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The Supply of Medical Radioisotopes

Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ^{99}Mo/^{99m}Tc Market, 2015-2020

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Acknowledgements

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

The Nuclear Energy Agency (NEA) greatly appreciates the information provided by supply chain participants on the current molybdenum-99 (^{99}Mo)/technetium-99m (^{99m}Tc) production capacity situation to facilitate the creation of an updated capacity and demand forecast for the 2015-2020 period. This forecast is intended to help policy makers, producers, and other stakeholders take appropriate actions to ensure the long-term security of supply of the key medical isotopes ^{99}Mo and its decay product, ^{99m}Tc.

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

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Chapter 1. Introduction

Medical diagnostic imaging techniques using technetium-99m (^{99m}Tc) account for approximately 80% of all nuclear medicine procedures, representing 30-40 million examinations worldwide every year. Disruptions in the supply chain of these medical isotopes – which have half-lives of 66 hours for molybdenum-99 (^{99}Mo) and 6 hours for ^{99m}Tc, and thus must be produced continuously – can lead to cancellations or delays in important medical testing services. Unfortunately, supply reliability has declined over the past decade due to unexpected or extended shutdowns at a few of the ageing, ^{99}Mo-producing research reactors and processing facilities. These shutdowns have created conditions for global supply shortages.

At the request of its member countries, the OECD Nuclear Energy Agency (NEA) became involved in global efforts to ensure a secure supply of ^{99}Mo/^{99m}Tc. Since June 2009, the NEA and its High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) have examined the causes of supply shortages and developed a policy approach, including principles and supporting recommendations to address those causes. The NEA has also reviewed the global ^{99}Mo supply situation periodically, using the most up-to-date data from supply chain participants, to highlight periods of reduced supply and underscore the case for implementing the HLG-MR policy approach in a timely and globally consistent manner.

In 2012, the NEA released a ^{99}Mo supply and demand forecast up to 2030, identifying periods of low supply relative to demand and potential global shortages. This report updates the 2012 forecast[1], focusing on the much shorter and potentially critical 2015-2020 period. In that period, the OSIRIS reactor in France will permanently shut down operations and one of the largest irradiators for medical isotopes, the National Research Universal (NRU) reactor in Canada, will cease ^{99}Mo production. In the same period, new reactor- and non-reactor-based ^{99}Mo/^{99m}Tc projects are expected to be commissioned in various countries. It is important to analyse the overall impact and timing of these events to understand how global production capacity might be affected.

This report presents global irradiation and processing capacity under three capacity scenarios. Unlike previous reports, the projected production capacity and demand are presented in six-month intervals (January-June and July-December) during the forecast period. The NEA recognises that, as forecast time intervals decrease (e.g. from one year to six months), the timing accuracy of the forecast may decrease too. The results in this report, however, should be interpreted in light of projected future trends as opposed to actual forecast values.

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[1] The scenarios presented by the NEA in this report should not be construed as a prediction, forecast or expectation of which projects will proceed and when. The scenarios are only meant to be illustrative of possible future situations, whether planned new projects materialise or not.

Chapter 2. Demand update

In 2011, the NEA released a study with the results of a global survey of future demand for ^{99}Mo/^{99m}Tc (OECD/NEA, 2011), developing a scenario based on a data assessment by an expert advisory group. The study showed ^{99}Mo/^{99m}Tc demand growth up to 2030 in both mature and emerging markets, with stronger growth forecast in emerging markets.

In a subsequent report, *A Supply and Demand Update of the Molybdenum-99 Market* (OECD/NEA, 2012), the NEA estimated global ^{99}Mo demand at 10 000 6-day curies per week[2]. This was a decrease from the previously estimated 12 000 6-day curies per week, resulting from a number of changes that had occurred in the market as a consequence of the 2009-2010 supply shortage. These changes included: better use of available ^{99}Mo/^{99m}Tc, more efficient elution of ^{99m}Tc generators and patient scheduling, and an increased use of substitute diagnostic tests/isotopes.

As a starting point, the demand scenarios in this report use the NEA 2012 estimate of 10 000 6-day ^{99}Mo curies from processors. However, the NEA has modified the expected demand growth rate from the 2011 study, based on more recent information from supply chain participants. The annual growth rate in mature markets (North America, Europe, Japan and the Republic of Korea) is assumed to be 0.5%, and in emerging markets 5% during the five-year forecast period[3]. These growth rates are also applied to the 2012-2015 period, although it is outside the scope of this report.

What is the "true" ^{99}Mo/^{99m}Tc demand?

As in previous reports, the NEA has no direct way to measure the amount of ORC in the market, but all supply chain participants agree that the principle of having ORC is essential to sustainability and reliable supply[4]. The need for ORC was illustrated recently, with unplanned outages at major ^{99}Mo producers (e.g. the HFR reactor and the Mallinckrodt processing plant in the Netherlands, and NTP's processing plant in South Africa) These outages tested the efforts by the supply chain to ensure reliable supply and resulted in a number of small but limited shortages. The ageing production infrastructure and the increasing likelihood of more similar outages in the future require the constant availability of ORC. As a result, the "true" demand for ^{99}Mo/^{99m}Tc should include some level of ORC, as the situation over the recent past has shown that ORC is in fairly constant use. In this report, demand is expressed at two different levels of ORC – 35% and 62%. Demand with no required ORC is also presented as a reference in the document for some irradiation cases. The method and reasons for choosing these particular ORC levels are explained on the next page.

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[2] A six-day curie is the measurement of the remaining radioactivity of ^{99}Mo six days after it leaves the processing facility (i.e. at the end of processing – EOP).

[3] In the modelling exercise, the 0.5% growth rate is applied to all mature markets together and the 5% rate is applied to all emerging markets together, and not to individual countries.

[4] Outage reserve capacity is required to ensure a reliable supply by providing back-up irradiation and/or processing capacity that can be called upon in the event of an unexpected or extended shutdown.

Given the recent producer outages and using the previous NEA approach to demand, an amount of ORC has been added to the demand curve and the production capacity is compared to these demand curves with ORC. Supply chain participants have indicated that an ORC of 50% would give an acceptable probability of reliable supply of irradiated targets to the processor. This means that the "true" demand curve is between the two demand curves shown in Chapters 4-6 in this document (at ORC levels of 35% and 62%).

In the HLG-MR principles, it was proposed that a processor should hold sufficient reserve capacity to replace the largest supplier of irradiated targets in their supply chain. This is the (n-1) criterion. In fact, there have been multiple occasions over the last few years when the (n-2) criterion (replacing the two largest suppliers) would have been more appropriate. Hence this report has calculated both these values for the global supply chain and used them in comparison with the supply capacity. Of course, the actual levels for (n-1) and (n-2) will change as producers enter and exit the market, and will depend on reactors' operating schedules and the largest reactor(s) available for production in a given week. However, this report has estimated the levels at the beginning of 2014. These levels have been estimated by utilising current data for the eight major reactors' normal available capacities and their estimated actual production[5]. They have been calculated by dividing the actual production of the largest reactor(s) by the total remaining available capacity in the system.

Given that the actual ORC levels will change in time, the ORC levels in this document should only be used with caution in providing advice or making decisions. For comparison some figures also show the demand curve with no ORC, but we do not believe that this is a good representation of the 'true' demand, given the history of periods of shortage over the past few years, the HLG principle that supports having ORC and the advice of the supply chain on the importance of ORC for reliability of supply.

More specifically, the 35% level is based on a calculation of required ORC to maintain supply after the exit of OSIRIS and the NRU from the market, when the largest remaining reactor (the HFR) has an unplanned outage. This reflects the (n-1) criterion for outage reserve capacity post-2016 (a scenario that is likely to happen). The 62% level is based on a calculation of required ORC to maintain supply prior to the exit of OSIRIS and the NRU, when both the NRU and HFR (the two largest irradiators) have unplanned outages. This reflects the (n-2) criterion pre-2016 (a scenario that is unlikely to happen). The "true" required level of ORC is likely between the 35% and 62% levels.

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[5] Actual production is estimated from normal available capacity, adjusted for the number of operating days in a year. The eight major reactors are: NRU, HFR, BR-2, SAFARI-1, LVR-15, MARIA, OSIRIS, and OPAL.

Chapter 3. Scenarios and assumptions for ^{99}Mo/^{99m}Tc production capacity

The NEA has updated the list of current and planned new ^{99}Mo/^{99m}Tc irradiation and processing projects, based on the most recent information available from the supply chain. The updates include: revisions to production start/end dates, additional potential projects and impacts of converting to using low-enriched uranium (LEU) targets on ^{99}Mo capacity and production. Appendix 1 provides a list of current and potential ^{99}Mo/^{99m}Tc producers, along with the status of projects as of April 2014. It should be noted that not all potential new production facilities may be operational by the stated times or at all. This is particularly the case for projects that rely on commercial funding, given the prevailing below-full-cost-recovery prices in the market and the resulting challenges to develop solid business cases.

Supply chain participants acknowledge that, given the inability to store these radioisotopes for later use, ^{99}Mo/^{99m}Tc supply will generally match demand. Therefore, the intent of this forecast is not to predict the actual ^{99}Mo/^{99m}Tc supply based on changes in production capacity, but to identify periods of increased risks of supply shortages, in order to inform government policy makers, industry, and nuclear medicine professionals. Such high-risk periods are when the production capacity curve is above but very close to the demand curve or where it is below the demand curve.

The forecast horizon for ^{99}Mo/^{99m}Tc production capacity is five years (2015-2020) to reflect important changes in global production capacity – the planned exit from the supply chain of the OSIRIS reactor in France and the NRU reactor in Canada, and the anticipated commissioning of new reactor- and non-reactor-based projects in Europe, North and South America, and Australia.

The capacity scenarios presented in this document are based on the data in Appendix 1, with a caveat for current irradiators and processors[6]. Appendix 1 provides the current normal available capacity for producing reactors and processors, including the projects at the Research Institute of Atomic Reactors (RIAR) and the Karpov Institute of Physical Chemistry in Russia. The capacity and production values used in the different scenarios also incorporate the impacts from LEU conversion, which will reduce overall production capacity (see *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* – OECD/NEA, 2012).

This document explains the results obtained from three capacity scenarios for the 2015-2020 period, presented in six-month intervals (January-June and July-December):

- Reference scenario – a baseline case that includes only current irradiation and processing capacity.
- "Technological challenges" scenario – adds some (but not all) of the planned new ^{99}Mo production capacity. New reactor-based projects, given their proven technology, are assumed to start production on their announced commissioning

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[6] In all three scenarios in this report, the BR-2 reactor in Belgium is assumed to increase its ^{99}Mo irradiation availability (i.e. have a higher annual capacity) when it re-enters the supply chain following its planned refurbishment in 2015-2016.

dates. New alternative (including reactor- and non-reactor-based) projects are assumed to have a 50% probability of starting production on their announced commissioning dates, given their unproven technologies in the market, i.e. only 50% of this new capacity is added in the forecast[7].

- "Project delays" scenario builds on the "technological challenges" scenario by further assuming that LEU conversion and all new projects are delayed by one year – and as a graphic illustration with a two-year delay.

An "all-in" scenario (where all planned new/replacement projects are included) is not considered in this updated forecast for two reasons:

(1) If all new projects proceed as announced, there will be a massive overcapacity in the ^{99}Mo/^{99m}Tc market, which is unsustainable in the long term.

(2) Including such a scenario will not significantly alter the conclusions, as most of the new/replacement capacity is expected to be commissioned towards the end of the forecast period 2015-2020 at the earliest, when large excess capacity is already projected (see the results from the three scenarios in the next sections).

Irradiation capacity in all three scenarios, for each six-month forecast interval, is forecast based on historical reactor operating schedules for the period 2011-2013. In that three-year period, normal available irradiation in each six-month interval has been estimated at approximately 50%, so an even 50/50 split between the two 6-month periods in a year is used in the forecast.

It should be noted that the two alternative scenarios in this report – "technological challenges" and "project delays" – do not include all announced new projects[8]. Two projects have been excluded due to the uncertainty of their commissioning dates. This is not to suggest that these projects will not become operational, but that they are not likely in the forecast horizon (2015-2020).

In this report, the NEA takes a slightly different approach with regards to the impacts from LEU conversion on ^{99}Mo/^{99m}Tc production capacity. In *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012), the presented capacity scenarios include three different impact levels on ^{99}Mo production capacity – "very low", "low", and "high". However, since the publication of that document, it has become clear that there are significant economic and technical challenges to conversion (possibly, bigger than initially thought), which have led to an extension of the timelines for full conversion at all major producers that are converting. Therefore, it is assumed that the impact from LEU conversion on ^{99}Mo production capacity will be high and, consequently, only this level is incorporated in all capacity scenarios.

A full list of the model assumptions can be found in Appendix 2.

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[7] It should be noted that new alternative technologies, if proven successful in the market, could be replicated in the future depending on the market conditions (e.g. to satisfy unmet demand) to provide greater supply.

[8] The NEA production capacity forecast includes only major projects that have a minimum production capacity of 1 000 6-day curies per week EOP. The only exception is Argentina, which has available capacity of 400 6-day curies per week.

Chapter 4. Reference scenario

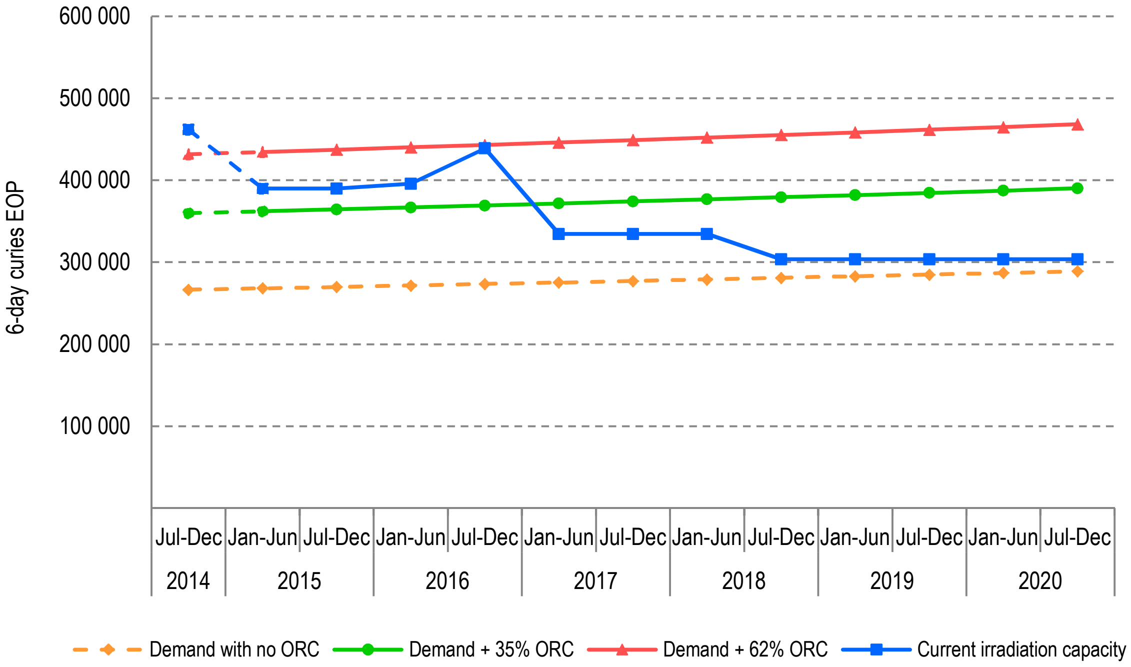
The reference scenario includes only current ^{99}Mo production capacity – major irradiators and processors that are part of the global supply chain plus Argentina. Although currently not a major producer, Argentina is working towards increasing its production capacity (both irradiation and processing) by the end of the decade to 2 500 six-day Ci/week, which would make it a leading global supplier.

Irradiation capacity

As discussed in previous NEA studies, the current fleet of irradiators is ageing and some are expected to stop irradiating targets for ^{99}Mo production within the next few years, while others may experience extended or more frequent periods of maintenance/refurbishment. The planned exit from the global supply chain of the OSIRIS and the NRU reactors will significantly decrease the available irradiation capacity, while sufficient new capacity may not be commissioned in time to compensate for this loss.

Figure 4.1 shows the projected 2015-2020 global ^{99}Mo irradiation capacity and demand based on the current fleet of irradiators. The NEA has added the 6-month period (July-December 2014) that precedes the forecast horizon to highlight the impact on current irradiation capacity from the planned, 16-month refurbishment of the BR-2 reactor in Belgium, projected to start at the beginning of 2015.

Figure 4.1. Current irradiation capacity and demand, 2015-2020



Global available irradiation capacity appears sufficient prior to the BR-2 refurbishment, then it sharply drops, as there is no immediate replacement for the lost BR-2 capacity. The increase in irradiation capacity in the second half of 2016 follows BR-2's return to service. Although this return is planned for the first half of 2016, the increase in global capacity in that period will not be significant, as OSIRIS will be offline too. The drop in capacity in January-June 2017 reflects NRU's exit from the global supply chain. In addition to the permanent loss of capacity from the OSIRIS and the NRU, the full conversion to LEU targets at most of the existing irradiators will further reduce available capacity from the current fleet, although this is not clearly identifiable in Figure 4.1, as the higher capacity of the BR-2 upon its return to service will provide an offset.

In 2015-2016, irradiation capacity appears to be sufficient to avoid supply shortages; however, as the capacity curve falls below the lower demand curve (i.e. with 35% ORC) post-2016, there is an increased risk of supply interruptions. Figure 4.1 shows clearly that current global irradiation capacity is on a decreasing trend throughout the forecast period. The ageing of major reactors and the consequent higher probability of unplanned or extended outages, along with the impact from LEU conversion, could also impact the processing capacity associated with such reactors and, therefore necessitate investment in new or replacement production capacity. This highlights the need to implement full-cost recovery for ^{99}Mo production to ensure that sufficient irradiation capacity is available in the market.

It should also be noted that the timelines for some current irradiators include an assumption that operating licence extensions will be granted by the relevant authorities. However, licence extensions may require refurbishments in the reactors and the decision to proceed with those investments may be subject to the economic conditions that prevail in the market at that time. If the decision is not to proceed with the necessary refurbishments, the capacity level in later years will be lower than presented in Figure 4.1.

Processing capacity

Although useful in understanding the global supply situation, irradiation capacity presents only a partial picture and does not account for geographical limitations relating to the production of bulk ^{99}Mo. Not all ^{99}Mo-irradiating reactors have associated processing facilities, which results in some regional constraints on processing production and the loss of product through more decay during extended transportation. This is especially the case in Europe, where irradiation capacity exceeds processing capacity. Therefore, for a more complete analysis of ^{99}Mo supply, it is important to consider processing capacity. Figure 4.2 below shows current processing capacity versus projected demand for ^{99}Mo.

Figure 4.2 shows that global processing capacity is insufficient to ensure secure supply of ^{99}Mo/^{99m}Tc in most of the forecast period. Even at the beginning of the period, when current processing capacity is above the lower demand curve, the gap between capacity and demand is too small to completely avoid any risk to supply. The loss of Canada's processing capacity in the second half of 2016 reduces current global processing capacity by approximately 25% in that period. The planned full conversion to LEU targets is projected to further reduce global processing capacity. Clearly, insufficient processing capacity will be a major risk for secure supply in the next five years.

The regional limitations on ^{99}Mo production mentioned earlier can be seen by comparing the two (irradiation and processing) capacity curves, which are plotted together in Figure 4.3. The gap between irradiation and processing capacity is small in 2015 and the first half of 2016 – irradiation capacity is higher by only 5-6% than processing capacity in that period. Following the return to service of BR-2 and the exit of AECL/Nordion's processing capacity, this gap widens to almost 30% in July-December 2016. While BR-2's higher future irradiation capacity is a positive development in the market, without an offset to the loss of AECL/Nordion's capacity, security of supply will not improve.

Figure 4.2. Current processing capacity and demand, 2015-2020

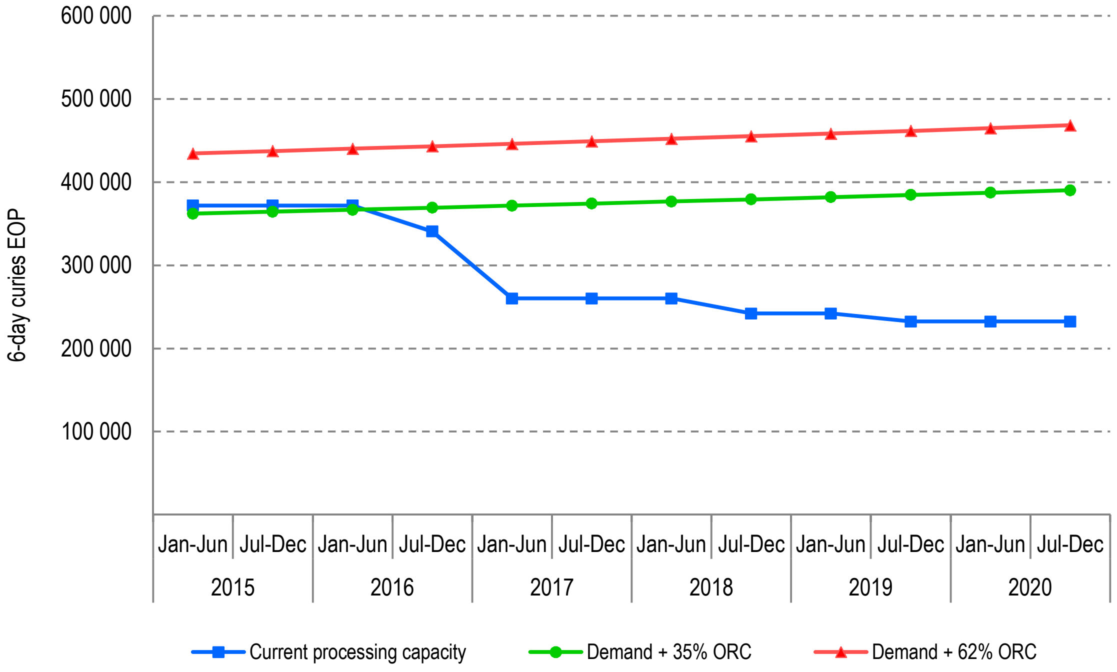
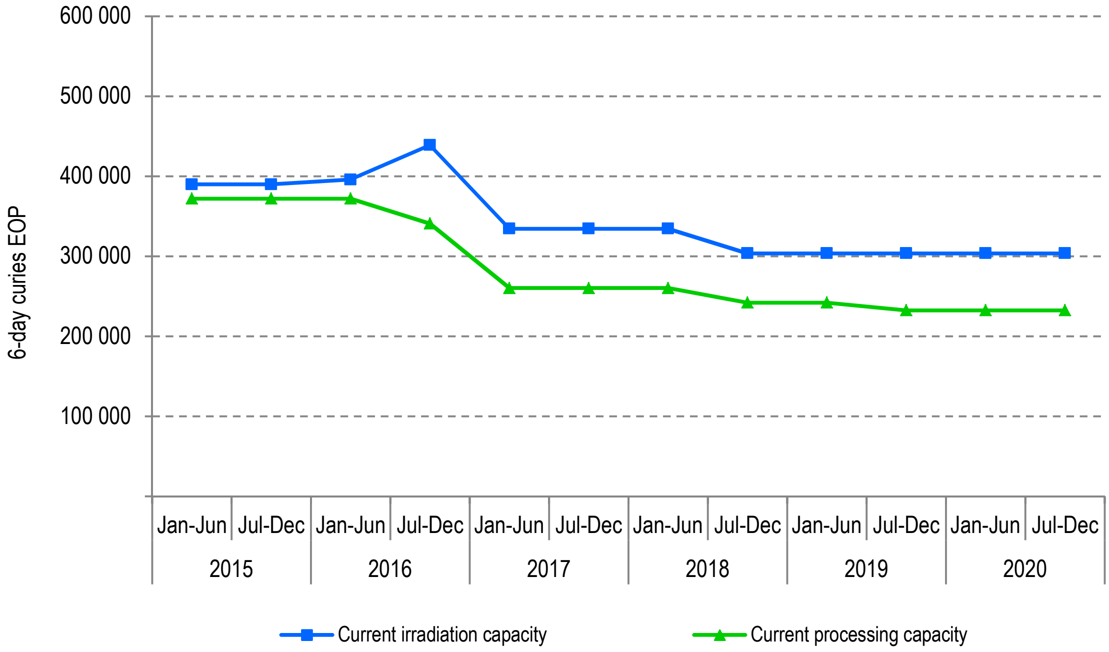


Figure 4.3. Current irradiation and processing capacity, 2015-2020



The gap between irradiation and processing capacity continues to be large post-2016 (between 25% and 31% higher irradiation capacity). This is due to the fact that NRU's share of global irradiation capacity is smaller than AECL/Nordion's share of global processing capacity[9], which underscores the importance of replacing AECL/Nordion's capacity as soon as possible. As seen in Figure 4.3, the bigger issue in the ^{99}Mo/^{99m}Tc market is insufficient processing capacity rather than insufficient irradiation capacity from 2016 onwards.

Figure 4.3 does not intend to provide justification for building or not building new irradiation and/or processing facilities, but to identify the greater relative importance of current processing capacity. Figures 5.3 and 6.3 in later sections of this report present a picture of the projected changes in irradiation and processing capacity under the two alternative scenarios and the impact on the gap between these capacities (a smaller gap is preferable to a larger gap).

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7. NRU's normal irradiation capacity and AECL/Nordion's normal processing capacity are equal; however, global irradiation capacity is higher than global processing capacity, which means that AECL/Nordion's capacity represents a larger share of global processing capacity than NRU's share of global irradiation capacity.

Chapter 5. “Technological challenges” scenario

The “technological challenges” scenario is an extension of the reference scenario, presented in the previous section, and includes selected new[10] reactor- and non-reactor-based projects around the world, in addition to the existing irradiation and processing capacity. It should be mentioned that not all of the announced new projects have been included in this scenario, given the uncertainty over whether some of them will be operational within the 2015-2020 forecast horizon. More specifically, the NEA has decided to consider only new projects that are most likely to be commissioned at least one year before the end of the forecast horizon[11]. Excluded projects are those that have yet to receive full financing or have unspecified construction start and commissioning dates, or for which there is inconclusive information about start dates and/or production capacity.

By making such a determination, the NEA is not suggesting that excluded projects will never materialise, but rather that they may not be commissioned within the forecast period. In the longer term, after 2020, the ^{99}Mo supply-demand schedule may look different with these projects operating, with potentially greater supply available in the market. Furthermore, all new alternative projects are assumed to have a 50% probability of being commissioned within their announced timelines. This assumption accounts for the fact that alternative technologies have yet to be proven on a large scale in the ^{99}Mo/^{99m}Tc market.

Appendix 1 (Tables A1.3 and A1.4) presents all planned new projects to be commissioned by 2020. The “technological challenges” and “project delays” (see Chapter 6) capacity scenarios include all but two of these projects. The two exclusions from the forecast scenarios are:

- the new reactor and processing facility in the Republic of Korea; and,
- the proposed Molybdenum 2010 processing facility in Poland.

For the former, it is not clear whether the new reactor will be built within the announced timelines (normal operation is anticipated in 2017), as its construction has not started yet. Reactor operation is a prerequisite for including Korea’s processing capacity. In the case of the latter project, its construction and operation timelines are also uncertain, as financing has not yet been secured; hence its projected capacity is also excluded.

Although it may be a matter of debate whether all officially announced production projects should be included in the scenario, for the purpose of ^{99}Mo security of supply, it does not make a notable difference during this forecast horizon (2015-2020) to global irradiation or processing capacity. Excluded projects are planned to be fully operational no earlier than the 2018-2020 timeframe, by which time ^{99}Mo irradiation and processing capacity are projected to significantly exceed demand (see Figures 5.1 and 5.2) even

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[10] Newly built facilities or modified facilities not previously producing ^{99}Mo on a large scale.

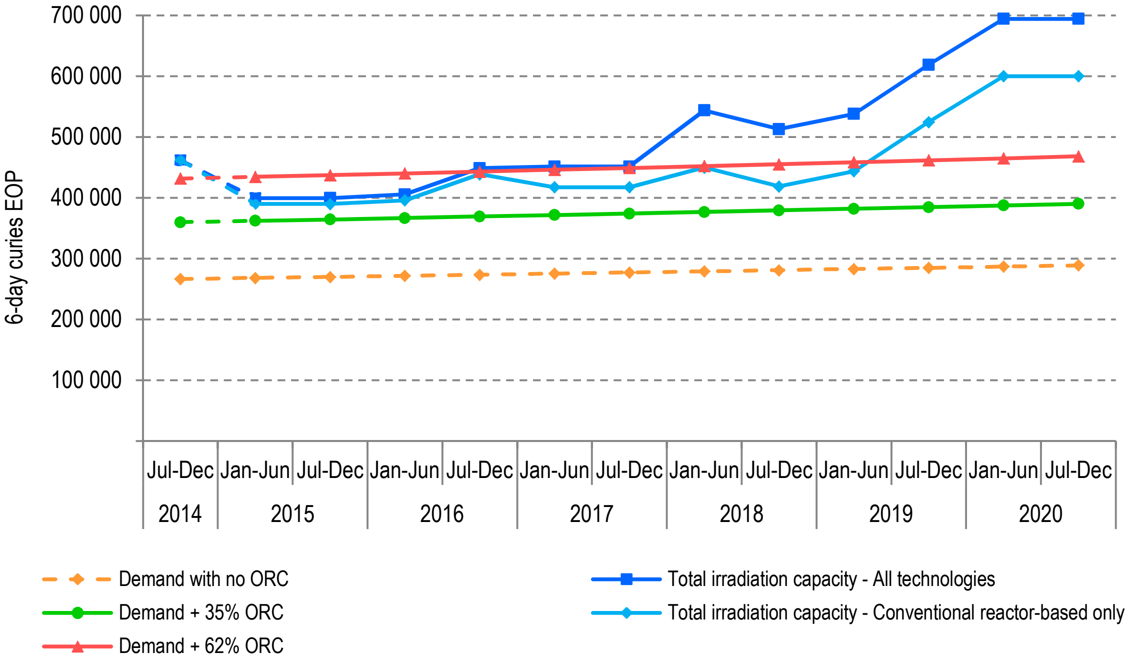
[11] In order to include their full capacity in the forecasting model, based on the assumption that new projects need ramp-up time before they reach full production capacity. The ramp-up time is assumed to be one year, so a project needs to be commissioned no later than July-December 2019 to be included in the forecast in July-December 2020.

without them. However, this apparent excess capacity should not imply that long-term security of supply is assured, because it does not take into account any current capacity being retired in the future, beyond 2020, or the sustainability of potential “over-capacity” in the market.

Irradiation capacity

Figure 5.1 shows the projected global irradiation capacity and demand under the technological challenges scenario. It can be seen that even without all planned new irradiation projects, global capacity looks to be sufficient to meet projected demand with a 35% ORC requirement, throughout the five-year forecast period. Notwithstanding the expected exit from the market of the OSIRIS and the NRU reactors, new capacity in Australia, North America and Europe should more than compensate for this capacity loss. However, there could be periods in 2015 and the first half of 2016 when irradiation capacity may be insufficient, depending on the actual dates of operation of planned new production facilities. Later in the forecast period, the capacity-demand gap increases due to the commissioning of new reactor capacity and associated processing production in South America and Asia.

Figure 5.1. Current and selected new irradiation capacity and demand, 2015-2020

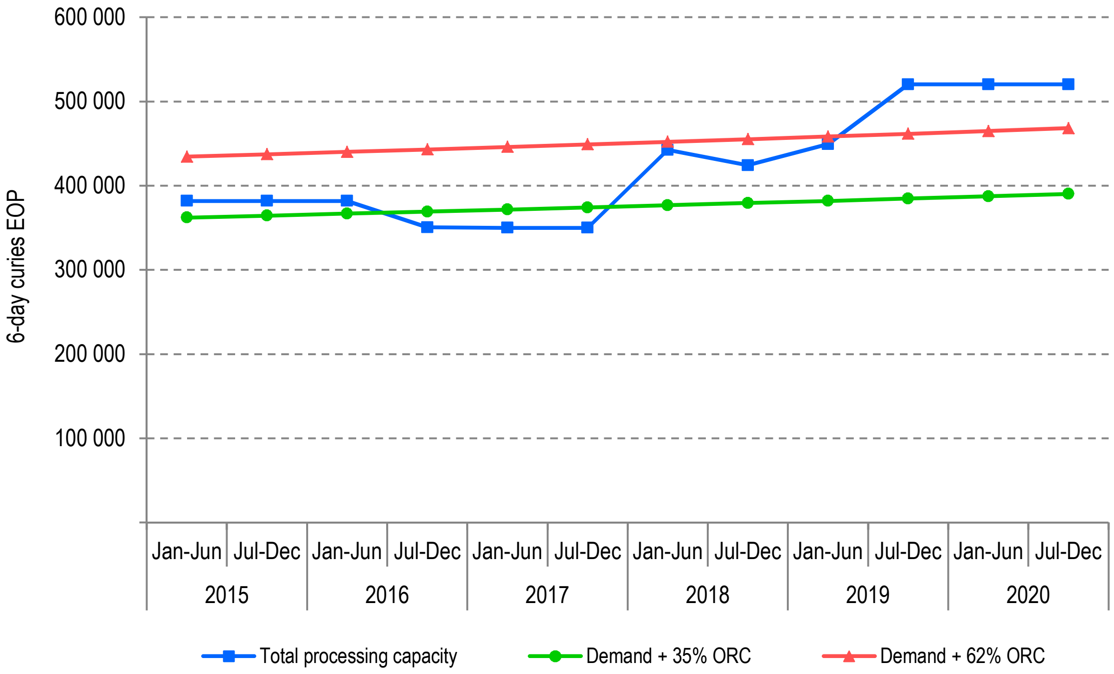


To account for the fact that alternative ^{99}Mo production technologies have not been used on a large scale to date and may not achieve significant market penetration initially, Figure 5.1 separates out conventional (reactor-based) irradiation capacity from total irradiation capacity. It can be seen that up to 2017, the two capacity curves overlap completely, implying that ^{99}Mo production will continue to be dependent on reactors in the short term. Post-2017, if all alternative projects are commissioned and able to compete in the market, global irradiation capacity would be sufficient to meet demand. However, if not, supply will be tight up to 2019.

Processing capacity

Figure 5.2 presents global processing capacity in the technological challenges scenario versus projected demand. Using the industry assertion that the required ORC to avoid supply shortages is approximately 50% of demand (or somewhere between the two demand curves in Figure 5.2, it is clear that processing capacity is likely to be insufficient to provide reliable supply in the 2015-2017 period. Post-2017, it increases to a level that appears to be high enough for secure supply (in each six-month interval in the second half of the forecast, processing capacity is projected to be more than 50% higher than demand). With the processing capacity curve too close to the lower demand curve in the first half of the forecast horizon, this scenario clearly shows the risks to ^{99}Mo/^{99m}Tc supply in the short term.

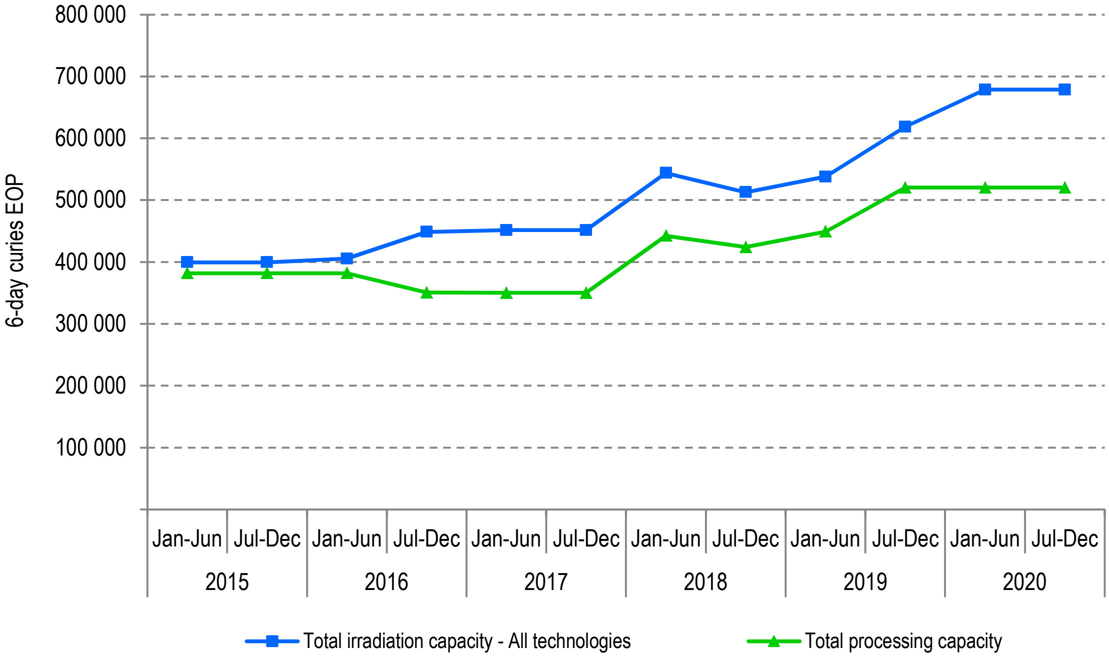
Figure 5.2. Current and selected new processing capacity and demand, 2015-2020



Since new projects are included in the technological challenges scenario, it is instructive to see the degree of potential improvement to the global supply situation, i.e. whether the gap between irradiation and processing capacity identified in the reference scenario decreases. For example, new irradiation capacity without corresponding, equal or higher processing capacity, would not improve the current global supply situation. Figure 5.3 shows a comparison of current and selected new irradiation and processing capacity under the technological challenges scenario.

Similar to the reference scenario, the gap between irradiation and processing capacity is relatively small at the beginning of the forecast period and widens in mid-2016. The gap remains large throughout most of the forecast period and, in fact, widens further in 2020. At the end of 2020, total irradiation capacity is projected to be more than 30% higher than processing capacity. Although most new ^{99}Mo/^{99m}Tc projects will have associated processing capacity, the FRM-II and JHR reactors in Germany and France are notable exceptions. When both of these reactors begin irradiating for ^{99}Mo, they will have more than offset the loss of OSIRIS' capacity (another reactor without associated processing capacity), which is the reason for the larger gap between global irradiation and processing capacity towards the end of the forecast period under this scenario. Earlier in the period, even after OSIRIS' anticipated exit and before FRM-II's entry in 2016, global irradiation capacity is projected higher than processing capacity, which again underscores the higher relative importance of processing capacity in a global context.

Figure 5.3. Current and selected new irradiation and processing capacity, 2015-2020



As a result, despite the improved global supply situation under the technological challenges scenario, insufficient processing capacity (relative to irradiation capacity) will continue to be a major potential risk for supply shortages. Therefore, for secure supply, it is important to ensure sufficient processing capacity.

Chapter 6. “Project delays” scenario

The project delays scenario has been developed from the technological challenges scenario by delaying all new projects and LEU conversion by one year. This scenario provides, perhaps, the most realistic picture of all three scenarios of future irradiation and processing capacity, given the technical complexity of new reactor-based projects and the ground-breaking efforts in reaching large-scale, commercial production by alternative technologies. Furthermore, the majority of the new projects included in this scenario intend to apply full-cost recovery for their future ^{99}Mo production and need to develop distribution networks for their product, which provides an additional challenge to implementation. Most importantly, however, experience has shown that nuclear-related projects more often than not take longer to complete than originally envisaged.

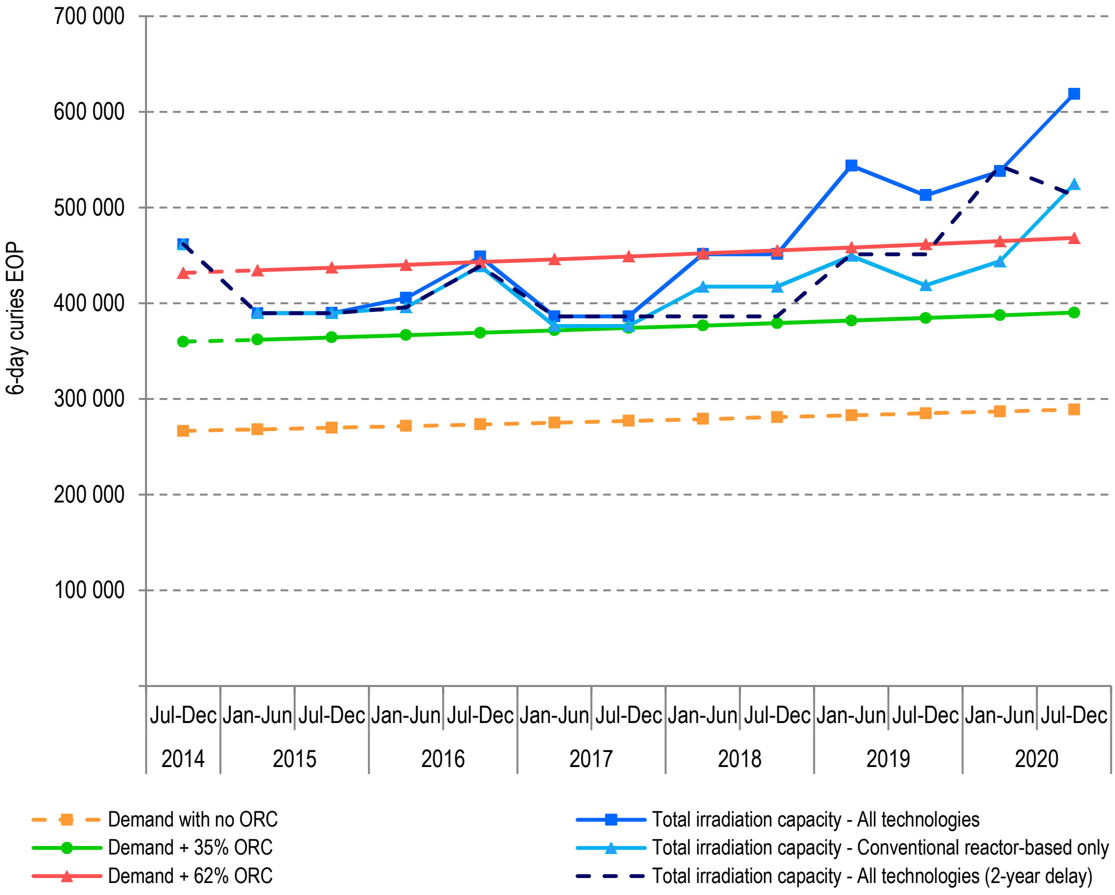
Given the somewhat arbitrary assumption of a one-year delay in the commissioning of new projects and LEU conversion, the NEA has also modelled global irradiation and processing capacity with a two-year delay. This provides an additional and more conservative capacity scenario that also acknowledges the potential difficulties in executing new projects or refurbishing existing production facilities. The irradiation and processing capacities with a two-year delay are represented by the purple dotted lines in Figures 6.1 and 6.2, respectively. The capacity lines for the different delay periods show that the risk of supply shortages lasts longer the longer the delay in the commissioning of new projects, as LEU conversion has a less significant impact on overall capacity.

Irradiation capacity

Figure 6.1 shows the projected global irradiation capacity under the project delays scenario. Compared to the technological challenges scenario, irradiation capacity under this scenario is almost identical in amount in 2015 and 2016, although it sharply drops in 2017 due to the one-year delay of the commissioning of major new projects. Under this scenario, delayed new capacity will have a negative effect on irradiation capacity, but at the same time, delayed LEU conversion will have the opposite effect. Over the five-year forecast period, the “delayed new capacity” effect will dominate, resulting in lower total irradiation capacity.

Irradiation capacity in Figure 6.1 is again split into total capacity and capacity only from reactor-based projects. Similar to the technological challenges scenario, the gap between the two capacity curves is equal to the amount of alternative capacity. However, this gap emerges one year later – in 2018, when the first alternative production project is expected to utilise its full capacity under this scenario. Supply without these non-reactor projects is tight until 2018.

Figure 6.1. Current and selected new irradiation capacity and demand, 2015-2020



Processing capacity

From the beginning of the forecast period until mid-2016, global processing capacity is just above the lower demand curve (with 35% ORC) in Figure 6.2, suggesting an increased risk of shortages. Processing capacity decreases sharply in 2017 (even higher risk of shortages due to the delay in planned new projects with processing capacity), before increasing in 2018.

Processing capacity fluctuates more than in the technological challenges scenario due to the larger time lag between the loss of AECL/Nordion's processing capacity in Canada and the operation of new processing capacity, primarily in North America and Australia. The delay of LEU conversion does not have a significant impact on total processing capacity, except for a temporary dip in the second half of 2019, when a large producer is expected to complete its conversion. Figure 6.2 shows that post-2018, processing capacity is projected to reach a level that presents a lower risk of global ^{99}Mo supply shortages.

Figure 6.3 below depicts global irradiation and processing capacity under the project delays scenario. Similar to the previous two scenarios, the gap between irradiation and processing capacity is small in the first 18 months of the forecast horizon. The exit of the NRU reactor and AECL/Nordion's processing capacity widens the gap in 2017, as that processing capacity has a larger share of global processing capacity than NRU's irradiation capacity and, in relative terms, its loss to the supply chain will be greater. Post-2018, the gap begins to close, albeit slowly, with the commissioning of new projects that have associated processing capacity, including a new processing plant in Australia.

Figure 6.2. Current and selected new processing capacity and demand, 2015-2020

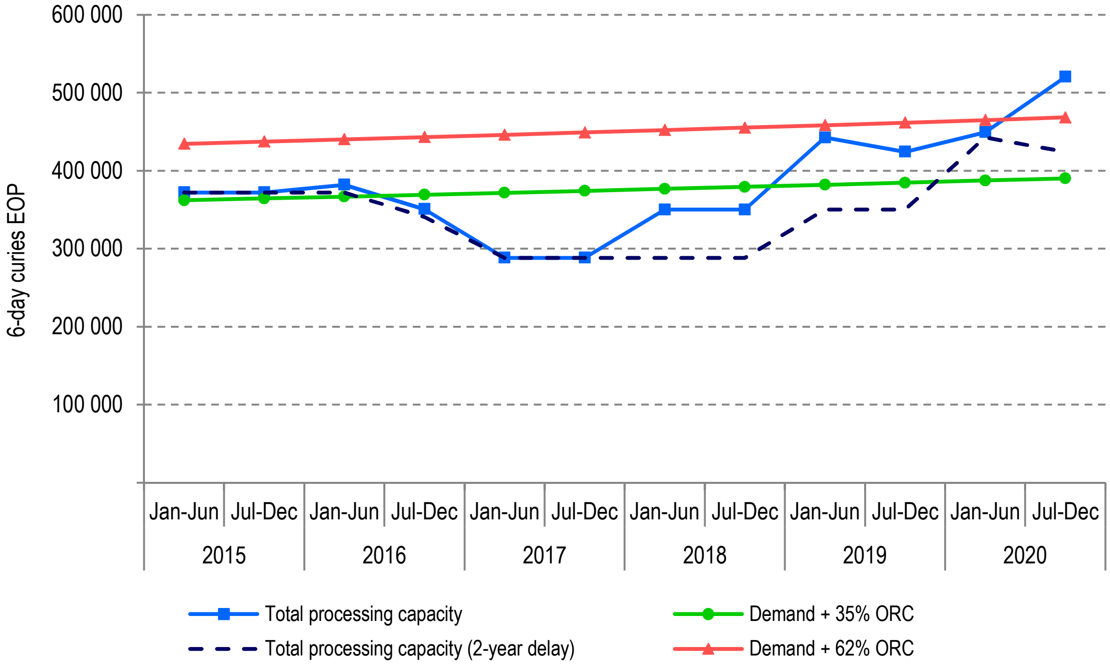
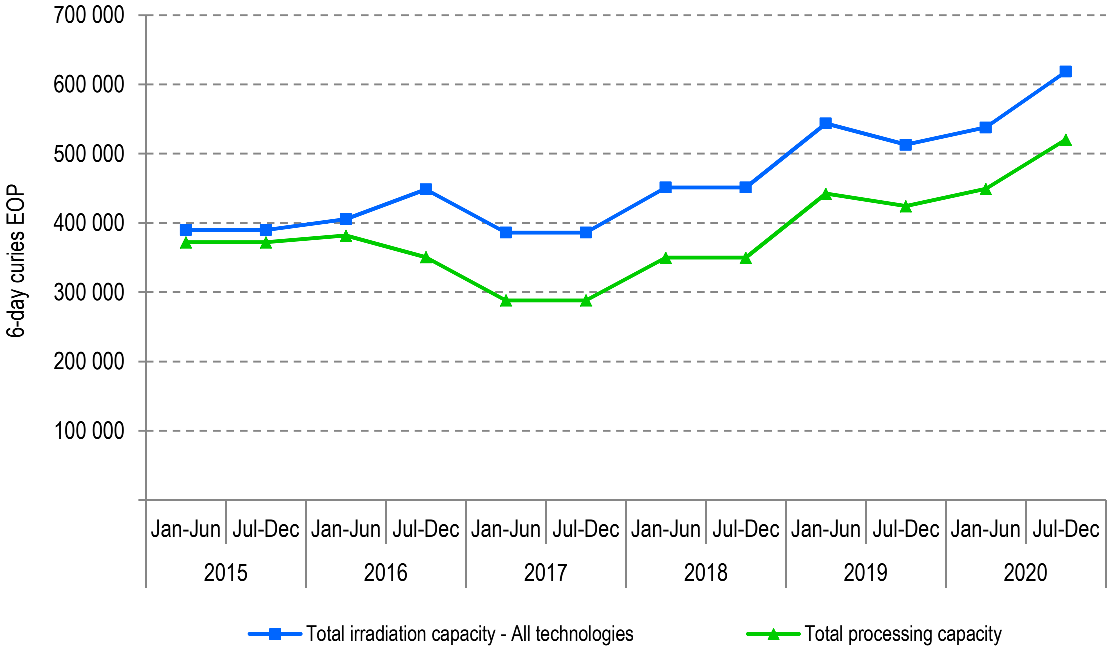


Figure 6.3. Current and selected new irradiation and processing capacity, 2015-2020



Chapter 7. Conclusions

Current global irradiation and processing capacity is predicted to be insufficient over the period analysed for reliable ^{99}Mo/^{99m}Tc supply, even with all producers operating under normal conditions, i.e. without any unplanned or extended outages. As a consequence, there is an increased risk of supply shortages, particularly in the 2015-2017 period, which suggests a need for additional capacity. A closer look at the forecast results under the three scenarios analysed in this report shows that there is a greater need for additional processing capacity to ensure the security of supply.

This ^{99}Mo/^{99m}Tc capacity forecast confirms previous forecasts of tight and potentially insufficient supply in the short term. The planned exit of the OSIRIS and the NRU reactors (and especially, NRU's associated processing capacity) from the global supply chain poses challenges to meet demand. On the other hand, the anticipated commissioning of new capacity as early as 2015 raises hopes that these short-term challenges can be overcome. However, any actual delays in production from that capacity, which are not unlikely given the innovative nature of the production technologies involved, could cause supply difficulties. Furthermore, it is not clear whether these alternative production technologies (which are to be commercially based) will be price competitive in the market, because not all current ^{99}Mo producers, many of whom are subsidised, will have implemented full-cost recovery by then.

Despite the risk of supply shortages in the first half of the forecast period, both alternative scenarios in this report that include new ^{99}Mo production capacity indicate significant over-capacity in the market by 2020. Much of this new capacity may not be commercially based, which would present future challenges for producers who have or will have implemented full-cost recovery by then, and other new projects that are being planned to operate on full-cost recovery. In the limit, those producers could be forced to exit the market because of a lack of ability to compete on price. This emphasises the need for all countries to implement the six HLG-MR policy principles in a timely and globally consistent manner.

The results from this 2015-2020 capacity forecast reinforce the need to establish an economically sustainable ^{99}Mo/^{99m}Tc supply chain as quickly as possible. This would enable investment in new/replacement, non-HEU-based production capacity and its timely entry in operation, and provide sufficient amounts of funded ORC to the market. The ageing fleet of research reactors – the backbone of global ^{99}Mo production at present and for the foreseeable future – and recent extended outages at major producers, underscore the importance of universally adopting full-cost recovery and funded ORC.

Furthermore, the supply chain should continue its communication and co-ordination efforts. In this respect, the work carried out by the Association of Imaging Producers and Equipment Suppliers (AIPES) Working Group on global reactor scheduling and ^{99}Mo supply monitoring contributes significantly to the smooth functioning of the entire supply chain. The Working Group manages information-sharing among the major ^{99}Mo producers and responds to periods of potential disrupted production by co-ordinating supply chain actions and thus, helps minimise any impact on the end-users of ^{99m}Tc. This work is critical for the long-term sustainability of the ^{99}Mo/^{99m}Tc market and the security of supply.

As mentioned earlier, this document does not intend to forecast future ^{99}Mo/^{99m}Tc shortages, including on a weekly/monthly basis, but identify periods over the next five years with increased risk for irradiation and processing production. The AIPES Working Group and individual reactor circumstances can determine the likelihood of any potential weekly/monthly supply disruptions.

References/further reading

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

OECD-NEA (2012), *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production*, OECD, Paris.

OECD-NEA (2012), “A Supply and Demand Update of the Molybdenum-99 Market”, OECD, Paris.

OECD-NEA (2011), “The Supply of Medical Radioisotopes: An Assessment of Long-term Global Demand for Technetium-99m”, OECD, Paris.

Appendix 1. Current and potential new irradiators and processors to be commissioned by 2020

Table A1.1. Current irradiators

Reactor	Targets	Normal operating days	Available capacity per week (6-day Ci)	Potential annual production (6-day Ci)[1]	Estimated stop production date
BR-2	HEU	140	7 800	156 000	2026
HFR	HEU	280	4 680	187 200	2024
LVR-15	HEU	210	2 800	84 000	2028
MARIA	HEU	210	2 200[2]	66 000	2030
NRU	HEU	280	4 680	187 200	2016
OPAL	LEU	300	1 000	42 900	2055
OSIRIS	HEU	182	2 400	62 400	2015
RA-3	LEU	336	400	19 200	2027
SAFARI-1	HEU[3]/LEU	305	3 000	130 700	2030

1. Based on operating days and normal available capacity – not necessarily what is actually produced currently, rounded.

2. Planned as of September 2014.

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

Table A1.2. Current processors

Processor	Targets	Available capacity per week (6-d Ci)	Available annual capacity (6-d Ci)[1]	Expected date of conversion to LEU targets
AECL/Nordion	HEU	4 680	187 200	Not expected[2]
ANSTO Health	LEU	1 000	52 000	Started as LEU
CNEA	LEU	900	46 800	Converted
Mallinckrodt	HEU	3 500	182 000	2017
IRE	HEU	3 500	182 000	2016
NTP	HEU[3]/LEU	3 500	182 000	2014[4]

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

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

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

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

Table A1.3. Potential new irradiators to be commissioned by 2020

Irradiation source	Targets/technology[1]	Expected operating days	Expected available capacity per week (6-d Ci)	Potential annual production (6-day Ci)[2]	Expected first full year of production[3]	Project status (April 2014)
RIAR [4] (Russian Federation)	HEU in CRR	350	1 000	50 000	2015	One production line operating, a second is being installed
Karpov Institute (Russian Federation)	HEU in CRR	345	300	14 800	2015	Already irradiating for small amounts of ^{99}Mo
NorthStar[5]/MURR (United States)	Non-fissile in CRR	365	750/2 500	39 100/130 400	2015/2017	Phase 1 Nearing completion/ Phase 2 Seeking financing
FRM-II (Germany)	LEU in CRR	240	1 600	54 300	2017	Infrastructure installed, pending LEU target design
Morgridge/SHINE (United States)	LEU solution with DTA and SAHR	336	2 500	120 000	2017	Construction not yet started
OPAL[6] (Australia)	LEU in CRR	300	2 600	111 400	2017	Construction not yet started
Korea	LEU in CRR	300	2 000	85 700	2018	Conceptual design
NorthStar[5] (United States)	Non-fissile from LINAC	336	2 500	120 000	2018	Construction not yet started
China Advanced RR	LEU in CRR	350	1 000	50 000	2019	Existing reactor under modification
Brazil MR	LEU in CRR	290	1 000	41 400	2019	Preliminary design
RA-10 (Argentina)	LEU in CRR	336	2 500	120 000	2019	Preliminary design
Jules Horowitz RR (France)	LEU in CRR	220	4 800	150 857	2020	Under construction

1. CRR = conventional research reactor; DTA = deuterium-tritium accelerator; SAHR = subcritical aqueous homogeneous reactor; LINAC = linear accelerators.
2. Based on expected operating days and normal available capacity announced publicly, rounded.
3. Assumed full-scale production starts one year after commissioning unless available information indicates differently, estimated by project proponents.
4. The project includes two reactors, both of which will be used to irradiate for continuous ^{99}Mo production.
5. Produces low-specific activity ^{99}Mo that requires the use of Northstar's own generator to produce ^{99m}Tc.
6. New production as a result of new processing capacity, in addition to ANSTO's current reactor capacity.

Table A1.4. Potential new processors

Processor	Targets and (expected date of conversion)	Expected available capacity per week (6-day Ci)[1]	Expected available annual capacity (6-day Ci)[2]	Estimated first full year of production[3]	Project status (April 2014)
RIAR	HEU	1 000	50 000	2015	Producing small amounts
Karpov Institute	HEU	300	14 800	2015	Producing small amounts
NorthStar/MURR	Non-fissile	750/2 500	39 100/130 400	2015/2017	Nearing completion/ seeking financing
ANSTO[4]	LEU	2 600	111 400	2017	Construction to start in 2014
Morgridge/SHINE	LEU solution	2 500	120 000	2017	Construction not yet started
NorthStar (LINAC)	Non-fissile	2 500	120 000	2018	Construction not yet started
MARIA: Molybdenum 2010	LEU	1 000	52 000	2018	Seeking financing
Korea	LEU	2 000	85 700	2018	Conceptual design
China Advanced RR	LEU	1 000	50 000	2019	No available information
Brazil MR	LEU	1 000	41 400	2019	Preliminary design
RA-10	LEU	2 500	120 000	2019	Preliminary design

1. Derived assuming ability to process irradiated sources linked with the project, unless additional information is available.

2. Based on the ability to process irradiated sources linked with the project, unless additional information is available, rounded; in some cases actual production may be less as processors may not have access to irradiated sources 52 weeks of the year. Irradiator limitations are taken into account where they exist. This may have the effect of some processing capacity not being fully used if there is not sufficient irradiator capacity to supply the processor with irradiated product.

3. Dates based on discussions with supply chain participants as well as publicly available statements, presentations and reporting.

4. In addition to current ANSTO processing capacity.

Appendix 2. Model assumptions

Supply

1. Irradiator capacity is the reactor/alternative technology capacity that is typically dedicated to ^{99}Mo/^{99m}Tc production. Outage reserve capacity (ORC) is excluded to provide consistency among the producers who have widely varying levels of ORC, which may or may not be accurately estimated.
2. Where new projects are included in the forecast, only their full capacity to be used for ^{99}Mo/^{99m}Tc production has been modelled. It is recognised that new irradiators and processors would not be able to begin utilising their full capacity immediately after commissioning, so the new (full) capacity has been added one year after commissioning to allow for a gradual ramp-up of production and regulatory approval. No new capacity has been added to the forecast during the ramp-up period, as it is unknown on a project-by-project basis.
3. An estimated level of ORC is added on the demand side, in line with previous NEA modelling, as higher demand in cases of unplanned or extended reactor outages.
4. In *Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production* (OECD/NEA, 2012), the capacity impact from LEU conversion was modelled as "very low", "low" and "high". For this document, only the high-impact capacity values have been modelled for all three scenarios, given the technical and economic difficulties already experienced by producers, and the delayed timelines for implementation.
5. The capacity values for each six-month period have been estimated based on the three-year (2011-2013) average reactor operational days in January-June and July-December, as a share of the annual total. Where a reactor was shut down for three or more months in a six-month period, its capacity has been adjusted to avoid a seasonal bias.
6. Regional restrictions have been applied to processing capacity incorporating the 1 000-km maximum distance for the surface transportation of irradiated targets. Therefore, within this distance, where irradiator and processing capacities differ, the lower value has been used in the forecast.

Demand

1. For the entire forecast period (2015-2020), global ^{99}Mo/^{99m}Tc demand is assumed to grow at 0.5% per year in mature markets (Europe, Japan, North America, and Republic of Korea) and 5% in emerging markets (South America, Africa and Asia – excluding Japan and the Republic of Korea). Mature markets are estimated to account for 84% of the global demand for ^{99}Mo/^{99m}Tc, while emerging markets – for 16%.