	0 (0/0)	0% (0%/0%)
Not started	1 (2/2)	400 (5 580/8 100)	3% (34%/45%)
No response	1 (1/1)	5 000 (3 500/3 500)	32% (21%/19%)
Total	7 (6/6)	15 400 (16 580/18 100)	
~~*Stopped Operation*~~	~~*1*~~	~~*4 680*~~	

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

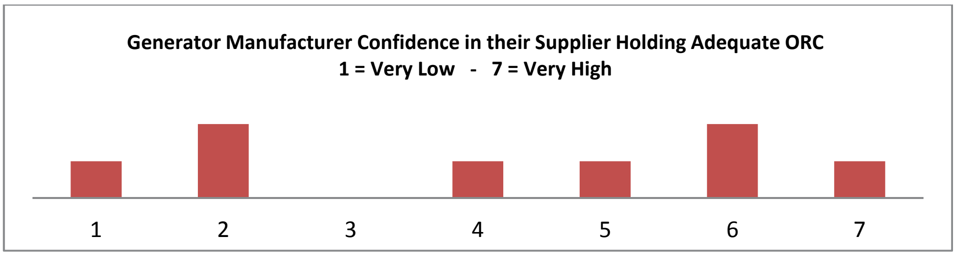
Generator manufacturers

There was a very good level of response to the third self-assessment at the generator manufacturer level, showing their strong involvement in the work of the HLG-MR. Almost all generator manufacturers who responded reported substantial cost increases from their bulk ^{99}Mo suppliers, the processors. A common theme in the generator manufacturer responses was the strong competition in the market, which made it challenging to increase the prices of generators supplied to nuclear pharmacies and to hospitals. As commercial entities, generator manufacturers are expected to fully recover their costs of production plus a profit. However, to the extent that below-full-cost-recovery prices are still passed down the supply chain from irradiators receiving some financial support, most generator manufacturers still do not pay the “true” FCR cost of bulk ^{99}Mo.

Nonetheless, almost all generator manufacturers that responded indicated substantial price increases in the cost of bulk ^{99}Mo from their suppliers. They also reported on average that they had achieved important price increases for the supply of their products. But at a detailed level, it was clear that generator manufacturers fell into two different subcategories: a group that indicated they had been able to make important price increases and a group that indicated they had been able to make little, or in some cases, no price increase during the whole period of 2012 to 2015. Analysis showed that both groups had experienced similar overall levels of cost increase during the same period; indicating that the degree of cost increase experienced by the generator manufacturer did not correlate with their ability to achieve higher prices with their own customers. In all cases, the degree of cost increase was reported as higher than the degree of price increase recovered, indicating that many generator manufacturers may have been cost squeezed in recent years and only some had been able to pass on some of the cost increases they had experienced.

It is interesting to note that the actual level of paid ORC that is being held by processors is unclear at the generator manufacturer level of the supply chain. Generator manufacturers were asked to comment upon their confidence level that their supplier was holding adequate levels of paid ORC, with a 7-point range starting with one being very low confidence and seven being very high. The results of this survey showed an almost flat level of response across the whole range (see Table 4.5).

Table 4.5. Level of generator manufacturer confidence in their supplier holding ORC



The underlying message was that the confidence that generator manufacturers had in their supplier holding adequate levels of paid ORC was directly linked to the communication that they experienced. This was combined with any first-hand experience they had of their supplier's responsiveness when supply was challenged. Generator manufacturers who were connected to integrated supply chains where the level of held ORC was clearly communicated had the highest confidence levels. More remote customers that relied on suppliers that did not clearly communicate or perhaps demonstrate their commitment to holding paid ORC had the lowest levels of confidence.

If all generator manufacturers had a high level of confidence that their suppliers were holding an adequate level of paid ORC, then this would be an improvement upon the present situation. If generator manufacturers have low confidence in the level of held ORC in their supply chain, then they are unlikely to value it correctly, or be prepared to pay for it. If all generator manufacturers had a high level of confidence in the level of paid ORC that their suppliers held, it would be more likely that the ORC would be valued correctly.

Fully implementing appropriate levels of paid ORC capacity, clearly communicating and demonstrating its provision, recognising it is full cost and accepting the need to transfer those costs down the supply chain are all vital steps to ensuring future economic sustainability. This would also underpin market confidence in the security of supply.

When ORC is not adequately held or sufficiently financed, the underfunded reserve production capacity that remains available acts in the market as a downward competitive pressure that works against achieving FCR implementation. Holding correctly valued ORC and paying for it is an essential component of achieving FCR. FCR without sufficient paid ORC does not cover all of the essential costs of ensuring an economically sustainable supply.

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

Governments are involved in the global ^{99}Mo/^{99m}Tc supply chain, initially by some continued support at the irradiator and processor steps and in particular concerning healthcare policy and reimbursement at the end-user step. Most ^{99}Mo supply chain participants in-between are commercial, for-profit entities.

Although governments have continued to reduce their support for ^{99}Mo irradiators, much remains to be done to achieve full implementation of FCR. Despite real progress since the adoption of the HLG-MR policy principles, some governments have indicated that they remain obliged to provide support to maintain ^{99}Mo production. While it is a government's prerogative to fund basic research, commercial ^{99}Mo production at every step of the global supply chain should comply with the principle of FCR to avoid market distortion. The principle of "user pays" has been agreed by the HLG-MR members and the cessation of third party support of the healthcare systems of other countries must be achieved to ensure a long-term, economically sustainable market structure.

Tables 4.6 and 4.7 below show the level of government support for ^{99}Mo production at existing irradiators and the intended level of government support for future $^{99}Mo/^{99m}Tc$ production projects. This is based on information from the supply chain and the NEA's understanding of announcements by various countries. The level of government support is classified on a three-level scale used to describe the degree of government support for future ^{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 must be fully repaid at a commercial rate over time. The data is expressed in terms of normal irradiation capacity per week, as reported in the latest NEA: *2017 Medical Isotopes Supply Review: $^{99}Mo/^{99m}Tc$ Market Demand and Production Capacity Projection 2017-2022* (NEA, 2017) report.

Table 4.6 shows little change in 2016 compared to the situation reported in 2014. Unfortunately, it is not possible to compare the level of partial subsidy being provided. Therefore the table hides the fact that governments have, in general, been steadily reducing the actual level of support for ^{99}Mo production at the existing irradiators.

Table 4.6. Level of government support for ^{99}Mo production at existing irradiators

Level of government support	Number of irradiators, 2016 (2014/2012)	Normal available irradiation capacity in 6-day Ci ^{99}Mo/week, 2016 (2014/2012)
Full subsidy	0 (0/0)	0 (0/0)
Partial subsidy	7 (7/7)	21 450 (24 260/23 480)
No subsidy	2 (2/2)	5 150 (4 000/4 000)

Table 4.7 shows a more positive situation; the number of projects likely to be operational by 2022 that are fully subsidised has reduced to zero and only one project remains as anticipating a partial subsidy. The total numbers of projects and also, their total anticipated production capacity reported in Table 4.6, have substantially reduced. This is partly due to a time window (ending in 2022) being introduced in this analysis; this is in line with the most recent NEA demand and capacity projections. Additionally a number of substantial time delays have been announced for some potentially government-subsidised projects, taking them outside of the 2022 time window.

Despite the decrease, the total anticipated capacity reported in Table 4.6 remains at a very substantial level of 21 850 six-day Ci ^{99}Mo per week of normal operation. This represents potential additional capacity of more than 240% of the present level of market demand. Whether all, or even any, of these projects actually reach maturity cannot be predicted, but the data indicates that the vast majority of new irradiator capacity that is likely to be introduced into service in the period up until 2022 will not rely upon government subsidy.

While this is a positive signal, the continued need for some governments to support the present irradiators because of their lack of ability to achieve FCR remains a concern. This raises the question of the ability of new irradiators operating without support, to be able to sustainably enter the market while the present market conditions prevail.

Table 4.7. Level of intended government support for $^{99}Mo/^{99m}Tc$ production, irradiation projects under development in 2017 with market launch by 2022

Level of intended government support	Number of new/replacement $^{99}Mo/^{99m}Tc$ projects 2016 (2014)	Potential anticipated production capacity per week in 6-day Ci ^{99}Mo/week 2016 (2014)
Full subsidy	0 (4)	0 (6 500)
Partial subsidy	1 (2)	2 500 (1 300)
No subsidy[1]	9 (11)	21 850 (32 000)

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

Progress by region

In Australia and South Africa, FCR and ORC have already been implemented and the role of governments in ^{99}Mo production clearly defined as being at arm's length. They are also the only major producers who have fully or substantially converted to the use of LEU targets.

In Canada, the federal government has supported the development of alternative technologies, focusing on the development of domestic, non-reactor-based technologies for future supply. With the implementation in October 2016 of the decision to cease routine ^{99}Mo production at the NRU reactor, the Canadian government has taken an important step in stopping their financial support of ^{99}Mo production and also in moving away from the use of highly enriched uranium (HEU) targets.

The United States and Europe account for approximately two-thirds of the global $^{99}Mo/^{99m}Tc$ demand, with the United States as the largest consumer, while Europe is the largest global producer. Both have important leadership responsibilities in the effort to implement the HLG-MR policy principles.

The United States has provided substantial support to facilitate initial development efforts for alternative production technologies on a 50%-50% cost-share basis up to a USD 25 million limit per project. They have also taken actions to encourage both FCR and LEU conversion in the supply chain through the introduction of an additional payment of USD 10 per dose in the United States for the specific use of non-HEU based ^{99}Mo (HCPCS code Q9969). They have also financially supported projects to convert from HEU to LEU targets. While good progress is being made in the conversion to LEU targets, the level of take-up of the HCPCS code Q9969 initiative has so far been slow, only at low levels and as such has not substantially changed local market dynamics.

In Europe, while the establishment of the European Observatory on the Supply of Medical Radioisotopes is in recognition of the importance of securing the supply of $^{99}Mo/^{99m}Tc$, concerted actions to investigate the European market structure and the co-ordinated implementation the HLG-MR policy principles have been slow, recent actions at the European Union level have led to some new initiatives planned to start in 2017. The supply from Europe has a specific challenge; it is an integrated network, with multiple irradiators supplying multiple processors, and those processors along with non-European processors supplying multiple generator manufacturers both inside and outside of Europe. This network approach supports security of supply through multi-sourcing but also results in some overall net redundancy in irradiation capacity within Europe that has inherent problems. When any redundancy of irradiation capacity is not correctly valued and not fully paid for as ORC, it potentially remains available in the market as excess capacity; presently, this seems to occur even in periods of apparent supply vulnerability. New irradiator capacity planned for introduction in Europe has indicated that it will be on a FCR basis.

In South America, governments are moving towards implementation of FCR as they understand that achieving FCR is essential for ensuring an economically sustainable market. But some support remains, with the intention to move to FCR for future ^{99}Mo production projects, or otherwise to restrict production projects to only supply the domestic market. Asia is moving in a similar direction, with the clear understanding that new ^{99}Mo production capacity needs to be established on a FCR basis from the start. In both cases, potential new sources of production need to participate in the provision of paid ORC services. This is a challenge that is well-recognised, although geographic considerations will influence the way in which potential new producers may be able to participate in providing and using paid ORC services.

Where future producers intend to become part of the global supply chain, government subsidy would not be consistent with the HLG-MR policy principles and would potentially exacerbate the existing unsustainable economic situation in the global supply chain. Subsidy by governments of new capacity would not be supporting their own industry; they would be actually subsidising the healthcare budgets in other countries while potentially destabilising the overall sustainability of the supply chain.

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

The continued effective, co-operative actions taken by the supply chain under the umbrella of the Association of Imaging Producers and Equipment Suppliers (AIPES) have successfully managed the supply of medical radioisotopes in the period since the second self-assessment. This has been achieved despite a number of challenges from the extended planned outages of some important facilities and also occasional unplanned outages. During that period, some existing supply chain members increased capacity in a number of stepwise measures and those increases mitigated the planned end of routine production of ^{99}Mo at the NRU reactor (Canada) and the end of operation of the OSIRIS reactor (France).

Australia has already managed the first steps of a very effective transition programme to increase processing capacity from their existing facilities from a capacity of 1 000 six-day Ci ^{99}Mo/week to 2 150 six-day Ci ^{99}Mo/week. Australia is also making an important and significant investment in new processing capacity that will unlock existing additional irradiation capacity at the OPAL reactor, with an anticipated total capacity of 3 500 six-day Ci ^{99}Mo/week by early 2018. However, Australia is faced with the prospect of introducing the new capacity based on a higher unit cost needed to pay for the substantial investment; this may challenge their existing position as a supplier that has achieved FCR.

Alternative technologies for $^{99}Mo/^{99m}Tc$ production have progressed, with the further addition of potential new projects. However, while the technical aspects of a number of different technologies have been well-demonstrated and $^{99}Mo/^{99m}Tc$ can clearly be produced by these alternative approaches, supply has not yet materialised and their economic sustainability therefore remains undemonstrated. Many alternative technology projects and also some large-scale conventional technology projects have suffered from project delays, some of a multi-year duration. The continued delay of projects is a concern, as the lack of an economically sustainable market structure may be a contributing factor in some cases.

In the medium term, the bulk of the ^{99}Mo supplied to the market will most probably remain based on a network of research reactors providing irradiation services. The technical promise of alternative $^{99}Mo/^{99m}Tc$ production technologies remains good, but whether they will be widely deployed on an economically sustainable basis remains to be seen. Whether based on conventional or alternative technology, it is essential that any new/replacement capacity is based on FCR principles to avoid subsidised capacity distorting the market. The entry of new supplies of subsidised product would risk driving down market prices to levels where some existing reliable FCR compliant producers may be forced to exit the market. This would be a negative market outcome.

The attempt to transition to FCR while in parallel moving to convert to using LEU targets for ^{99}Mo production has compounded the economic difficulties for some supply chain participants, with the externality of LEU conversion leading to additional costs and reduced overall efficiency of processes. As the LEU conversion process is an externality, some temporary government support to those supply chain participants would be consistent with the HLG-MR principles; however, only the United States (US) government has taken concrete actions to date to directly recognise the importance of non-HEU supply.

There have been positive moves with increased levels of paid ORC since the second self-assessment and it is within networks established to improve security of supply that the full recognition of the need to pay for ORC is most important. However, market expectation to pay directly for ORC effectively stops at the processor level in the supply chain. The processors recognise the need for holding paid ORC in order to be able to guarantee supply 52 weeks of the year; but processors report that they remain unable to separately charge generator manufacturers for the efforts and costs incurred in holding ORC. From the generator manufacturer onwards in the supply chain, the sequential customers all assume that their suppliers will hold sufficient essential ORC. However, in most cases those customers continue to expect their suppliers to absorb all of the costs for holding the ORC within their own cost structure and do not pay separately for ORC provision.

The network approach by definition introduces direct competition at every step of the supply chain, i.e. competition at the irradiator step to supply the processors, competition at the processor step to supply generator manufacturers and competition at the generator step to supply nuclear pharmacies, hospitals and clinics. In some markets, competition also exists between the users of generators, in particular in markets where commercial nuclear pharmacies compete to provide individual patient doses. The additive competitive pressures of the network approach can act as strong resistance to the implementation of FCR as it acts in an additive way through each step of the supply chain. This is especially the case in markets where the final reimbursement mechanisms and rates are not at the level necessary to support an economically sustainable service. For this reason, it is essential that governments take the responsibility to monitor and understand their local market structure and the cost pressures in their areas of jurisdiction and implement appropriate policy to move to an economically sustainable market structure.

In the second self-assessment, end users report higher prices from their suppliers over the preceding period without corresponding increase in reimbursement; this situation was again frequently reported in the third self-assessment. There has been no substantial breakthrough yet with regard to achieving durable reimbursement levels that are able to support an economically sustainable supply chain.

Much of the experience since the 2009-2010 supply crisis has shown that short-term commercial market share considerations have been more highly valued by some supply chain participants than achieving long-term sustainable supply conditions. Short-term gain often being put ahead of the long-term interests of security of supply for patients is an inefficient market outcome. It also has the risk of sending negative signals to potential investors in future commercially-based projects and jeopardises long-term security of supply by perpetuating below FCR pricing. If capacity that would otherwise be unsustainable is maintained by subsidy, it potentially blocks the market entry of more cost effective sustainable supplies; if this occurs, it would be a negative market outcome.

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 (FCR) and outage reserve capacity (ORC) overall and since the second self-assessment in 2014 in particular. The chapter also assesses the role of individual 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 to which this production is equivalent. Global demand is estimated at approximately 9 000 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 900 six-day curies per week, it is estimated to provide 10% of global demand in the week when it is operating, although not 10% 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 irradiator and processor level are assessed by the NEA on their progress towards implementing the HLG-MR policy approach, using indicators for FCR and ORC. A "report card" is then created for each country assessing the degree of progress made on FCR and ORC services provided by the organisations there. Other important aspects of the local supply chain including government actions and domestic generator manufacture are discussed where relevant.

Argentina 2016

Argentina is a regional supplier of ^{99}Mo in South America with plans to become a global supplier in the coming years. The country's RA-3 reactor and processing plant produce 350-400 six-day curies EOP in a normal week of operation. The RA-3 reactor uses low-enriched uranium (LEU) for both fuel and targets. The reactor and associated processing facilities are operated by the Argentine National Commission of Atomic Energy (CNEA). CNEA, a governmental institution, manages the supply of medical radioisotopes in domestic and regional markets. It is vertically integrated with target manufacture, target irradiation and bulk ^{99}Mo production. Argentina is one of two manufacturers of LEU targets for ^{99}Mo irradiations in the world. Due to the geographic location, neither the reactor nor the processing facilities provide ORC services to the global supply chain.

The RA-3 reactor and processing facilities receive some direct government support for ^{99}Mo production, mostly directed to the CNEA Waste Management Division. The government also provides capital funding for refurbishment and infrastructure needs. Notwithstanding the financial support, CNEA has moved towards implementing FCR and

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

has reported significant increases in the price of bulk ^{99}Mo driven by higher input costs for both irradiation services and processing operations. This is a specific move towards FCR implementation, but the process is not yet fully achieved. Waste from ^{99}Mo production is managed by CNEA but remains funded by the Argentine government.

Argentina is planning to build a new reactor (RA-10) and processing facilities, which are intended to irradiate LEU targets for ^{99}Mo production, with a capacity of 2 500 six-day curies per week when operating; this would make the country an important global producer. Commissioning is scheduled for 2020; the new ^{99}Mo production infrastructure is being designed and built with government financial support. Argentina has domestic competencies in the design and building of this infrastructure and already exports that technology in a commercial way.

Based on CNEA's responses, the organisation has taken steps to implement the HLG-MR policy principles and appears to be in a transitional 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, however, the need to move to FCR is recognised. At present, Argentina largely produces for its domestic market, with small exports to South American countries, and has limited impact globally. However, the direct support for the construction of the new RA-10 reactor and processing plant can only be in line with the HLG-MR policy principles when FCR is fully implemented for the existing facilities and production from the new facilities are launched on a FCR basis.

Argentina'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: CNEA – Argentina (irradiator and processor)

Full-cost recovery: Progress made

Comments:

CNEA has started to address the issue of FCR for irradiation services and bulk ^{99}Mo production and has introduced aspects of FCR methodology and has substantially increased prices. Some direct government support is received, mainly for capital expenditures and waste management. The planned, new reactor (RA-10) and processing facilities will be fully funded by the government, so FCR methodology needs to be implemented if product from the new facilities is to be sold into the global market.

Important progress has been made since the second self-assessment in 2014.

Outage reserve capacity: The geographic location does not presently allow ORC services to be provided

Comments:

CNEA is not presently in a position to provide ORC services to the global supply chain. When the new facilities become operational, Argentina could become a regionally significant supplier and should consider entering into back-up ORC agreements with other parties.

Australia 2016

Australia is an important and growing global supplier of irradiation services and bulk ^{99}Mo. In Australia, irradiation, bulk ^{99}Mo production and generator manufacture are vertically integrated. The Australian Nuclear Science and Technology Organisation (ANSTO) operates the OPAL multipurpose reactor that uses LEU for both fuel and targets. ANSTO has recently completed an upgrade of its existing processing facility to increase production capacity to more than 2 000 six-day curies EOP in a normal week of operation, doubling its previous output. ANSTO is also building a new ^{99}Mo processing facility with a total production capacity of 3 500 six-day curies EOP per normal week of operation. When completed, Australia's overall ^{99}Mo production capacity will rise to represent about 30% of global demand. OPAL is the newest reactor in the worldwide supply network and despite its geographical distance from major markets already plays an important role in the global supply chain. Although ANSTO is a government agency, its ^{99}Mo production activities are commercialised and based on full-cost recovery principles. On completion of the Mo-99 processing facility, the additional significant investments made by the government will be fully included in their FCR approach. Furthermore, ANSTO is bound by the Australian government's competitive neutrality policy.

ANSTO has a reciprocal commercial agreement in place with NTP Radioisotopes in South Africa for the provision of ORC services which are charged at commercial rates.

At the generator point of the supply chain, ANSTO has seen modest cost increases and has achieved modest price increases for the supply of generators. Australia operates an overall fee-for-service policy for the reimbursement of nuclear medicine procedures, which do not specifically identify the costs associated with the medical isotopes that are used.

The Australian government has provided ANSTO with an equity injection for the construction of the new ^{99}Mo processing facility and a co-located Synroc waste treatment plant to condition the waste from processing into a form which will be stable over geological time periods. Apart from the initial equity injection, which must be repaid in full over time, government provides no financial support to the ^{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, processor and generator manufacturer)

Full-cost recovery: Fully implemented

Comments:

ANSTO applies FCR pricing principles (including the cost of treatment and final disposal of wastes, as well as future decommissioning costs of the manufacturing plant) to its production from existing plant (irradiation services, bulk ^{99}Mo production and generator manufacturing operations). ANSTO also intends to apply FCR to all production from the new plant which is due to start production in the latter half of 2017. At present, in advance of establishment of a new national radioactive waste storage and disposal facility, pricing includes waste and decommissioning estimates which will be adjusted as planning for the facility is developed.

There has been no change in policy since 2014.

Outage reserve capacity: Fully implemented

Comments:

ANSTO has made arrangements for the provision of ORC and charges market rates for its availability and maintenance, based on its FCR methodology. The increase in capacity from Australia will allow the possibility of providing additional ORC services to the global market at the processor level.

Belgium 2016

Belgium is an important supplier in the world market for bulk ^{99}Mo, with both irradiation and processing facilities. However, there is no ^{99}Mo/^{99m}Tc generator production, so all bulk ^{99}Mo is exported and then reimported as finished generators for use in Belgian clinics and hospitals. The BR-2 reactor in Belgium has the highest normal weekly available capacity for ^{99}Mo irradiations and can produce up to 7 800 six-day curies EOP in a typical week of operation, which represents greater than 85% of the normal global weekly demand. The reactor has undergone a number of major refurbishments, the most recent of which was completed in July 2016. The reactor returned to service on schedule after a 16 month absence with the capability of operating more irradiation cycles per year and able to operate until at least 2026. It is proposed that the BR-2 will be replaced at the end of its operating life by a new, multipurpose reactor system (MYRRHA), which is in the design stage.

The Belgian Nuclear Research Centre SCK-CEN operates the BR-2 with highly enriched uranium (HEU) fuel and presently irradiates HEU targets. SCK-CEN is actively working towards the timely conversion of the BR-2 fuel to LEU and the processes needed to allow the irradiation of LEU targets are well progressed; the first pilot production batch has been irradiated and shipped in 2016 and the first commercial LEU target irradiations are anticipated in 2017. The BR-2 irradiates targets for processing at the Institute for Radioelements (IRE) in Belgium and Mallinckrodt (now part of Curium) in the Netherlands.

IRE operates an important processing facility, with irradiation services presently provided by three different reactors. IRE can process up to 3 500 six-day curies EOP in a typical week of operation, which represents greater than 35% of the normal global weekly demand. IRE presently processes HEU targets and is well advanced in a programme to convert completely to LEU targets, utilising a refurbished processing line that can be run in parallel with the existing HEU production line allowing conversion without a capacity reduction. The conversion programme to LEU targets has been partially subsidised by the Belgian and the United States governments.

SCK-CEN has its own FCR methodology in place and has taken major steps towards implementing FCR pricing, inclusive refurbishment and decommissioning costs. However, due to resistance from the downstream supply chain, some important steps are still to be taken to complete FCR implementation. It is not known when FCR for all cost elements can be achieved. SCK-CEN has indicated that it receives important levels of ORC payment (take or pay arrangements) from its customers.

IRE operates on a FCR basis, within the boundaries of being supplied by reactors that have not yet fully achieved FCR. IRE has identified that it has experienced substantial cost increase in recent years and anticipates that cost increases will continue in future years. Positive progress has been reported in increasing prices for bulk ^{99}Mo to enable FCR to be achieved, but overall cost pressures have increased at the processor point in the supply chain. IRE provides substantial ORC payments to all of its irradiators and is committed to maintaining adequate ORC coverage through diversified supply and also through back-up contracts held with other processors. However, direct ORC costs are reported as being impossible to transfer down the supply chain and have to be absorbed within operational overheads.

The Belgian government provides partial financial support for capital costs and complete support for decommissioning and waste management costs for IRE. Following the 2016 terrorist attacks IRE has also received exceptional Belgian government support for the provision of increased physical protection of its site. The Belgian government is committed to ensuring that appropriate nuclear security and non-proliferation measures are in place.

At the end-user level, Belgium implemented new legislation in 2015 that separates reimbursement for the ^{99m}Tc isotope from the rest of the medical diagnostic procedure. This process will increase the transparency of costs for ^{99m}Tc and allow the more accurate assessment of the effects of FCR implementation and how it should influence reimbursement decisions. The process of collecting and analysing data from this change in policy is taking place now, but it remains too early to make a detailed assessment of the impact of this action.

Belgian'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: SCK-CEN – Belgium (irradiator)

Full-cost recovery: Further progress made

Comments:

SCK-CEN has a FCR methodology in place which is implemented at the BR-2 reactor for the provision of irradiation services. For the ^{99}Mo production irradiation services all major cost elements, inclusive the refurbishment and decommissioning costs, are being included in the pricing. However, some important steps still need to be taken to complete FCR implementation. SCK-CEN did not provide detailed information about cost or price changes for ^{99}Mo-related services since 2012.

Some progress made since the second self-assessment in 2014.

Outage reserve capacity: Fully implemented

Comments:

SCK-CEN is providing ORC services to processors and recovers the full costs associated with this service.

Company/organisation name: IRE – Belgium (processor)

Full-cost recovery: Further progress made

Comments:

IRE has experienced important price increases for irradiation services and costs from LEU conversion activities and has increased its own prices for bulk ^{99}Mo supply 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, but still needs to include the full waste management costs. IRE still continues to receive some subsidy support from governments for LEU conversion and some exceptional support for essential upgrades and security.

Further progress made since the second self-assessment in 2014.

Outage reserve capacity: Fully implemented

Comments:

IRE is paying to maintain ORC at several reactors. IRE also has ORC back-up agreements with other processors to provide/receive product in the event of an unexpected or extended reactor shutdown.

Brazil 2016

Brazil is essentially a closed market with a universal public healthcare policy and is 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 domestic hospitals and clinics. The country is applying a FCR methodology at the generator manufacturer level of the supply chain and has experienced substantial upward pressure on bulk ^{99}Mo prices in recent years resulting in ^{99}Mo/^{99m}Tc generator price increases.

The Brazilian Nuclear Energy Commission (CNEN) has a monopoly on the manufacture of ^{99m}Tc generators for the Brazilian market and the Ministry of Health is responsible for reimbursement policy for isotopes within the public health system. The overall provision of Brazilian healthcare is 75% public; however, the provision of nuclear medicine services is different, with only 30% being by public provision and the majority, 70% provision, being from the private sector. The strong regulation of the country's health care systems, including reimbursement policies, creates a barrier to timely reviews and adjustments of ^{99m}Tc isotope reimbursement rates.

To improve control over its domestic supply of ^{99}Mo/^{99m}Tc, Brazil is working on a project to build a new reactor and ^{99}Mo processing facility, to ensure that the country can largely meet its own demand. The new proposed ^{99}Mo production capacity of 1 000 six-day curies EOP per normal production week would meet domestic demand for most of the calendar year; at present commissioning is not scheduled until after 2021. The project would be fully funded by the Brazilian government, but Brazil does not presently plan to export bulk ^{99}Mo to other countries, with the priority focused on meeting its own demand, which is projected to grow over time. In the event that Brazil decided to sell bulk ^{99}Mo to other countries, it would be essential that FCR pricing policies were followed in order to ensure that Brazilian subsidised production did not distort the global market. Even though Brazil may become self-sufficient in ^{99}Mo supply in the future, it will need to develop new ORC agreements with other suppliers in order to ensure continuity of supply through the whole year and to manage any unplanned events.

Canada 2016

As planned, Atomic Energy of Canada Limited's (AECL's) National Research Universal (NRU) reactor, operated by Canadian Nuclear Laboratories (CNL), ceased routine production of ^{99}Mo at the end of October 2016. While the NRU had historically been one of the world's largest irradiators of (HEU) targets for ^{99}Mo production, the reactor's contribution to total global irradiation had diminished significantly as a result of the Government of Canada's 2010 plan to help transition away from publicly-subsidised ^{99}Mo production to a more diversified and market-driven global supply chain. The Government of Canada has supported the extension of the NRU operations for other purposes from 1 November 2016 until 31 March 2018, while maintaining the capacity to produce ^{99}Mo in the event of a significant global shortage that could not otherwise be mitigated. The processing capability and capacity at AECL and Nordion Inc. facilities will also remain available as part of the contingency during that period.

The Canadian government supports the policy objective of FCR and intends to apply it to non-reactor-based isotope production in Canada going forward. In preparation for this, the Government of Canada has supported the development of alternative technologies for the production of ^{99}Mo and technetium-99m (^{99m}Tc) – specifically, linear accelerators and cyclotrons – with a view to providing a more distributed, market-driven supply chain. In the case of cyclotrons, ^{99m}Tc is produced directly, which, given its short half-life, would only be useful for domestic supply to locations close to the cyclotron. Linear accelerator production of ^{99}Mo would provide for diversity and redundancy in the supply chain. The Canadian government intends for future non-reactor-based isotope production to be non-HEU based, fully commercial and with no government participation in production.

Nordion, the commercial company previously involved in the supply of ^{99}Mo from the NRU, has been actively developing a new project for the supply of ^{99}Mo from an LEU target source, in co-operation with General Atomics and the MURR reactor. The project is anticipated to provide 3 200 six-day curies ^{99}Mo EOP in a normal week of operation starting in 2019. This project would be LEU based, utilise the existing processing facilities at the Nordion site and will be supplied on a FCR basis.

Canada'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: AECL – Canada (former irradiator)

Full-cost recovery: NRU no longer in routine production.

Comments:

The Government of Canada has supported the development of alternative technologies for medical radioisotope production, which are expected to operate on a FCR basis post-2017.

Routine non-FCR based production has ceased.

Outage reserve capacity: No longer in service

Comments:

None.

Company/organisation name: Nordion – Canada (processor on hot standby)

Full-cost recovery: Not presently in routine production

Comments:

As a commercial entity, Nordion was fully recovering its costs of bulk ^{99}Mo production. Nordion is developing a new project for the supply of ^{99}Mo from an LEU target source, in co-operation with General Atomics and the MURR reactor and future supply will be on a FCR basis. Future waste management costs will be the subject of new commercial agreements.

Not presently in routine production.

Outage reserve capacity: None

Comments:

Nordion will need to consider ORC within the boundaries of their new project.

Czech Republic 2016

The Czech Republic is an established participant in the global ^{99}Mo/^{99m}Tc supply chain. The LVR-15 reactor is commercially operated by the Nuclear Research Centre Rež and has irradiated (HEU) targets for isotope production since 2010 and is fully ready to convert to the irradiation of LEU targets. The reactor now has an irradiation capacity of 3 000 six-day curies EOP per week and has been typically producing more than 10% of global demand on an annualised basis. The reactor also routinely provides significant ORC, which is paid by the processor.

The LVR-15 has made good progress towards implementing FCR and anticipates achieving FCR inclusive of waste management by 2018. The LVR-15 does not receive financial support from the Czech Republic government for ^{99}Mo production. The Czech Republic government has actively worked on preparing for FCR by implementing changes in the reimbursement mechanism in their country and reimbursement rates have been substantially increased.

The Czech Republic'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: Řež – Czech Republic (Irradiator)

Full-cost recovery: Important progress made

Comments:

The LVR-15 has implemented its own full-cost recovery methodology for ^{99}Mo irradiations and currently recovers a substantial portion of ^{99}Mo production costs from ^{99}Mo revenues, with contracts in place to achieve FCR pricing by 2018. However, these costs do not recover capital costs. Target waste management is a responsibility of their customers; reactor operational waste will be covered when FCR is fully implemented.

Important progress made since 2014.

Outage reserve capacity: Fully implemented

Comments:

The LVR-15 now provides ORC, which is fully paid for on a routine basis.

France 2016

France has been an important supplier of irradiated (HEU) targets for ^{99}Mo production through its OSIRIS reactor, which typically produced 5 to 10% of global demand on an annualised basis when in operation. The OSIRIS reactor ended operations in late 2015 and the reactor will be decommissioned. During recent years of operation OSIRIS also provided some ORC that was partially paid for by the processor.

The Commissariat à l'énergie atomique et aux énergies alternatives (CEA), is in the process of constructing a new, multipurpose reactor (Jules Horowitz – JHR) that will be capable of irradiating (LEU) targets for ^{99}Mo production. The construction of the JHR is financially supported by the French government. It is the intention to provide ^{99}Mo irradiation services on a fully FCR basis.

France still plays an important role in the global supply chain with the production of ^{99m}Tc generators by the organisation IBA Molecular, performed on a commercial basis. France also plays an important role in the global supply chain with the production of targets by the commercial organisation CERCA.

The French government have taken no actions with regards to assessing or adjusting reimbursement for ^{99m}Tc based radiopharmaceuticals.

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

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

Company/organisation name: CEA – France (irradiator)

Full-cost recovery: No longer in service

Comments:

The French government is supporting the construction of the JHR reactor.

Irradiation services will be provided on a FCR basis.

Outage reserve capacity: No longer in service

Comments:

The OSIRIS reactor provided some ORC that was partially paid for by the processor. The provision of ORC services are planned at the JHR on a commercial basis.

Germany

Germany is not currently producing ^{99}Mo, but is planning to join the global supply chain as an irradiator in mid-2019, irradiating LEU targets to be processed elsewhere in Europe. The FRM II research reactor at the Technische Universität München (TUM) is being modified to accommodate LEU target irradiation and is estimated to be able to produce approximately 2 100 six-day curies EOP in a normal week of operation when operational.

Limited financial support for research and development activities related to future ^{99}Mo production has been provided by the German federal government and the Free State of Bavaria. The investment costs for the production facility will be made from the TUM operational budget and fully recovered through the implementation of FCR for all ^{99}Mo production, including also the provision of any ORC services.

Japan 2016

Japan participates in the $^{99}Mo/^{99m}Tc$ supply chain as a manufacturer of both generators and unit doses of ^{99m}Tc based radiopharmaceuticals to be used directly at hospitals. The country does not have a reactor used for target irradiation for ^{99}Mo production or a processing facility but has considered a number of alternative technology approaches to produce material domestically. Japan does not have control over the upstream activities of the supply chain and is largely a price-taker for ^{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 manufacturers, hospitals and patients.

The two Japanese manufacturers are commercial organisations that operate on a FCR basis and have reported substantial increases in the cost of bulk ^{99}Mo material in the last few years. During the same period there have been no increases in the reimbursement rates for ^{99m}Tc based radiopharmaceuticals and all cost increases have had to be absorbed by the commercial organisations. Mainly due to its geography, Japan is vulnerable to unplanned producer outages that disrupt supply. Higher costs, concerns about security of supply and cost pressures have driven efficiency actions along with changes to medical practice that have contributed to a continuing decline in the demand for $^{99}Mo/^{99}Tc$ in Japan over recent years.

Korea 2016

Korea does not have bulk ^{99}Mo production capabilities, but it is a producer of $^{99}Mo/^{99m}Tc$ generators for the local area market and is dependent on the global market for supply as a price-taker. To resolve this dependency on outside sources of supply and with increasing costs for bulk ^{99}Mo, the Korean government decided to start building new ^{99}Mo production infrastructure. The Kijang Research Reactor (KJRR), with both a reactor and a processing facility, will use domestic competencies they have in the design and build of nuclear facilities. Korea intends to be initially a domestic, then later a global ^{99}Mo producer. Preparations are underway for the construction of the new infrastructure and it is expected to be commissioned in 2021.

The most recent plans are to initially produce about 400 six-day Ci/week EOP in a normal week of operation, which is approximately 4-5% of global demand, with a progressive increase in capacity planned at a later stage.

The Korean government is providing financial support for the construction of the new reactor and processing plant, and has indicated that it will manage the operation of the reactor. A decision on whether the government or a private company will operate the processing plant has not yet been made. The Korean government fully supports the six HLG-MR policy principles and intends to implement them for the new facilities.

The Korean government has indicated that it intends to provide ORC services to the global supply chain. Given Korea's geographical location, a realistic approach could be to provide reciprocal ORC services with other processors, as Korea will require ORC services itself for the periods when the new reactor would be under maintenance.

The Korean generator manufacturer has reported substantial recent price increases for bulk ^{99}Mo supply, and as a price-taker, the Korean reimbursement rates for ^{99m}Tc based imaging studies have been partially adjusted.

The Korean government is currently carrying out studies to develop policy, including considering the implications for reimbursement rates, for the application of FCR and ORC principles for KJRR based on the NEA FCR methodology.

Netherlands 2016

The Netherlands is an important supplier in the world market for bulk ^{99}Mo, playing important roles as target irradiator, processor and ^{99}Mo/^{99m}Tc generator producer and distributor to nuclear pharmacies and hospitals. However, although the Netherlands has the full supply chain, the chain is only partially integrated. The HFR research reactor in Petten is owned by the European Commission but separately operated by the Nuclear Research and Consultancy Group (NRG) and has increased normal available capacity to produce up to 6 200 six-day curies ^{99}Mo EOP in a normal week of operation, which represents a capacity of more than 65% of global demand.

The HFR uses LEU fuel but still presently irradiates HEU targets, which are supplied to two processors, Curium and IRE, for the production of bulk ^{99}Mo. NRG is completing the activities needed to convert to using LEU targets for irradiations for both processors, with conversion anticipated to start in 2017. NRG is also responsible for waste management from the extraction and purification of ^{99}Mo that takes place by Curium 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, it does not fully recover its costs. For example, certain waste management support services are not fully paid for.

Following major outages in recent years, NRG has conducted a thorough cost review of reactor operations. The full costs of future reactor operations have been identified, and these are allocated to specific activities such as ^{99}Mo production. NRG has not yet implemented its FCR methodology for ^{99}Mo production but has estimated how far it has progressed in completing transition to FCR, or when that may be completed. The HFR has reserve capacity available, albeit a small amount relative to its total available irradiation capacity. Much of this is not 'true' ORC, but results from operational flexibility. NRG receives some payments for ORC, but only a portion of the costs are recovered.

The Dutch government together with the French government provides support funding for the general operation of the HFR through a Supplementary Programme, this funding is for non-isotope activities and does not subsidise the production of bulk ^{99}Mo. However the Dutch government has separately provided support with an EUR 82 million loan to NRG staged over a 10-year period to 2024, to allow a lifetime extension programme to be implemented for the HFR. The loan is based on market conforming interest rates and risk surcharges that must be repaid during the term of the loan. The Dutch government fully supports the HLG-MR 6-principles, but feels obliged to support NRG to ensure operational stability during a period of transition and increased costs. NRG has substantially increased prices for the irradiation services provided and anticipates further important price increases to be implemented.

Curium, a commercial company with majority activities in the US, operates a ^{99}Mo processing facility on the same site as NRG. The processing facility is owned by the Energieonderzoek Centrum Nederland (ECN) and operated by Curium under a long-term contract. Curium processes HEU targets irradiated in the HFR and two other reactors in Europe. Curium are well advanced in a programme to convert completely to LEU targets and are in the process of increasing processing capacity up to 5 000 six-day curies ^{99}Mo EOP in a normal week of operation, which represents more than 60% of global demand. Curium has received some financial support from US government for the LEU conversion programme, but no financial support from Dutch government. In addition to processing bulk ^{99}Mo, Curium also manufactures ^{99m}Tc generators in the Netherlands and ships bulk quantities of ^{99}Mo to the US for the production of ^{99m}Tc generators in their US production facility for the North American market and they also sell some bulk ^{99}Mo radiochemical to the open market. Mallinckrodt (now part of Curium) did not respond to the 3rd Self-Assessment but operates as a commercial entity that fully recovers its costs in normal operation, although the processing operation is presently supplied by reactors that have not yet fully achieved FCR.

The Netherland’s progress report indicators are presented in the boxes below.

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

Company/organisation name: NRG – Netherlands (irradiator)

Full-cost recovery: Significant progress made

Comments:

NRG has identified its full ^{99}Mo-specific costs at the HFR reactor, and has allocated the common costs to specific services such as ^{99}Mo irradiations. NRG plans to implement FCR but has no fixed timescale for full implementation. It has been increasing its prices and is communicating the reasons to its customers.

Some progress has been made since the second self-assessment in 2014.

Outage reserve capacity: Some progress made

Comments:

NRG holds ORC capacity when irradiation positions are not fully utilised by processors (not ‘true’ outage reserve capacity, but rather operational flexibility). However, the costs of this service are only partially paid for.

No change since 2014.

Downstream, the Dutch government is not directly involved in setting reimbursement rates for medical diagnostics. Data provided indicates that there has been a minor increase in the overall reimbursement level of imaging procedures in the period since 2012. Reimbursement in the Dutch healthcare system is on a bundled ‘per procedure’ basis, where reimbursement payments are made between medical insurance companies and hospitals, while ^{99m}Tc generator price agreements are made between the hospitals and the generator manufacturers. This makes it difficult to directly identify the cost and value of the radioisotope. Hospitals have some freedom to allocate the reimbursement resources they receive to the different components of a medical diagnostic procedure, including the radioisotope.

The Dutch government addressed the security of supply of medical isotopes and the implementation of full-cost recovery during the EU-Presidency in the first half of 2016, resulting in a research project that will be carried out by the European Commission. The study will, among other aspects, investigate the reimbursement systems in EU member states.

In the long term, the HFR is planned to be replaced by a new reactor, PALLAS, which is anticipated to start irradiating targets for ^{99}Mo production around 2024. It is the objective of the Dutch government and the PALLAS organisation to irradiate targets for ^{99}Mo production on a FCR commercial basis.

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

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

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

Comments:

No change since 2012 and 2014

Outage reserve capacity: NO RESPONSE – unable to assess the implementation status of ORC

Comments:

No change since 2012 and 2014

The NEA is unable to assess the company's progress and commitment to implementing the HLG-MR policy principles of FCR and paid ORC.

Poland 2016

Poland is an established participant in the global ^{99}Mo/^{99m}Tc supply chain. The MARIA reactor has been converted to LEU fuel and has increased irradiation capacity to 2 700 six-day curies EOP in a normal week of operation and has been typically producing more than 5% of global demand on an annualised basis. The reactor is ready to start irradiation of LEU targets. The reactor operator, the National Centre for Nuclear Research (NBCJ), has experienced increased costs and has achieved increased prices with the objective of achieving FCR, but this is unlikely to be achieved before 2020.

The Polish government still provides specific financial support to NBCJ; it provides funds covering part of the spending related to reactor safety and supporting infrastructure, this is considered essential support to ensure appropriate safety levels are maintained at the facilities. MARIA has the ability to provide ORC services on a paid basis, but at this time does not receive any ORC funding.

Poland also plays a role in the supply chain with the production of ^{99}Mo/^{99m}Tc generators and other isotopes by the Polish Institute of Atomic Energy (POLATOM) which are supplied on a commercial basis in Poland and to surrounding countries. Increases in bulk ^{99}Mo prices have been reported, but it has been difficult to increase ^{99}Mo/^{99m}Tc generator prices.

There remains a plan to build a new processing plant for bulk ^{99}Mo in Poland, with a capacity of 300 six-day Ci/week, but financing has not yet been agreed and commissioning of the facility will not be before 2022. The intent would be to introduce processing on a FCR basis.

Poland’s progress report indicators are shown in the box below.

Progress towards ensuring a long-term reliable supply of $^{99}Mo/^{99m}Tc$
Company/organisation name: NCBJ – Poland (irradiator)
Full-cost recovery: Some progress
Comments:
NCBJ is trying to apply FCR for irradiation services at the MARIA reactor; however, despite price increases, FCR levels have not yet been reached. Some government funding is received for essential safety related spending.
Some progress since the second self-assessment in 2014, but full implementation of FCR remains distant.
Outage reserve capacity: Not started
Comments:
The MARIA reactor has significant capacity to offer ORC services, but at present it is not paid for ORC provision.
No change since 2014.

Russia 2016

The Russian Federation has become a player in the global supply of $^{99}Mo/^{99m}Tc$, operating three reactors and two processing facilities in a local area network to provide bulk supplies of ^{99}Mo for international supply and for domestic production of $^{99}Mo/^{99m}Tc$ generators. The network has a production capacity of up to 1 350 six-day curies EOP in a normal week of operation, equivalent to around 15% of total global demand. Production has been established on FCR principles, but full achievement of FCR has yet to be achieved as production has been in a scale-up phase. Full capacity is not being utilised, allowing for ORC to be provided from within the local area network. Production is based upon HEU targets, but the Russian Federation intends to convert to LEU targets for irradiations by 2018.

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).

There has been some past investment in LEU target technology R&D from the Russian government, but recent limited investments in ^{99}Mo production infrastructure have come from the domestic operational budgets of the producers. Each producer has responsibility for fully funding the management of waste from their facilities.

Progress towards ensuring a long-term reliable supply of $^{99}Mo/^{99m}Tc$
Company/organisation name: Russia (irradiator and processor network)
Full-cost recovery: Some progress
Comments:
The facilities apply their own FCR methodology for irradiations, processing and waste management and have been in an expansion phase as they increase their production capacity. FCR has not been fully achieved yet.
Outage reserve capacity: Significant progress made
Comments:
ORC is provided within the operational network. Payment for it is provided by default since processors cover the whole reactor operational costs, regardless of the engaged production capacity.

As a result, ORC provision presently exceeds recommended values. As utilisation of the total production capacity increases, the ability to provide its own ORC services will decrease. New production facilities are planned and overall future production capacity will increase thus increasing the ORC values.

External ORC services are not required.

South Africa 2016

South Africa is a significant participant in the global $^{99}Mo/^{99m}Tc$ supply chain as an irradiator and processor. NTP also makes $^{99}Mo/^{99m}Tc$ generators, solely for their domestic market. The South African Nuclear Energy Corporation (NECSA) operates the SAFARI reactor and NTP Radioisotopes (NTP), a subsidiary of NECSA, produces bulk ^{99}Mo from both HEU and LEU targets irradiated at SAFARI. The reactor uses LEU fuel and has the processes in place to fully convert to LEU targets for ^{99}Mo production. NTP has paid for the process to convert to LEU, with some financial contributions from the US DoE. Full conversion to LEU targets has been delayed by a combination of lack of market demand and some delays in the licencing of LEU based $^{99}Mo/^{99m}Tc$ and ^{131}I products in certain markets. The maximum production capacity is 3 000 six-day curies in a typical week of operation and NTP has been typically producing around 20% of global demand in recent years.

Both NECSA and NTP have implemented a FCR methodology and operate the reactor and processing plant, including waste management on a fully 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 and receive ORC capacity services which are paid for on commercial terms, including a reciprocal commercial agreement in place with ANSTO in Australia. Specific quantities of paid ORC are not held; SAFARI maintains in-house ORC, the costs of which are covered by the general supply agreement. NTP are also working to re-establish on-site redundancy within their processing infrastructure.

FCR analysis has also been performed for the production of $^{99}Mo/^{99m}Tc$ generators and discussions with the South African Department of Health have allowed for the increases in generator prices, although South Africa operates a reimbursement by medical procedure model.

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 FCR methodology including capital and waste management costs. NECSA also includes decommissioning and decontamination costs in its FCR methodology and applied it to the price they charge for irradiation services, resulting in the price increasing when costs increase, or when capacity utilisation varies. NECSA have experienced important increases in irradiation costs in recent years.

Outage reserve capacity: Fully implemented

Comments:

NECSA provides internalised ORC services to NTP based on FCR methodology NTP pay for all operational costs of the SAFARI reactor whether full capacity is used or not.

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

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

Full-cost recovery: Fully implemented

Comments:

NTP has implemented a FCR methodology including capital and waste management costs. NTP also includes decommissioning and decontamination costs in its FCR methodology. NTP have experienced important increases in processing costs in recent years, primarily related to investments needed to solve production problems experienced during LEU conversion. NTP has been unable to fully recover these cost increases through associated price increases for its products down the supply chain as several supply chain members refuse any form of price increase.

Outage reserve capacity: Fully implemented

Comments:

NTP has back-up agreements conducted under commercial contracts to provide and receive ORC with other processors in the supply chain.

Spain 2016

Spain is a downstream participant in the ^{99}Mo/^{99m}Tc supply chain, primarily as a purchaser of ^{99}Mo/^{99m}Tc generators and consumer of ^{99m}Tc. Following the 2009-2010 global supply shortage, the Spanish National 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. At the initiative of the marketing authorisation holders, this was reviewed again by the National Commission in 2014 and a further significant increase of up to 65% was agreed for generators.

At the end-user level, no specific examination has taken place to assess the effect of the increase of generator prices on the overall cost of a patient dose in the clinic, or the sufficiency of the ^{99m}Tc-related reimbursement to cover the full costs of the isotope, although in principle, the Spanish National Health Service funds 100% of the costs that are incurred in the public hospitals. Spain has made very specific positive actions to help fund the move towards the supply chain achieving FCR pricing.

United Kingdom 2016

The United Kingdom (UK) participates in the global ^{99}Mo/^{99m}Tc supply chain as a generator manufacturer and consumer of ^{99m}Tc. The generator manufacturer endeavours to implement FCR as a commercial entity and has reported substantial bulk ^{99}Mo cost increases in recent years, but also continued resistance to generator price increases from their customer base. Information from the end-user market indicates that long duration fixed price purchase agreements and supplier switching has tended to insulate the end-user market from substantial generator price increases.

In the UK, health care funding (including for radioisotope/radiopharmaceutical reimbursement) is managed through local NHS Health Trusts. Hospital nuclear medicine departments are responsible for purchasing the final radiopharmaceutical product from in-house or centralised nuclear pharmacies, some of which operate commercially. The main contracting structure is often regionalised, with the end users being relatively disconnected from the price negotiation process for ^{99m}Tc generators. The UK reimbursement system is primarily based on a fee for procedure basis; there is little interest in separating out radioisotope costs, so the radioisotope is not separately reimbursed.

There is a good awareness in the UK about ^{99}Mo/^{99m}Tc security of supply issues, including the need for price increases throughout the supply chain for long-term market sustainability. The market has responded to supply uncertainty by implementing measures to increase the efficiency of ^{99m}Tc use, such as increasing ^{99m}Tc elutions per generator, procurement of smaller generators and the adoption of more intelligent generator purchasing patterns. The UK has generated a number of reports on the local market and has shown some interest in the possibility of introducing alternative technologies for supply, in particular direct production of ^{99m}Tc with Cyclotrons operated by commercial nuclear pharmacies.

United States 2016

The United States (US) is the single largest consumer of ^{99m}Tc, accounting for approximately one-half of global demand. The US is involved in the $^{99}Mo/^{99m}Tc$ supply chain as a generator manufacturer and patient dose distributer through nuclear pharmacies that operate on a commercial basis. The US-based generator manufacturers apply FCR principles. One manufacturer is an integrated operation with processing capabilities in The Netherlands, and the other is a generator producer only and contracts with a number of processors. In both cases, bulk ^{99}Mo supply is dependent on imports from Australia, Europe and South Africa and, until recently, also from Canada.

To reduce dependence on ^{99}Mo imports while advancing non-proliferation goals, the US, through the National Nuclear Security Administration (NNSA) is supporting three US commercial entities to accelerate the establishment of four technologies, each with the objective to develop the capability to produce at least 3 000 six-day curies of ^{99}Mo EOP per normal week of operation without the use of HEU. NNSA provides up to $25 million to facilitate initial development efforts for each project on a 50%-50% cost-share basis and, in accordance with the HLG-MR policy principles, all additional costs are the responsibility of the commercial entity and any investors. The commercial entities will be responsible for the management of wastes attributable to their ^{99}Mo production. NNSA does not currently plan to support any new projects beyond the four it is currently supporting.

The American Medical Isotopes Production Act of 2012, which is the legal basis for NNSA's ^{99}Mo program, also directs the US Department of Energy (DOE) to establish a Uranium Lease and Take-Back Program (ULTB). Under ULTB, established in January 2016, DOE makes LEU available through lease contracts to US commercial producers of ^{99}Mo, and DOE retains responsibility for the final disposition of any spent nuclear fuel or radioactive waste that was 1) created by the production of ^{99}Mo using the leased LEU and 2) determined by the Secretary of Energy to have no commercial disposition pathway available to the producer. The legislation directs DOE to implement the ULTB program under full-cost recovery principles.

The US government supports the HLG-MR policy approach by implementing all six principles, including providing financial support to existing $^{99}Mo/^{99m}Tc$ producers to convert to LEU targets. It is anticipated that DOE's support to international ^{99}Mo projects will cease upon their completion of conversion to LEU targets.

With no current direct influence on the ^{99}Mo supply side, the US government is encouraging demand-side changes to help move the market towards LEU conversion, while ensuring the application of FCR in domestic projects.

The US government has examined the feasibility of providing a separate, supplemental payment for the isotope when used in radiopharmaceutical and diagnostic procedures but has determined that a single payment mechanism is not feasible across the hundreds of payer systems. Instead, for fee-for-service Medicare, the Centers for Medicare and Medicaid Services (CMS) reviewed ^{99m}Tc reimbursement mechanisms, including both current reimbursements and projections of the impact of cost changes due to conversion to LEU. Current cost estimates and their projections were then evaluated against current payments and evaluated against the projected responses of the market and its components to future increases. Based on historical changes in both the price of ^{99m}Tc and in the cost/price of other components of the nuclear medicine diagnostic services, it was concluded that demand should be relatively inelastic, and that even large percentage increases in the cost of ^{99}Mo would be relatively insignificant compared to the variation in the total cost of the imaging service and should be able to be readily absorbed by the healthcare system. Nevertheless, sudden local supplier switches from subsidised ^{99m}Tc to FCR ^{99m}Tc could create competitive disadvantages for a time after the switching took place.

To address that possibility, CMS introduced a payment adjustment policy as an interim payment mechanism to smooth the transition while the healthcare market adapted to more fully absorb the price increases based on non-HEU production and FCR transitions. Under this policy, hospitals paid under the Outpatient Prospective Payment system are paid USD 10 for billing outpatient tests that use ^{99m}Tc-based products derived without the use of HEU. The use of non-HEU derived ^{99m}Tc-based products is reported with HCPCS code Q9969. Medicare payment for HCPCS code Q9969 payment remains in place for calendar year 2017, but the overall utilisation by healthcare providers of the additional payment remains relatively low. Nevertheless, recent independent activities have identified that other health insurers (i.e. beyond CMS) have now also adopted the principles of the additional Q-code payment, indicating an additional measure of progress resulting from this initiative. It will be important that this initiative remains in place until at least such time as full LEU conversion has been established.

Chapter 7. Conclusions

The results from the third self-assessment of the global ^{99}Mo/^{99m}Tc supply chain show some further progress towards achieving implementation of full-cost recovery (FCR) and paid outage reserve capacity (ORC), but also reconfirm that overall progress is slow and not yet complete. Slow progress in implementing the six HLG-MR policy principles agreed by the governments represented on the HLG-MR, led to the deadline for full implementation of June 2014 being missed. The slow rate of progress has continued despite the formal agreement of 14 HLG-MR countries to adhere to the Joint Declaration that was established in December 2014, with the purpose of reconfirming government support to implement the policy principles.

Not all irradiators are achieving FCR (Principle 1) or receive full payment for holding and providing ORC services; in addition, not all processors fully source and/or pay for ORC at irradiators (Principle 2) and thus, they do not incur the associated ORC costs. When not all processors maintain and fully pay for adequate levels of ORC, ORC remains undervalued and at risk of appearing as excess capacity in the market. This negatively impacts overall reliability of supply. At present, security of supply still relies upon some unpaid goodwill and support from some governments, incomplete implementation of FCR continues to put downward pressure on global ^{99}Mo prices and can act as an impediment to investment needed in new or replacement capacity.

Almost all prospective multipurpose reactors intended for ^{99}Mo production, and potential suppliers using alternative technologies are planning to implement FCR, although it remains to be seen if all of them will do so. Even if not all of the planned new/replacement irradiation and processing projects come online, there is potential for significant overcapacity in the global market from around 2020 and thereafter, as described in the *2017 Medical Isotopes Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2017-2022 (*NEA, 2017). If any projects do not implement FCR, existing ^{99}Mo producers at all levels of the supply chain would be under price pressure in order to stay in business. Such an undesirable scenario might conceivably force some existing market participants to exit.

At the processor and generator manufacturer levels of the supply chain, most participants are commercial entities and recover their full costs (plus profit) related to ^{99}Mo production. However, when they purchase through supply chains from irradiators, which are not yet able to charge FCR price levels, the lack of FCR achievement at the irradiator level affects the whole supply chain and is not transparent.

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 FCR prices are passed down the supply chain from supported reactors and where insufficient paid ORC is held, the generator manufacturers do not presently pay the “true” cost of bulk ^{99}Mo and insufficiently pay for the ORC needed to ensure security of supply. However, as many generator manufacturers are unable to fully pass on cost increases they receive to their customers, they are becoming squeezed, with their commercial viability being put at risk. Generator manufacturers and beyond in the supply chain, recognise the need for ORC, but in general, the supply chain participants at those steps are unwilling to separately pay for ORC, so the burden of ORC costs is loaded at the processor step in the supply chain.

The third self-assessment process itself (a response to Principle 6), has been slow and painstaking. The lack of prompt response from some governments has been an important part of the delay. A concern has also been the partial response, or no response, received from some important supply chain participants and some governments. The most prompt response to the third self-assessment came from generator manufacturers. This was not the case in the first self-assessment, and this may reflect the greater commercial pressure that is now being felt by generator manufacturers.

In many countries there have been only limited actions taken by government towards assessing and adjusting reimbursement and in some countries there have been no increases in reimbursement rates at all, not even to match the effects of normal inflation. A number of countries (e.g. Brazil, Czech Republic and Spain) have taken specific independent actions to adjust reimbursement policy.

While progress has been made, the $^{99}Mo/^{99m}Tc$ market continues to be economically unsustainable in its present form, with FCR implementation incomplete, ORC still undervalued and not universally implemented and with actions to address reimbursement challenges often being limited or lacking. Insufficient reimbursement to pay for the full cost of supply of medical radioisotopes, including the full costs of providing adequate reserve capacity, maintains substantial backpressure in the commercial supply chain. That backpressure is transferred back through the supply chain and directly acts against the implementation of the HLG-MR policy objectives.

While it is critical that participants at the start of the supply chain take every action possible to implement FCR and participants in the middle of the supply chain take responsibility for holding and paying for sufficient ORC; it is essential that actions are taken to ensure sufficient reimbursement is available to adequately fund those demands. An economically sustainable market structure can only be established when the policy principles have been fully implemented and funded.

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Annex 1. List of self-assessment questionnaire responses

Government of Argentina via National Commission of Atomic Energy (CNEA) (reactor/economic)	Completed questionnaire
CNEA (irradiator) – Argentina	Completed questionnaire
CNEA (processor) – Argentina	Completed questionnaire
Government of Australia via the Australian Nuclear Science and Technology Organisation (ANSTO) (reactor/economic)	Completed questionnaire
Government of Australia, Department of Health (healthcare)	Completed questionnaire
ANSTO – Australia (irradiator)	Completed questionnaire
ANSTO – Australia (processor)	Completed questionnaire
ANSTO – Australia (Generator Manufacturer)	Completed questionnaire
Government of Belgium (Ministry of Economy, Small and Medium Enterprises, the Self-employed and Energy) (reactor/economic)	No response provided
Government of Belgium (Federal Agency for Medicines and Health Products) (healthcare)	Completed questionnaire
Nuclear Research Centre SCK-CEN – Belgium (irradiator)	Partial response
Institute for Radioelements (IRE) – Belgium (processor)	Completed questionnaire
Brazilian Commission of Nuclear Energy (CNEN) (generator manufacturer)	Completed questionnaire
Government of Brazil via Brazilian Society of Nuclear Medicine (healthcare)	Completed questionnaire
Government of Canada (Natural Resources Canada) (reactor/economic)	Completed questionnaire
Government of Canada (Health Canada) (healthcare)	Completed questionnaire
Atomic Energy of Canada Limited (AECL), (former irradiator)	Completed questionnaire
Nordion – Canada (former processor)	Completed questionnaire
Government of the Czech Republic (Ministry of Industry and Trade) (reactor/economic)	Completed questionnaire
Government of the Czech Republic (Ministry of Health) (healthcare)	Completed questionnaire
Research Centre Řež – Czech Republic (irradiator)	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) (reactor/economic)	Completed questionnaire

Government of France (Ministry of Health)	No response provided
CEA – France (former irradiator)	Completed questionnaire
IBAM Group – France (generator manufacturer)	Completed questionnaire
Government of Germany via Bavarian State Ministry of Education, Culture, Science and Art (reactor/economic)	Completed questionnaire
Government of Germany (Federal Ministry of Health) (healthcare)	Completed questionnaire
Technical University of Munich – Germany (potential irradiator)	Completed questionnaire
Government of Japan via the Japan Radioisotope Association (reactor/economic)	Completed questionnaire
Government of Japan via the Japan Radioisotope Association (healthcare)	Completed questionnaire
FUJIFILM RI Pharma Co. Ltd. – Japan (generator manufacturer)	Completed questionnaire
Nihon Medi-Physics Co. Ltd. – Japan (generator manufacturer)	Completed questionnaire
Government of Korea (reactor/economic as future irradiator)	No response provided
Government of Korea (healthcare)	No response provided
KAERI (generator manufacturer)	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 (now part of Curium) – Netherlands (processor)	No response provided
Mallinckrodt (now part of Curium) – Netherlands (generator manufacturer)	No response provided
Government of Poland (Ministry of Economy) (reactor/economic)	Completed questionnaire
Government of Poland (Ministry of Health) (healthcare)	No response provided
National Centre for Nuclear Research (NBCJ) – Poland (irradiator)	Completed questionnaire
Polatom – Poland (generator manufacturer)	Completed questionnaire
Government of the Russian Federation via Atomic Energy Corporation – ROSATOM (reactor/economic)	Completed questionnaire
Government of the Russian Federation (healthcare)	No response provided
ROSATOM – RIAR and Karpov Institute – Russian Federation (irradiators)	Completed questionnaire
ROSATOM – RIAR and Karpov Institute – Russian Federation (processors)	Completed questionnaire
Government of South Africa via NTP Radioisotopes (reactor and economic)	Completed questionnaire
Government of South Africa via NTP Radioisotopes (healthcare)	Completed questionnaire
Nuclear Energy Corporation South African (NECSA) via NTP Radioisotopes – South Africa (irradiator)	Completed questionnaire
NTP Radioisotopes – South Africa (processor)	Completed questionnaire
Government of Spain (Ministry of Health) (healthcare)	Completed questionnaire

Government of the United Kingdom (Department of Health) via British Nuclear Medicine Association (BNMA) (healthcare)	Completed questionnaire
GE Healthcare – United Kingdom (generator manufacturer)	Completed questionnaire
Government of the United States (National Nuclear Security Administration) (reactor/economic)	Completed questionnaire
Government of the United States (Centers for Medicare and Medicaid Services and Food and Drug Administration) (healthcare)	Completed questionnaire
Lantheus Medical Imaging – United States (generator manufacturer)	Completed questionnaire
Mallinckrodt (now part of Curium)– United States (generator manufacturer)	No response provided

Annex 2. Comments by self-assessment participants

During the 3rd self-assessment process, all of the supply chain participants and governments were asked their opinion about "main barriers that remained to implement full-cost recovery" and given the opportunity to express any concerns about the implementation, or not, of full-cost recovery. They were also asked about their observations concerning the HLG-MR policy approach in general and whether aspects should be revisited.

During the questionnaire assessment process, the NEA Secretariat collated together in an anonymised fashion, important comments and opinions that had been expressed. They were put into four separate sections based upon the source of the comments (e.g. irradiators, processors, generator manufacturers and governments). These were then circulated to all HLG-MR participants for review, requesting that the participants should identify where they felt support for individual comments or otherwise, to indicate if they had specific concerns about the content of a comment that should be reviewed further.

The feedback from this process identified a number of comments that had a greater level of support from a range of different participants. Unsurprisingly, some participants supported their own original comments, but such "double support" of a comment was discounted. A number of the more strongly supported comments had similar themes and were often supported by the same reviewers.

From this input and review process, the NEA Secretariat synthesised three main statements for each section. This was done by taking the phrasing from the most strongly supported comments and combining them together where they had a common theme. These statements included input from a broad range of participants in each case. The synthesised statements identify the most strongly supported comments made by the 3rd self-assessment participants during the process and were then circulated for further review by all HLG-MR participants. There was overall strong support for those statements and they are presented here in this Annex.

Irradiators

Very significant fuel and target cost increases have been experienced and nuclear facility investment costs have increased to manage safety and security issues.

Not all governments are actively pushing implementation of FCR; governments continue to fund the operation of many reactors.

The market cannot absorb the price increase needed to fully implement FCR, it is not possible to transfer the total costs to the price of the final product.

Processors

Reimbursement policies are not moving in the direction of the HLG-MR policy principles; there is no current mechanism to increase reimbursement in order to account for FCR and ORC. The concept of ORC "take or pay" is impossible to pass down the supply chain.

A high level of market competition is the main barrier to being able to implement FCR; margins are under heavy pressure forcing intense productivity improvement.

Customers continue to value cheapest price over compliance with the HLG-MR principles; there are examples of generator prices that are controlled by government where they refuse to accept price increases.

Generator manufacturers

It is difficult to support the move to FCR due to the cost containment efforts in the national health systems; the rigidity of reimbursement systems and tight government budgets create pressure. Despite discussions to increase prices to compensate for the significant cost increases, no clear vision is available.

Implementation of FCR and ORC should be obligatory, but reimbursement should be increased first. The market still views any increase in price at the generator step of the market as being an increase in the manufacturer's profit, which is incorrect.

There is no visibility about how cost increases are linked to components like FCR and ORC implementation or to LEU conversion. We receive no or very limited information concerning ORC from our present suppliers.

Governments

It is necessary to recruit the Ministry of Health of all countries in this debate; they are part of the problem and part of the solution. Without a specific methodology to implement the effects of FCR, the reimbursement situation will remain unchanged; suppliers have had to absorb the cost increases so far.

The investment environment for new ^{99}Mo production capacity continues to be challenging, there is reticence in the market to accept an increase in the price of radiopharmaceuticals needed to implement FCR. No additional funds have been specifically allocated to cover the increased costs of radioisotopes.

Countries not operating on the basis of FCR will interfere with global efforts to move to a truly commercial paradigm. An independent review of implementation of FCR accounting principles and independent inter-comparison of its implementation, facility to facility, is needed.

Annex 3. 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.