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

Final Report of the Fourth Mandate of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR)

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This report was written by Kevin Charlton of the NEA Division of Nuclear Technology Development and Economics. Detailed review and comments were provided by HLG-MR members and participants.

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Executive summary

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

In its first mandate, the HLG-MR conducted a comprehensive economic study of the ^{99}Mo/^{99m}Tc supply chain, which identified the key areas of vulnerability and major issues to be addressed. It was clearly demonstrated that the fundamental issue in the market was an unsustainable economic model. The pricing structure at nuclear research reactors prior to the 2009-2010 supply shortage was based on some government subsidisation that had led to market prices that were below full cost. This often led to an under-valuation of the product and of the associated medical procedure and to chronic underinvestment in the infrastructure necessary for production. It was identified that pricing must recover the full cost of production to promote the economic sustainability needed to ensure a long-term secure supply of medical radioisotopes. The NEA also examined the global demand and supply capacity for ^{99m}Tc and assessed potential alternative ^{99}Mo/^{99m}Tc production technologies.

The HLG-MR released a policy approach, including six principles (see Appendix 1) and supporting recommendations to help resolve the economic issues in the ^{99}Mo/^{99m}Tc market. The aim was for full implementation within three years of adopting the policy approach, so that is to say by June 2014; but that objective was not achieved and in general progress in implementing policy principles was slow.

To encourage the supply chain participants in the implementation of the policy approach and to continue to provide an international forum for discussion and collaboration, the HLG-MR mandate was subsequently renewed three times.

In the second mandate (2011-2013) and the third mandate (2014-2015), the HLG-MR worked to encourage the implementation of the six policy principles and an industry transition away from the use of highly enriched uranium (HEU) targets for ^{99}Mo production. Projects were undertaken by the NEA that resulted in the publication of documents and reports to assist in implementing the HLG-MR policy approach. These focused efforts towards encouraging the implementation of full-cost recovery (FCR) pricing and the holding of paid outage reserve capacity (ORC). FCR is necessary to allow essential investments to be made in the supply chain and paid ORC helps ensure that adequate reserve production capacity is available at short notice in the event of an unplanned outage. Payment for ORC services is an essential feature of a reliable and economically sustainable supply structure.

The NEA, with the participation of key stakeholders, devised a methodology for calculating the full costs of ^{99}Mo production and for valuing and paying for ORC. The NEA evaluated supply chain participants through two self-assessments on progress towards implementing HLG-MR principles related to FCR and ORC, and also evaluated the role of governments in the $^{99}Mo/^{99m}Tc$ market. These reviews found that most reactor operators and processors were gradually implementing FCR for ^{99}Mo production, although this process was happening at differing speeds and not everywhere. The reports identified that while the use of paid ORC capacity was increasing, it was not yet fully accepted and was held at an insufficient level by the market to ensure secure supply.

The NEA also carried out a comprehensive study of the potential level of impact of converting from HEU to low-enriched uranium (LEU) targets for ^{99}Mo production, concluding that the impact would be felt mostly in the upstream segment of the supply chain and would increase costs and waste. Another report presented a number of policy options for government decision-makers to consider how supply chain participants could be encouraged to convert to LEU targets. The NEA also published an update on likely ^{99}Mo demand and supply capacity for the period to 2030, identifying some periods of potential supply shortage that required attention.

To increase awareness among governments of the importance of appropriate reimbursement for ^{99m}Tc and to assist in identifying potential actions, the NEA issued a discussion document on separate reimbursement for the radioisotope from the diagnostic medical procedure. This so-called “unbundling” was proposed to achieve greater transparency in determining the cost and the value of the radioisotope.

During its normal bi-annual meetings, the HLG-MR reconsidered the six policy principle approach. While this was supported as still being an appropriate approach, the Association of Isotope Producers and Equipment Suppliers (AIPES, now Nuclear Medicine Europe - NMEu) on behalf of supply chain participants proposed a 7th policy principle. They proposed that “Sufficient medical reimbursement should be available to cover full-cost recovery throughout the supply chain in all markets.” The proposal was debated in detail, but not adopted as government stakeholders felt that the principle of sufficient reimbursement was adequately covered by the first policy principle of implementing FCR.

In summary, the second and third mandates showed that, while commendable progress had occurred in many areas, major issues remained in the $^{99}Mo/^{99m}Tc$ market, in particular, continued government subsidies in some markets, insufficient paid ORC and inadequate final reimbursement for ^{99m}Tc. Potential future periods of supply shortage were identified, particularly concerning the anticipated planned loss of significant irradiation and processing capacity around the 2016 period.

In late 2015, it was agreed that the HLG-MR mandate should be renewed for a further two years. The initial objective had been to complete the work of the HLG-MR by late 2017, but reviews in 2017 identified continuing concerns about potential capacity levels during the 2017-2018 period and an extension of the fourth mandate was proposed and agreed, with the final end date of 31 December 2018.

This report concerns the fourth mandate including its extension and represents the final concluding report of the HLG-MR, which concluded its work on 31 December 2018. During the fourth mandate, the HLG-MR continued its efforts to help ensure the global security of supply of $^{99}Mo/^{99m}Tc$ through implementation of the six policy principles. The NEA undertook a further self-assessment review of the $^{99}Mo/^{99m}Tc$ supply chain, focusing again on progress with the implementation of FCR and paid ORC and the role of governments in the market, on both an economic and on a healthcare level.

The third self-assessment (NEA, 2017b) again confirmed that overall progress was slow (see Chapter 2), in particular at the irradiator step of the supply chain where FCR was still not achieved by a majority of irradiators. General pressure on health care budgets had continued, with increased “bundling”, rather than “unbundling” for medical isotope reimbursement and with some consequent negative effects on nuclear medicine utilisation rates. Only limited progress was reported on adjustments to reimbursement rates, hampering overall progress and reconfirming that an economically sustainable supply chain had not yet been achieved.

The NEA conducted a series of annual studies of market demand and production capacity looking at a 6-year rolling window, with the final report during the fourth mandate period covering the 2018 to 2023 supply period (see Chapter 3).

During the course of the fourth mandate, the HLG-MR delegates requested that the NEA co-operate with the OECD Health Division to look at aspects of healthcare policy with regard to the need for radioisotopes in national healthcare systems and to analyse the current market structure and identifying barriers to implementation of FCR. Co-operation was agreed and a scope of work set out and approved by the HLG-MR delegates and additional Voluntary Contributions were provided to fund the work. The Health Division report is discussed in this report (see Chapter 4) although the work was not completed until after the end of the fourth mandate.

1. Introduction to the fourth mandate

In April 2009, following the shortages of the key medical radioisotopes ^{99}Mo and its decay product ^{99m}Tc, the NEA Steering Committee for Nuclear Energy established the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). During its first mandate (2009-2011), the HLG-MR, working with medical isotope stakeholders, examined the major issues that affected the short-, medium- and long-term reliability of ^{99}Mo/^{99m}Tc supply. They completed a comprehensive assessment of the key areas of vulnerability in the supply chain and identified the issues that needed to be addressed. The NEA also examined the supply and demand for ^{99m}Tc, undertook a full economic analysis of the supply chain, and reviewed potential alternative ^{99}Mo/^{99m}Tc production technologies. This work resulted in the release of several reports that have been issued under *The Supply of Medical Radioisotopes* series (see the References section). In conclusion of the first mandate, the HLG-MR released a policy approach to move the ^{99}Mo/^{99m}Tc supply chain towards a sustainable economic basis. The policy approach included six principles (see Appendix 1), with an aim for these to be implemented within three years of their release; this was not achieved.

In April 2011, the NEA Steering Committee approved a second mandate (2011-2013) for the HLG-MR, in which the main objective was to implement the agreed policy approach in a timely manner. The NEA Steering Committee also agreed that the group would report to the Committee for Technical and Economic Studies on Nuclear Energy Development and the Fuel Cycle (NDC). Since then, the group's activities have been included in the NDC programme of work, but separately paid for by Voluntary Contributions.

During the second HLG-MR mandate, the focus was on implementing the six principles and analysing the impact on the market of conversion from HEU to LEU targets. Priority was given to investigating the implementation by supply chain participants of the first two policy principles (on FCR and paid ORC) in a timely and globally consistent manner. The NEA, in co-operation with key stakeholders, created methodologies for calculating full costs and for valuing and paying for ORC. Reports on these methodologies and their implementation were issued, and were particularly useful to the upstream segment of the industry where the most change was needed. The NEA also worked with key stakeholders to ensure that the methodologies were applied in a consistent manner.

To better understand the transition from HEU to LEU targets for ^{99}Mo production, the NEA undertook a project to study the impacts on the ^{99}Mo/^{99m}Tc supply chain and to propose actions to support that transition, resulting in the release of two reports.

The NEA undertook a review by self-assessment of the progress made in the ^{99}Mo/^{99m}Tc supply chain in implementing the policy approach. The review focused on progress with FCR and paid ORC, and government's economic role in the market. This identified those supply chain participants that were making good progress towards the implementation of the HLG-MR policy approach; it also highlighted players that had not made significant progress (or perhaps had not yet started). The results were published as the first self-assessment report. The NEA also produced an update on the likely ^{99}Mo/^{99m}Tc demand and supply capacity for the period to 2030.

During the third HLG-MR mandate, the focus continued on implementing the six principles of the HLG-MR policy approach. Two further studies were undertaken to review the global market demand and capacity looking at a six-year window (e.g. the period 2015 to 2020) as this time-period had been identified in earlier studies as being at higher risk of supply shortage. These reports reviewed and updated the capacity of the existing supply chain participants and investigated and reviewed the potential capacity of prospective projects. The second of the studies looked into demand in more detail, using a different approach to collect data and introduced a standardised approach to data collection for timelines of prospective new projects. The latest study is discussed in more detail in Chapter 3 of this report.

The NEA organised a second self-assessment review of the $^{99}Mo/^{99m}Tc$ supply chain with key supply chain participants. The review focused on progress with implementing FCR and paid ORC and government's role in the market at both an economic and also a healthcare level. This again identified slow progress overall and concluded that it was unlikely that the supply chain itself would take the necessary actions needed without some further direct actions from governments.

In that context, at the 21-23 January 2014 HLG-MR meeting, the NEA was asked to develop a more formal statement of commitment to the HLG-MR principles. Discussions with member countries led to a consensus document, the Joint Declaration on the Security of Supply of Medical Radioisotopes. On 17 December 2014, the OECD Council formally noted that eleven countries had officially signed up to the Joint Declaration; subsequently three more countries confirmed their adherence.

During its normal bi-annual meetings, the HLG-MR reconsidered the six policy principle approaches. This was supported as still being an appropriate strategy; however, the Association of Isotope Producers and Equipment Suppliers (AIPES, now Nuclear Medicine Europe - NMEu) on behalf of supply chain participants proposed a 7th policy principle. They proposed that "Sufficient medical reimbursement should be available to cover full-cost recovery throughout the supply chain in all markets." The proposal was debated in detail, but not adopted as government stakeholders felt that the principle of sufficient reimbursement was adequately covered by the first policy principle of implementing FCR.

In the final report of the third mandate, the NEA expressed concerns that a market that was financially contracting near the end of the supply chain was at odds with a market where increased costs were being pushed through the supply chain in the move towards FCR pricing. The final HLG-MR meeting of the third mandate included a representation from Cardinal Healthcare, the world's largest nuclear pharmacy group that represents between 20 and 25% of all ($^{99}Mo/^{99m}Tc$) generators purchased worldwide. The Cardinal Healthcare representative gave a presentation from the perspective of the nuclear pharmacy operator, which stated that the nuclear pharmacy point in the supply chain was under heavy stress from increasing upstream costs (implementation of FCR), but simultaneously was experiencing downward price pressures from the healthcare system on the services they were providing.

On 25 June 2015, the fourth mandate of the HLG-MR was approved by the NDC at its 67th meeting. The broad deliverables for the fourth mandate of the HLG-MR included:

- Carrying out studies related to the security of supply, e.g. updating the global 99Mo/99mTc medium- and long-term demand and capacity forecast.
- Evaluating progress towards the implementation of the HLG-MR policy approach through a third self-assessment by the global supply chain. This should include progress with conversion from highly enriched to low-enriched uranium targets for ^{99}Mo production and an analysis of key issues affecting the supply chain (e.g. implementation of full-cost recovery, the availability and

commitment to paid reserve capacity, the investment environment for new infrastructure and sufficient isotope reimbursement).

- Closer engagement with downstream supply chain participants (e.g. ^{99m}Tc generator manufacturers, nuclear pharmacy operators, nuclear medicine and other associated healthcare professionals and healthcare policy makers) to understand the impact of economic forces throughout the entire supply chain.
- Re-examining the six HLG-MR policy principles, in particular, those where market participants have reported having significant implementation challenges and consider if adjustment is required and additional policy principles appropriate.
- Sharing of information on the status of the ^{99}Mo/^{99m}Tc market and regular reporting on developments within the market, to increase transparency and encourage consistency in approach, implementation and communication.
- Communicating the need to implement the HLG-MR policy approach to governments and supply chain participants, including working more closely with nuclear medicine and associated healthcare professionals and healthcare policy makers.
- Supporting the implementation of all aspects of the HLG-MR policy approach (e.g. through the identification of specific, local actions individual members would take within fixed timescales, where appropriate and feasible and reporting back to the HLG-MR at subsequent meetings the progress made in implementing those actions). These could include: encouraging the implementation of full-cost recovery for new/replacement ^{99}Mo production infrastructure; pursuing options to encourage conversion to low-enriched uranium targets for ^{99}Mo production; working with healthcare policy makers to explore reimbursement approaches that would help achieve economic sustainability in the whole supply chain; studying different isotope reimbursement models.
- Reporting regularly on HLG-MR actions to governments and other major stakeholders.

Many technical achievements associated with the introduction of new technologies were successfully demonstrated during the fourth mandate period and it was considered that the remaining market problems were no longer technical, but were solely economic. It was proposed that the HLG-MR activities should in the future take a different direction to concentrate more upon the economic aspects and a joint project working on Healthcare Economics aspects of the market with the OECD Health Division was proposed.

Good overall progress was made and supply was solidly maintained until the NTP facility in South Africa sustained an extended unplanned shutdown in November 2017, leading to some chronic shortages of material. The HLG-MR delegates were concerned that overall capacity would still be relatively low in 2018 and proposed an extension of the fourth mandate from late 2017 until the end of 2018. The proposed new work on Healthcare Economics aspects was further developed and agreement was reached with the OECD Directorate for Employment, Labour and Social Affairs for a joint project to be developed and additional Voluntary Contributions were made available to fund the extension of the HLG-MR fourth mandate until the end of December 2018 and to co-develop the new joint project with the OECD Health Division.

By early 2018 a substantial conversion to LEU targets (Curium, the Netherlands) was successfully achieved, moving the market to greater than 70% conversion to non-HEU usage. The first alternative technology project from NorthStar successfully achieved product registration and market introduction in the United States. Despite these achievements, continuing problems at the NTP facilities in South Africa meant that the market remained in a period of chronic shortage throughout 2018.

This report concludes the fourth and final mandate of the HLG-MR.

2. Third self-assessment of the global $^{99}Mo/^{99m}Tc$ supply chain

In June 2011, the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) released its policy approach to move the $^{99}Mo/^{99m}Tc$ supply chain to a sustainable economic basis to ensure the security of supply of medical isotopes. The policy approach is based on six principles, which the HLG-MR agreed to implement by June 2014, but the objective was not achieved by that time.

As a direct action to implement HLG-MR principle 6, in November 2015, the NEA initiated a third self-assessment of the $^{99}Mo/^{99m}Tc$ supply chain. The main objective was to evaluate progress towards the implementation of the HLG-MR policy principles made by supply chain participants since the second self-assessment in 2014.

A total of 60 questionnaires were sent to key supply chain participants – reactor operators, processors and generator manufacturers, and governments. A total of 51 responses were received for an overall response rate of 85% (compared to 77% in the first self-assessment and 84% in the second self-assessment). While the final overall rate of response was good, the time and effort required to collect sufficient self-assessment returns was very significant. Initial poor response rates were discussed at a number of HLG-MR meetings, where a minimum level of response rate for a successful study was established. The final report was substantially delayed as a result, with publication finally achieved in late 2017. At that time, the minimum response rate had been achieved for all groups with the exception of governments concerning health policy aspects (only 69% final response rate).

The other final response rates were similar to those achieved 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.

Full-cost recovery - Irradiators

Progress towards implementing full-cost recovery (FCR) by irradiators continued at a slow pace and only the irradiators wholly integrated with a processor (e.g. Australia and South Africa) had fully implemented FCR. The percentage of irradiator capacity classified as "Fully implemented" increased slightly due to an increase in services available from irradiators already fully implementing FCR and partly due to a reduction in total irradiation capacity (i.e. non-implementers were diluted by FCR implementers who increased capacity). Progress had been made in other classifications, with "Significant progress made" reported at 74% of the total world irradiator capacity and no irradiators remained classified as having not started the process.

An increased recovery for operational costs related to ^{99}Mo production was reported by all irradiators through higher prices, but all also reported substantial cost increases well above inflation levels due to increased costs for essential maintenance, safety related activities and low-enriched uranium (LEU) conversion. Increased costs played an important role in offsetting the progress made increasing prices towards achieving FCR.

Some capital, decommissioning and waste management costs are still being subsidised by governments. And yet, the assessment shows that in many cases the subsidy exists due to the government's perceived obligation to keep facilities safe and operational rather than for the objective of subsidising the actual production of medical isotopes.

The total normal available weekly irradiator capacity reported for 2016 was slightly lower (5.9%) than the level that had been reported in 2014 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.

Irradiators were each asked to estimate their progress in terms of the percentage of FCR pricing that had been achieved at the end of 2015. Irradiators that responded represented more than 70% of normal global irradiation capacity. They could be split into two groups, those already achieving FCR and the others that reported a level of FCR achievement that ranged between only 45% and 70%. Analysis on a weight-averaged basis of the two groups combined showed an overall average FCR achievement of around 70%, indicating a substantial increase was still needed to achieve 100% FCR pricing at the irradiator level of the supply chain. However, this also indicated that the level of change needed to achieve 100% FCR should not be insurmountable.

Full-cost recovery - Irradiators

There was a mixed picture at the processor level. As with irradiators, it was only processors wholly integrated with an irradiator (e.g. Australia and South Africa) that had 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 was 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 perhaps technically correct, the NRU reactor that supported that processing capacity was itself not FCR compliant, so this could be considered as being a "phantom" implementation of FCR. Another important factor was that the processor in the "No response" classification substantially increased capacity; as a result, the "No response" classification increased to 32% of all capacity in 2016 from 21% in the 2014 report.

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 likely be a "phantom" claim of FCR from the total supply chain perspective.

Like irradiators, the processor step in the chain also saw a loss of important processing capacity in the period between 2014 and 2017 (i.e. Atomic Energy of Canada Limited/Nordion capacity moved to hot standby in October 2016 and ceased operation in early 2017). There had been partially compensation by increased capacity from remaining supply chain participants. As a result, the total normally available weekly processing capacity reported for 2016 at 15 400 six-day Ci ^{99}Mo per week at the end of processing (EOP) was 7.1% lower than the equivalent level reported in 2014. Overall, it can be concluded that there had 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 their 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 had their margins squeezed during the period. They reported substantial resistance to price increases from the generator manufactures and from further downstream the supply chain.

Outage reserve capacity

The implementation of outage reserve capacity (ORC) by irradiators improved, with the percentage of irradiator capacity classified as "Fully implemented" increased to 60% from 42%. Although there was some progress, a concern remained in that two irradiators still made no progress, although for different reasons.

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

Progress was also reported regarding paid ORC at the processor level of the supply chain, with 65% of the processing capacity reporting significant progress or having fully implemented ORC, up from 45% in 2014. The improvement is substantially due to an increase in capacity of existing processors that were already holding paid ORC and from the exit from service of processors that were not holding paid ORC. A substantial quantity of overall processing capacity (32%) was again classified as "No response" concerning ORC implementation, increasing the uncertainty of the overall progress towards ORC implementation by processors.

Generator manufacturers

There was a very good level of response 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. A common theme was strong competition in the market, which made it challenging to increase the prices of generators supplied to nuclear pharmacies and to hospitals.

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, they fell into two different subcategories: a group that had been able to make important price increases and a group that had been able to make only little, or no price increase during the whole period from 2012 to 2015. Both groups had experienced similar overall levels of cost increase during the same period. In all cases, the degree of cost increase was reported to be higher than the degree of price increase recovered, indicating that many generator manufacturers may have had their margins squeezed in recent years.

The confidence that generator manufacturers had in their supplier holding adequate levels of paid ORC was directly linked to their experience of the responsiveness of the supplier when supply was challenged. More remote customers who relied on suppliers that did not clearly communicate or perhaps did not demonstrate their commitment to holding paid ORC had the lowest levels of confidence. If all generator manufacturers had a high level of confidence in the level of paid ORC that their suppliers held, then it would be more likely that the ORC was being correctly valued. Fully implementing appropriate levels of paid ORC capacity, clearly communicating and demonstrating its provision, recognising its full cost and accepting the need to transfer those costs down the supply chain are all vital steps to ensuring future economic sustainability and to underpinning market confidence in the security of 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 are commercial, for-profit entities.

Although host 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 domestic ^{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 clearly agreed by all HLG-MR members.

A review of likely future government subsidy showed positive progress, with the number of fully government-subsidised projects likely to be operational by 2022 reduced to zero, and only one project remaining as anticipating partial subsidy. The total number of projects, and also their total anticipated production capacity, has substantially decreased since 2014. This is partly due to a specific time window being introduced in the latest analysis and substantial time delays for some potentially government-subsidised projects that took projects outside of the 2022 time window used in that report.

Despite the decrease, the total anticipated capacity reported remained substantial, representing 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 was likely to be introduced into service in the period up until 2022 would 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 successfully and sustainably enter the market while present market conditions prevail.

Third self-assessment conclusions

The results from the third self-assessment of the global $^{99}Mo/^{99m}Tc$ supply chain showed some further progress towards achieving full-cost recovery (FCR) and paid outage reserve capacity (ORC), but also reconfirm that overall progress is slow and incomplete. 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 (Principle 2); in addition, not all processors fully source and/or pay for ORC 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. 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 activities. However, when they purchase through supply chains from irradiators, which are not yet able to charge FCR price levels, the lack of FCR 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 government 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 was an important part of the delay. A concern has also been the partial response, or non-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, the 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 limited or lacking. 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 also 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 all the policy principles have been fully implemented and funded.

3. Demand and capacity reviews for the period until 2023

In August 2012, the NEA released an updated ^{99}Mo supply and demand projection from 2012 to 2030. According to that update, the period of greatest concern was 2016-2020, when ^{99}Mo/^{99m}Tc supply was projected to become strained from the scheduled permanent shutdown of the NRU reactor in Canada and of the OSIRIS reactor in France.

During the period of the third mandate of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR), two demand and capacity updates for the period 2015 to 2020 were conducted to look in detail at this period of concern and this series of reports were extended during the fourth mandate period with a report produced every year. During the period 2012 to 2017, market supply was maintained successfully on an almost continuous basis, although some limited supply shortages were reported as occurring in 2013-2014 and supply became stressed late in 2017 due to an unplanned outage at the NTP facility (South Africa). Supply would continue to be stressed in 2018 due to different problems at NTP, and some transient problems elsewhere in the supply chain and periods of chronic supply shortage were experienced.

Below is a summary abstracted from the August 2018 report (for full details see "The Supply of Medical Radioisotopes: 2018 Medical Isotope Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2018-2023" [NEA, 2018]).

Demand update

Supply chain participants were requested to provide capacity utilisation data for their facilities in terms of the percentage of their production capacity utilised during each operating quarter during the period from 2012 to 2017, along with the actual operating periods per facility (e.g. operational days). Analysis of that data was used to determine the level of recent market demand, with reported global utilisation capacity being taken as a surrogate for the demand in the market.

The global estimate of demand growth has been maintained as in previous reports and used the same levels of projected annual increase since 2014; as a result, the projected demand level in 2018 has increased to approximately 9 400 6-day Ci 99Mo per week at the end of processing (EOP). The level of production required at EOP at the processor point in the supply chain has likely increased since the end of routine production in Canada due to the lengthening of some supply lines that has increased overall decay loss during transportation.

This increase in production requirement is unlikely to represent an actual increase in product demand at the final end-user level in the supply chain, so should be considered primarily as extra stress and extra costs to the system.

Capacity update

The NEA regularly updates the lists of current and planned new ^{99}Mo/^{99m}Tc irradiation and processing projects based on the most recent information available from the supply chain. Updates include revisions to production start/end dates, additional "qualified" potential projects and the anticipated impact of some existing supply chain participants converting to the use of LEU targets.

The capacity analysis looks at three capacity scenarios and presents them in six-month intervals. The scenarios are:

- Scenario A: A "Reference" scenario – a baseline case that includes only currently operational irradiation and processing capacity.
- Scenario B: The "Technological challenges" scenario – this adds all of the anticipated projects, but does not include all of their planned new ^{99}Mo production capacity in some cases. For example, new reactor-based projects, given their proven technology and direct access of product to the existing supply chain, are assumed to start production on their announced commissioning dates and are included from their first full year of production. On the other hand, new alternative technology projects (including reactor- and non-reactor-based), given the unproven nature of these technologies, are assumed to have a 50% probability of starting full scale production on their announced commissioning dates.
- Scenario C: A "Project delayed" scenario – built on the "technological challenges" scenario by further assuming that LEU conversion and all new projects are delayed by one year beyond their anticipated first full year of production.

In all three scenarios, the six-month forecast intervals are based upon a 50/50 split of operating capacity between the two six-month periods in a year, unless a specific adjustment has been identified for a specific period. Scenarios B and C in the report did not include all of the announced new projects. Four projects were excluded as their likely commissioning dates had been delayed beyond 2023. It was not suggested that these projects would not become operational, but that they were not scheduled to operate in the forecast horizon (2018-2023).

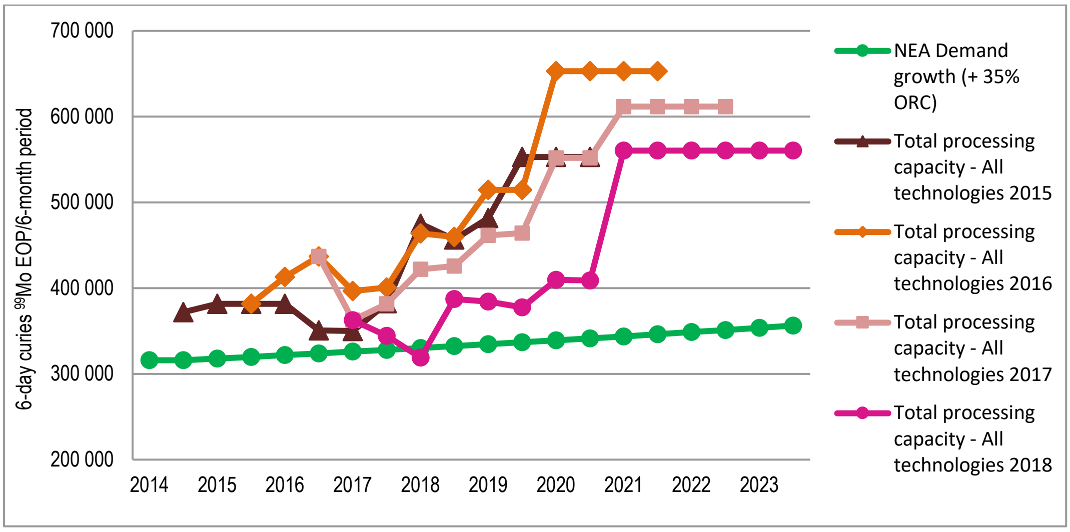
The approach for the report concerning the effects of LEU conversion was consistent with earlier reports and a simple blanket effect of a 10% level of efficiency loss has been applied in all cases where LEU conversion was still to take place, although more than 70% of the market had already converted by very early 2018, so the future effects of LEU conversion had decreased.

Project delays have been significant in recent years, so an additional analysis of the cumulative effects of project delays was included in the most recent report. Figure 3.1 shows the cumulative effect of project delays by modelling the change to the "Technological challenges scenario B" projection line for total processing capacity on a year-to-year basis for the period starting in 2015 until the projection in 2018.

The projection for total processing capacity for scenario B in 2015 (dark brown line) anticipated a reduction of processing capacity by 2017 (e.g. the period after the end of NRU routine production), followed by a recovery in capacity by 2018, which then continued to mostly increase in a number of steps out to 2020.

By 2016, the equivalent scenario B projection (orange line) showed that substantial actions had been planned by the existing supply chain members, either through increasing capacity from existing facilities, or by adding additional capacity and making transition plans. These actions anticipated adding some capacity in 2016 ahead of the end of routine production at the NRU reactor and still anticipated some reduction in capacity in 2017 when the NRU reactor stopped routine production. The projection then stabilised in 2017 and increased from 2018 onwards, with the total anticipated capacity by the start of 2020 being higher as other new projects were added.

Figure 3.1. Scenario B – "Technical challenges": Effect of multi-year delays



The 2017 projection of scenario B (pink line) showed that not all of the additional capacity anticipated in the 2016 report had been achieved and that the effect of reduced capacity anticipated at the end of NRU routine production would be deeper than in the 2016 projection. The 2017 projection also anticipated some minor project delays from 2018 onwards (the graph line moves to the right) and a decrease in the anticipated total capacity by 2021 as some project capacity estimates were scaled back.

The 2018 scenario B projection (red line) showed the first negative effect of the NTP unplanned outage on the short-term outlook (in 2018) and identified more extended delays to the introduction of planned additional capacity. The 2018 projection also identified a further decrease in the total anticipated capacity that would be achieved by 2021 as a result of the withdrawal of a substantial project.

When compared with the 2016 projection (orange line), the 2018 projection (red line) showed the main bulk of the anticipated projects had been progressively delayed to later years. The effect of the delays can be seen in the sequential scenario B projection lines that progressively move in steps both to lower levels (less capacity) and also to the right side of the graph (delayed capacity). The total processing capacity projected to be available in the 2019-2020 period in the 2018 scenario B projection was at the lowest level since the start of this series of reports.

The cumulative effect of unplanned outages, project delays and project cancellations suggests that total processing capacity would remain under pressure until at least 2020. It should be noted that the projections shown in figure 3.1 are from scenario B and are therefore relatively optimistic projections.

Demand and capacity conclusions

There have been positive developments, with conversion to 100% production using low-enriched uranium (LEU) targets at the Curium processing facility in early January 2018 and the licensing of the first alternative technology, the NorthStar RadioGenix generator system in early February 2018. However, further processing capacity from the new ANM facility was delayed, and some irradiation capacity reductions that resulted from LEU conversion confirmed decreased efficiency in LEU target irradiation.

The extended unplanned outages at the NTP facility pushed processing capacity below the NEA demand +35% outage reserve capacity (ORC) guideline in 2018. Further delays were experienced in the introduction of some alternative irradiation and processing technologies and a substantial project was withdrawn on economic grounds. Delays to large conventional technology projects continued and pushed back some projects beyond 2023. The multi-year delays of many projects remain a concern.

The 2018 report concluded that when existing facilities were well-maintained and well-scheduled and when unplanned outages were avoided, the total irradiator and processor capacity should be sufficient. However, the NTP problems continued through 2018 and into 2019, with a return to service under increased regulatory surveillances and at reduced capacity levels. As a result, the processing capacity available in early 2019 remained below the NEA demand +35% ORC guidelines and supply remained under pressure.

The importance of the supply chain fully implementing the recommended level of paid ORC has been reiterated. When further project delays occur and no additional processing capacity is added above the 2018 levels, then the capability to manage any adverse events, particularly concerning processing will be low and will reduce progressively with time.

4. Joint work with the OECD Health Division

By 2017, it was considered that the supply of ^{99}Mo/^{99m}Tc had stabilised as a result of the actions of existing supply chain participants co-ordinated by the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) and the continued support of some governments. Many of the technical problems that led to the 2009-10 crisis had been solved. However, self-assessment by the HLG-MR showed that full implementation of the six policy principles was slow and, in particular, that participants in the supply chain struggled to implement policy principles 1 and 2, related to full-cost recovery (FCR) and outage reserve capacity (ORC) (NEA, 2017b). Prices that do not reflect the full costs of medical isotope production and of their distribution throughout the supply chain pose risks of delay or cancellation of investments in existing or new facilities and could imply an increased risk of further supply disruptions or shortages in the future.

During the course of the fourth mandate, the HLG-MR delegates requested that the NEA co-operate with the Health Division (HD) of the OECD Directorate for Employment, Labour and Social Affairs (ELS), to look at aspects of healthcare policy with regard to the need for radioisotopes in national healthcare systems, analyse the current market structure, and identify barriers to implementation of FCR, the first policy principle developed by the HLG-MR. Co-operation was agreed and a scope of work set out and approved by the HLG-MR delegates and additional Voluntary Contributions were provided by governments to fund the work.

The publication *The Supply of Medical Radioisotopes: An Economic Diagnosis and Possible Solutions* (OECD, 2019) that resulted presents findings of the joint work between the NEA and the OECD Health Division. Joint work focused on nuclear medicine (NM) diagnostic procedures that use ^{99m}Tc, which is the most common diagnostic radioisotope. It did not cover supply of other diagnostic or therapeutic radioisotopes. The geographic scope of the report included the United States and all countries that responded to the OECD Health Division Survey on Health Care Provider Payment for Nuclear Medicine Diagnostic Services: 13 of 23 countries that are members of the European Union and the OECD as well as Australia, Canada, Japan and Switzerland.

The report contains five main sections: Chapter 1 summarises the utility of NM diagnostic procedures from a clinical perspective and outlines the main alternatives to ^{99m}Tc-based procedures; Chapter 2 provides an overview of the volume of NM diagnostic procedures conducted in the countries in scope; Chapter 3 summarises health care provider payment for NM diagnostic services and the financial incentives that arise from provider payment mechanisms; Chapter 4; analyses market structures in the ^{99}Mo/^{99m}Tc supply chain; and, Chapter 5 identifies the main barriers to FCR and outlines possible policy options that governments could take to achieve FCR in the production of ^{99m}Tc.

The HD report proposes a number of possible policy options that may need to be implemented in some type of combination and identifies that there is no single solution. Five policy options are described to move towards FCR within the supply chain and a further two policy options are discussed to reduce reliance on the present supply chain.

The policy options are presented along with general words of caution and with a discussion about some of the likely strengths and weaknesses of each of the options.

The policy options to move towards FCR within the supply chain are:

1. Phased and co-ordinated discontinuation of funding of nuclear research reactor (NRR) costs attributable to Molybdenum-99 production by governments of producing countries

2. Increasing price transparency in the supply chain

3. Setting a temporary price floor for irradiation

4. Introducing a commodities trading platform for bulk Mo-99

A possible alternative to a market-based approach is:

5. Direct funding of Mo-99 production by governments of end-user countries

The policies to reduce reliance on the current supply chain are:

1. Increasing use of substitute diagnostic imaging modalities or substitute isotopes

2. Move towards alternative methods to produce Mo-99/Tc-99m (NEA, 2019: 17-18).

The details of the various policy options are not discussed in this summary note as the Health Division report was completed after the end of the 4th HLG-MR mandate and it would be more appropriate for interested parties to read that full report.

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Appendix 1. HLG-MR Policy Principles

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

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

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

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

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

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

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

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