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The Supply of Medical Radioisotopes

2017 Medical Isotope Supply Review: $^{99}Mo/^{99m}Tc$ Market Demand and Production Capacity Projection 2017-2022

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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, nuclear pharmacies, governments and associations representing nuclear medicine professionals, nuclear pharmacies, hospitals and industry.

The OECD 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 demand and capacity projection for the 2017-2022 period. This projection 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 Kevin Charlton of the NEA Division of Nuclear Development. Detailed review, comments and suggestions were provided by members of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR).

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ANM	ANSTO Nuclear Medicine
ANSTO	Australian Nuclear Science and Technology Organisation
CNL	Canadian Nuclear Laboratories
EOP	End of processing
FCR	Full cost recovery
HEU	High-enriched uranium
LEU	Low-enriched uranium
NEA	Nuclear Energy Agency
NRU	National Research Universal
ORC	Outage reserve capacity

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 only 6 hours for ^{99m}Tc, and thus must be produced continuously – can lead to cancellations or delays in important medical testing services. Supply reliability has been challenged over the past decade due to unexpected shutdowns and extended refurbishment periods at some of the ^{99}Mo-producing research reactors and processing facilities. These shutdowns have at times created conditions for extended global supply shortages (e.g. 2009-2010).

At the request of its member countries, the Nuclear Energy Agency (NEA) became involved in global efforts to ensure a secure supply of $^{99}Mo/^{99m}Tc$. Since June 2009, the NEA and its High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) have examined the causes of supply shortages and developed a policy approach, including principles and supporting recommendations to address those causes. The NEA has reviewed the global ^{99}Mo supply situation periodically, to highlight periods of potential reduced supply and to 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 potential low supply relative to demand. That 2012 forecast was updated with a report in 2014 that focused on the much shorter 2015-2020 period. That report was updated in 2015 and then in 2016 with a report, “2016 Medical Isotope Supply Review: $^{99}Mo/^{99m}Tc$ Market Demand and Production Capacity Projection 2016-2021” (NEA, 2016), which likewise focused on a six-year period.

This report[1] updates the 2016 report, and focuses on the important 2017-2022 period that follows a period when some facilities have been removed from service. At the end of 2015, the OSIRIS reactor in France permanently shut down operations. At the end of October 2016, the National Research Universal (NRU) reactor in Canada ceased routine ^{99}Mo production and the associated processing capacity moved to a “hot standby” mode; they retain the capability to provide contingency capacity until the end of March 2018, but only in exceptional circumstances of an unplanned global shortage that cannot otherwise be mitigated. Additional reactor capacity and associated processing capacity from existing supply chain members were added during 2016, but non-reactor-based $^{99}Mo/^{99m}Tc$ projects that were anticipated to start in 2016 have not yet entered operation. It remains important to analyse the likely overall impact and timing of anticipated projects to understand how global production capacity may be affected.

This report presents global irradiation and processing capacity under the same three main capacity scenarios as set out in the 2015 and 2016 reports. It is intended that it offers a high added value to the international community and the HLG-MR has

1. The scenarios presented by the NEA in this report should not be construed as a prediction or forecast 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.

emphasised the need for future updates on at least an annual basis. The information in this report should be interpreted in terms of projected future trends as opposed to actual forecast values and dates.

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 (NEA, 2011), based on an 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" (NEA, 2012a), the NEA estimated global ^{99}Mo demand at 10 000 6-day curies ^{99}Mo per week[1] at end of processing (EOP). This was lower than the previously estimated 12 000 6-day curies ^{99}Mo per week EOP and resulted from a number of changes that had occurred in the market as a consequence of the 2009-2010 global supply shortages. Those changes included: better use of available ^{99}Mo/^{99m}Tc, more efficient elution of ^{99m}Tc generators, adjustments to patient scheduling, and some increased use of substitute diagnostic tests/isotopes that continued after the ^{99m}Tc supply shortage period was over.

The April 2014 report "Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ^{99}Mo/^{99m}Tc Market, 2015-2020" (NEA, 2014) used as a starting point, the NEA 2012 estimate of 10 000 6-day curies ^{99}Mo EOP per week from processors, but with modified annual demand growth rates of 0.5% for mature markets and 5% for developing markets, based on information provided at the time by supply chain participants.

The August 2015 and June 2016 reports used an adjusted estimate of demand of 9 000 6-day curies ^{99}Mo EOP per week from processors, based on data collected from supply chain participants on capacity utilisation data during each operating quarter of the period 2012 to 2015. This data along with the actual operating time periods per facility (e.g. operational days) provided useful data for periods of supply stress when a number of facilities suffered outage periods. This report builds upon that approach and includes analysis of the same data set up to and including 2016.

The data was analysed to determine the level of recent market demand, with reported utilised capacity being taken as a surrogate for the demand in the market. The data set was not 100% complete; again one processor did not provide data. The latest data received for 2016 reconfirms that recent global demand for ^{99}Mo is close to 9 000 6-day curies ^{99}Mo EOP per week with some quarterly fluctuations.

During the period, from 2012 to 2016, market supply was maintained successfully on an almost continuous basis, but with some limited supply shortages reported as occurring, for example in 2013, 2014 and in late 2015.

For the purposes of this report, the market demand for ^{99}Mo activity has been held at 9 000 6-day curies ^{99}Mo EOP per week with a starting reference time-point of the end of 2014. This has been reviewed and confirmed by supply chain participants. The market growth rates have been kept unchanged at 0.5% for mature markets and 5% for developing markets during the forecast period. Mature markets are estimated to account for 84% of the global demand for ^{99}Mo/^{99m}Tc, while emerging markets account for 16%

1. A 6-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). In International System (SI) Units, 1 Ci is equal to 37 Giga becquerels.

starting from the same time-point; that is “end of 2014”. The latest NEA market demand analysis, made with the present available data, does not fully confirm or disprove this level of projected market growth. As such, for the purposes of this report and to maintain continuity where that is possible, these rates have been retained in this report.

The reasons behind the market demand being now lower than estimated in earlier reports are not fully clear. The continuation of the previously mentioned measures to increase efficiency of use of ^{99m}Tc at the nuclear pharmacy and in the clinic, combined with some reduction in average injected dose due to some gamma camera improvements and protocol changes may have played some role. Also, in a market where full cost recovery (FCR) pricing is being increasingly implemented in steps along the supply chain, with the result of steadily increasing materials prices, it would be understandable that efficiency of use of materials continues to be a priority for supply chain participants who have an objective of minimising costs.

What capacity level is required to ensure that ^{99}Mo/^{99m}Tc demand is met?

As in previous reports, the NEA has no direct way to measure the amount of paid outage reserve capacity (ORC) that is held in the market, but all supply chain participants agree that the principle of having paid ORC is essential to sustain reliable supply. The need of the market for ORC was illustrated in 2013, 2014 and 2015, with some unplanned outages at major ^{99}Mo producers occurring during those periods. Those significant outages tested the supply chain’s ability to ensure reliable supply. This challenge was largely met by the supply chain using available ORC and resulted in only a small number of limited supply shortages in some countries.

The capacity level required to ensure that ^{99}Mo/^{99m}Tc needs are met must include some level of paid ORC. In the HLG-MR principles, it was proposed that a processor should hold sufficient paid reserve capacity to replace the largest supplier of irradiated targets in their supply chain and likewise participants further down the supply chain should hold similar levels of ORC. This is the so-called (n-1) criterion. In fact, there have been occasions over the last few years when, for some participants, the (n-2) criterion (replacing the two largest suppliers) may have been a more appropriate measure. The actual levels for (n-1) and (n-2) criterion vary depending upon the supply diversity of each supply chain participant and the actual levels of ORC required also change as part of a dynamic process, for example as producers enter and exit the market.

In this report, the minimum capacity level required to meet demand has been held at the same level as the preceding report – at a level of market demand plus ORC of +35%. Analysis of historical data has shown that the security of supply comes under stress whenever the theoretical maximum available production capacity falls below the level of demand +35% ORC. Potential production capacity in this report is compared to “demand +35% ORC” and with the level of demand without ORC also shown as a reference line.

Given that the actual ORC level required for each participant will change over time, the ORC level in this document should only be used with caution in providing advice or making decisions. The NEA believes that the demand curve with +35% ORC is a good representation of a “safe” level of capacity required to meet market demand with an adequate level of security.

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

The NEA regularly updates the list of current and planned new ^{99}Mo/^{99m}Tc irradiation and processing projects. The updates include: revisions to production start/end dates, review of "qualified" potential projects and the anticipated impacts of some existing supply chain participants converting to using low-enriched uranium (LEU) targets. Appendix 1 provides tables that list current and some potential new ^{99}Mo/^{99m}Tc producers, along with the status of "qualified" projects as of January 2017. It should be noted that the tables are not exhaustive and do not include every potential project for ^{99}Mo/^{99m}Tc production that exists around the world. Inclusion in the tables does not indicate that potential new production facilities may be operational by the indicated times, or even at all.

Supply chain participants acknowledge that, given the inability to store these radioisotopes for later use, the weekly ^{99}Mo/^{99m}Tc supply will generally match demand. Therefore, the intent of this forecast is not to predict the actual level of ^{99}Mo/^{99m}Tc supply based on changes in production capacity. It is intended to identify periods of increased risks of supply shortages in order to inform government policy makers, industry and nuclear medicine professionals. Such higher-risk periods are when the production capacity curve is close to or below the projected NEA demand curve +35% ORC, the green line shown in the graphs in this report.

In this report, the forecast horizon for ^{99}Mo/^{99m}Tc production capacity is the six-year period 2017-2022, a period that includes important anticipated changes in global production capacity, including the period when the NRU reactor and Canadian Nuclear Laboratories (CNL) and Nordion processing capacity will be held on "hot standby" (until March 2018). The period also anticipates the commissioning of new reactor- and non-reactor-based projects around the world. The capacity scenarios presented in this document are based on the data in Appendix 1, with some caveats[1]. Appendix 1 provides the current available maximum capacity for producing reactors and processors under normal operating conditions.

This report explains the results obtained from three capacity scenarios for the 2017-2022 period, presented in six-month intervals (January-June and July-December):

- Scenario A: "Reference" scenario – a baseline case that includes only currently operational irradiation and processing capacity.
- Scenario B: "Technological challenges" scenario – this adds all of the anticipated projects, but not all of their planned new ^{99}Mo production capacity in most cases. Conventional 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 in the analysis from their first full year of production. Alternative technology projects (including reactor- and non-reactor-based) projects are assumed to have a 50% probability of starting full scale production on their announced commissioning dates; so given the unproven nature of these technologies and in some cases, more difficult access routes to the market, only 50% of this new capacity is included in the projection.

1. See the notes appended to each table in Appendix 1.

– Scenario C: "Project delayed" scenario – this builds on the "technological challenges" scenario by further assuming that LEU conversion and all new projects are delayed by one year beyond their present anticipated first full year of production.

A so-called "all-in" scenario (where all the planned new/replacement projects are included at full projected capacity) is not reported in this projection. If all new potential projects proceed at the capacities and times as announced, there will be significant overcapacity of supply in the $^{99}Mo/^{99m}Tc$ market by 2022, a capacity level which is unlikely to be sustainable by the market in the long term.

In all three scenarios, the six-month forecast intervals are based upon a weighted split of operating capacity between the two six-month periods in a year based upon expected operational patterns provided by the operator where that is known.

It should be noted that the scenarios B and C in this report do not include all of the announced new projects included in Appendix 1. In this report, a total of four projects have been excluded as their likely commissioning dates have been delayed beyond 2022. This is not to suggest that the projects will not become operational, but that they are now not scheduled in the forecast period (2017-2022).

The approach for this report concerning the effects of LEU conversion is the same as that used in the June 2016 report and a simple blanket effect of a 10% level of efficiency loss has been applied in all cases where LEU conversion will take place. The timing of this effect is guided by the latest LEU conversion time plans provided by the relevant supply chain members to the NEA.

Chapter 4. Reference scenario: A

The reference scenario includes only current ^{99}Mo production capacity; that is, the irradiators and processors that are part of the current global supply chain, including Argentina and Russia. It should be noted that in this report, capacity that was previously transitional (e.g. anticipated to be introduced during 2015 or 2016) and that has now been successfully added to global supply has been included in the reference scenario. The effect of the supply chain successfully implementing additional capacity has been to progressively raise the level of the baseline reference scenario in small steps in the last two years.

Reference scenario: A – Irradiation and processing capacity

As discussed in previous NEA studies, most irradiators are ageing; the OSIRIS reactor ceased operation in December 2015 and the NRU reactor ended routine ^{99}Mo production in October 2016, both reducing irradiation capacity. The end of routine NRU reactor production also took the processing capacity provided by CNL/Nordion offline. In response to this, irradiators and processors in the current fleet added capacity through facility adjustments in a number of steps, leading overall to substantial additional capacity. This has increased the baseline capacity projected in the reference scenario.

Figure 4.1: Demand (9 000 6-day Ci ^{99}Mo/week EOP) and demand +35% ORC vs. current irradiation and current processing capacity, 2017-2022: Scenario A

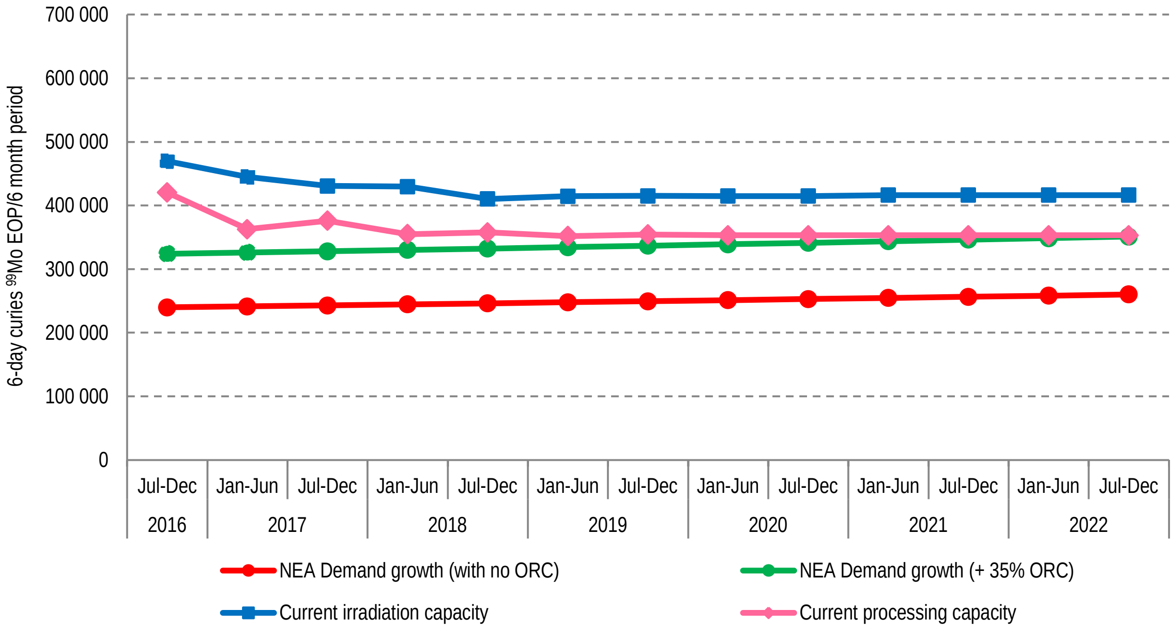


Figure 4.1 shows the projected 2017-2022 global NEA demand estimate for ^{99}Mo, the NEA demand estimate +35% ORC, and the projected current irradiation capacity and current processing capacity based on the reference scenario of the present fleet of irradiators and processors, inclusive of any further planned additional capacity adjustments to those facilities. The NEA has added the preceding six-month period (July-December 2016), a period that precedes the forecast period, to all graphs; this is to identify the actual capacity status in the preceding six-month period.

In the reference scenario, the global irradiation capacity decreases in the January-June 2017 period due to the end of routine production from the NRU reactor. The NRU reactor was in operation for part of the July-December 2016 period and the BR-2 reactor returned to service during the same period following an extended refurbishment outage. Irradiation capacity is projected to fall slightly in the July-December 2017 period due to reactor scheduling effects that include a planned maintenance break at the LVR-15 reactor. Capacity then increases slightly in the January-June 2018 period as the LVR-15 returns to a full operating schedule, then reduces slightly again in the July-December 2018 period due to some LEU conversion effects. It then stabilises for the rest of the period to 2022 well above the NEA demand + 35% ORC line.

Compared to the 2016 report, the overall irradiation capacity is slightly lower in the reference scenario through the 2019 to 2022 period, because the BR-2 reactor has reduced the number of planned cycles anticipated during that period. The BR-2 has returned from the extended refurbishment outage with a higher level of operating capability, but the present commercial environment does not justify operating the additional cycles that could be made available. Overall irradiation capacity appears to be sufficient to assure supply throughout the projection period.

In the reference scenario, the global processing capacity increased in July-December 2016 period with the increased transition capacity at ANSTO being successfully implemented. As expected, it is then projected to drop in the January-June 2017 period as the CNL/Nordion processing capacity moves to a “hot standby” mode, but then moves higher again in the July-December 2017 period with introduction of some additional processing capacity from Mallinckrodt. Processing capacity then falls slightly in 2018 as some LEU conversion efficiency losses feed in. It then remains stable at a level above the NEA demand +35% ORC line for the rest of the period to 2022, but is very close to that reference line by 2022.

Throughout the projection period, the global processing capacity should be sufficient, but from 2018 onwards the processing capacity is close to the important NEA demand +35% ORC line. The planned full conversion to LEU targets is projected to slightly reduce global processing capacity, although the processors involved continue to work on mitigation strategies to minimise or neutralise that effect.

The non-European ^{99}Mo-irradiating reactors each have associated processing facilities, while in Europe, at present, a network of four reactors supply two processing facilities. The total European irradiating capacity under normal operating conditions has been greater than the total European processing capacity. The level of that additional irradiation capacity can be seen by comparing the irradiation and processing capacity curves in Figure 4.1. Following the return to service of the BR-2, the gap between irradiation and processing capacity is almost constant for the projection period.

Overall, the current irradiator and processor supply chain, if well maintained, planned and scheduled, will be able to manage limited unplanned outages of a reactor, or a processor throughout the projection period to 2022. The level of capability to manage adverse events will reduce slowly with time and processing capacity in particular has only limited additional capacity above the NEA demand +35% ORC level for the final 4 years of this reference scenario.

Figures 5.1, 5.2, 6.1 and 6.2 in later sections of this report present the projected changes in potential irradiation and processing capacity under the scenarios B and C. It should be noted that these do not include assumptions of any production from the NRU reactor after October 2016.

Chapter 5. Technological challenges scenario: B

The technological challenges scenario in this report has carried over the principles from the 2014, 2015 and 2016 reports. The scenario is a direct extension of the reference scenario A presented in the previous section, and includes the addition of "qualified" new reactor- and non-reactor-based projects to the existing capacity. In the preparation of this report, the tables A1.1 to A1.4 shown in Appendix 1 were thoroughly reviewed and revised in consultation with the supply chain participants using a standard format of project timeline reporting. It should be mentioned that not all new projects announced around the world have been included in this technological challenges scenario. Only those projects that have been "qualified" are included, those where adequate levels of data have been provided to the NEA and where the operational timeline is within the 2017-2022 forecast period. More specifically, the NEA has decided to consider only new projects that are likely to be commissioned and operational at least one year before the end of 2022. Excluded projects include those that have unspecified construction start and commissioning dates, or for which there is inconclusive information about likely operational dates.

By making such a determination, the NEA is not suggesting that any excluded projects will never materialise, but rather that they may not be commissioned within the forecast period. Projects are not excluded on the basis of their proposed technology. In the longer term, after 2022, the ^{99}Mo demand-supply schedule may look different with other projects operating.

Furthermore, all new alternative technology projects whether reactor-based or non-reactor-based are assumed to have a 50% probability of being commissioned within their announced timelines. This assumption is to account for the fact that alternative technologies have yet to be proven on a large scale in the ^{99}Mo/^{99m}Tc market. This has been translated as applying only 50% of the expected maximum capacity to the forward projections for each of those projects.

Appendix 1 (Tables A1.3 and A1.4) presents the planned "qualified" projects expected to be commissioned by 2022. The scenarios B and C (see also Chapter 6) include all but four of these projects. The four exclusions from the scenarios are:

- The proposed Korean reactor and processing facility; the project is in very early construction phase, but has been put on hold due to a recent earthquake and will be the subject of further seismic investigations before proceeding. For the purposes of this projection, the cautious position has been taken of assuming that the Korean project will not start before 2022.
- The Polish processing facility associated with the MARIA reactor which has reduced its expected capacity and is now scheduled to have its first full year of operation later than 2022.
- The Brazil MR reactor and processing facility project is now scheduled to have its first full year of operation later than 2024.
- The China Advanced Research Reactor and associated ^{99}Mo processing facility, where no firm project planning to achieve operation by 2022 could be ascertained.

The number of potential projects where project timeline slippage has moved the project beyond 2022 (shown as 2022+ in the tables) has increased since the 2016 report, indicating that these projects are not just delayed, but are now being pushed out further into the future. These delays and the reported delay in a number of the projects that remain within the 2017 to 2022 projection period is a concern. It should be assumed that timeline slippage will continue to influence many projects that have not yet finalised a detailed project build timetable, secured full funding and/or acquired relevant licence approvals.

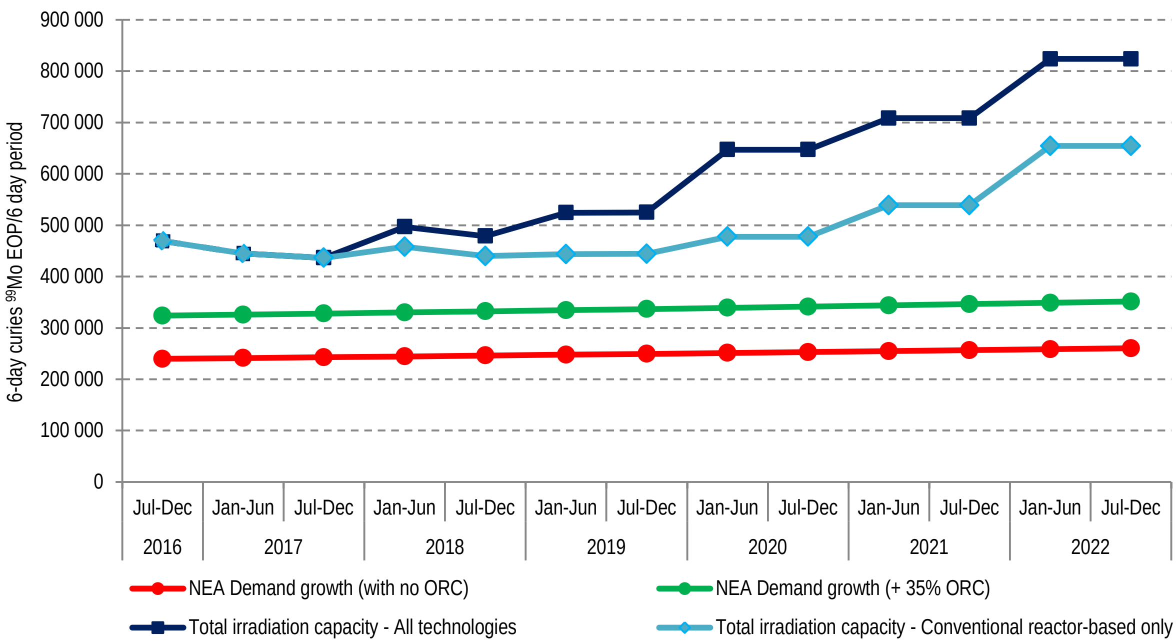
No new projects with the potential for becoming operational earlier than 2022 have been added to this analysis. The Nordion/General Atomics processing project added in the 2016 report has reduced the expected capacity from the project.

In the time frame beyond 2022, the proposed projects for ^{99}Mo/^{99m}Tc irradiation and associated processing capacity, if all completed, would significantly exceed projected market demand. However, this apparent future excess capacity should not imply that long-term security of supply is assured as it does not take into account any current capacity being retired early, the continued delay of projects, or consider the commercial sustainability of any potential "overcapacity" in the market.

Technological challenges scenario: B – Irradiation capacity

Figure 5.1 presents the NEA projected demand, projected demand +35% ORC and the irradiation capacity under the technological challenges scenario B. This shows both total capacity "all technologies" and capacity "conventional reactor-based only". It can be seen that even without all planned new irradiation projects being fully included, the global capacity of both lines looks to be sufficient to meet projected demand +35% ORC throughout the six-year forecast period. Notwithstanding the end of the NRU reactor capacity, the planned new capacity in Australia, Europe and North and South America, should more than compensate the mild capacity losses seen in the reference scenario A.

Figure 5.1: Current demand (9 000 6-day Ci ^{99}Mo/week EOP) and demand +35% ORC vs. irradiation capacity – total and conventional reactor-based only, 2017-2022: Scenario B



To compare the effect that alternative $^{99}Mo/^{99m}Tc$ production technologies may have upon irradiation capacity, Figure 5.1 separates out conventional (reactor-based) irradiation capacity from total irradiation capacity. These lines now start to diverge in the January-June 2018 period when initial quantities of product from alternative technologies are expected to fully enter the market.

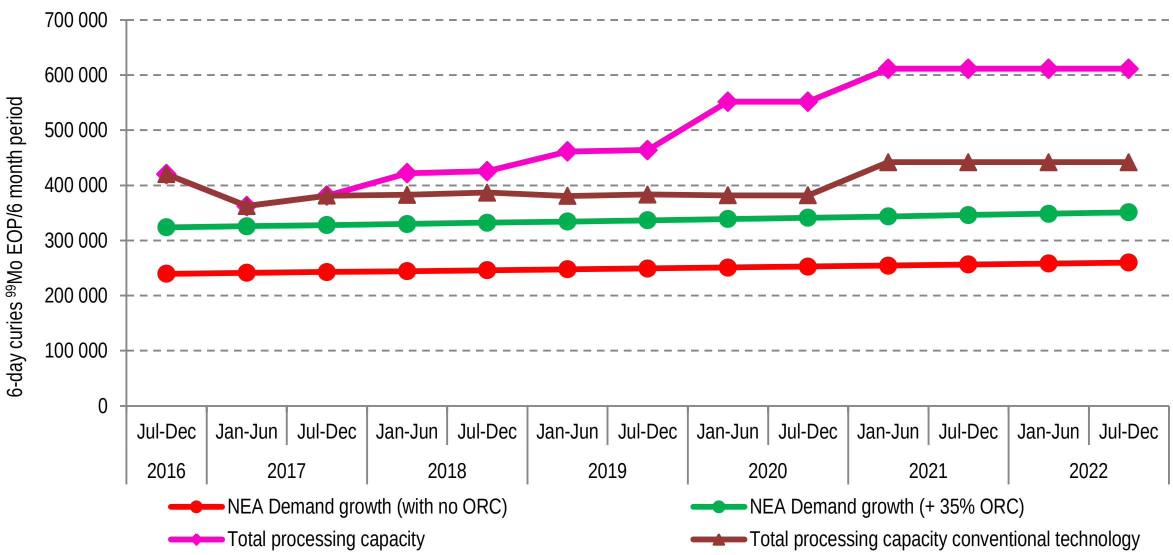
As in the reference scenario, the capacity drop in the January-June 2017 period is due to the end of routine production from the NRU reactor and irradiation capacity is projected to fall slightly in the July-December 2017 period due to reactor scheduling effects that include a planned maintenance break at the LVR-15 reactor. From the January-June 2018 period onwards, overall capacity increases throughout the course of the projection period with only some minor variations at a six-monthly level due to some reactor scheduling and LEU conversion effects. Additional conventional irradiation capacity added in Germany has been delayed (to second half 2019) and additional new-build reactor-based capacity has been delayed to 2021 and 2022, confirming the long lead-times associated with these facilities. The additional capacity is due to the commissioning of new reactors in Europe and South America. Additive irradiation capacity from "alternative technology" will only support overall security of supply from 2018, the additive capacity from "alternative technology" projects primarily in the United States and Canada is progressive and quite substantial throughout the projection period, with a substantial increase projected from 2020.

The total irradiation capacity projected by 2022 is 10% lower than the equivalent capacity projected to 2021 in the 2016 report, reflecting an overall delay in projects.

Technological challenges scenario: B – Processing capacity

Figure 5.2 presents the NEA projected demand, projected demand +35% ORC and the processing capacity under the technological challenges scenario B. This shows both total processing capacity "all technologies" and processing capacity "conventional technology only". It can be seen that even without all planned new processing projects being fully included, the global capacity of both lines look to be sufficient to meet the projected demand +35% ORC requirement, throughout the six-year forecast period.

Figure 5.2: Current demand (9 000 6-day Ci ^{99}Mo/week EOP) and demand +35% ORC vs. processing capacity – total and processing capacity – conventional only, 2017-2022: Scenario B



As in the reference scenario, the global processing capacity increased in July-December 2016 period with the successful implementation of increased transition capacity at ANSTO (Australia). As expected, capacity is then projected to drop in the January-June 2017 period as the CNL/Nordion processing capacity moves to a "hot standby" mode, but moves higher again in the July-December 2017 period with introduction of some additional processing capacity from Mallinckrodt. The global processing capacity then moves higher again in the January-June 2018 period with the introduction of the additional ANSTO Nuclear Medicine (ANM) capacity, but with some of the increase offset by LEU conversion effects. From 2018 to 2020, the Total processing capacity from conventional technology is projected to remain stable and then increases further in 2021.

The processing capacity from alternative technologies in the technological challenges scenario is projected to start later than in the equivalent scenario in the 2016 report. This is because alternative technology projects have not yet been successfully introduced, with some projects delayed again by a further year. As a result, the first full year of additional processing capacity from alternative technologies is now anticipated in 2018, after this, addition is projected to be progressive and quite substantial through the period until 2021, then flattens. Alternative technology will only start to support security of supply from 2018 onwards.

The total processing capacity projected by the end of the reference period in 2022 is now 7% lower than the equivalent capacity projected in 2021 in the 2016 report, reflecting an overall delay in projects.

Some alternative technology processing capacity is linked one-to-one with alternative technology irradiation capacity; in those cases, both the irradiation and the processing components of those projects must be successfully deployed for those technologies to provide additional processing capacity to the supply chain.

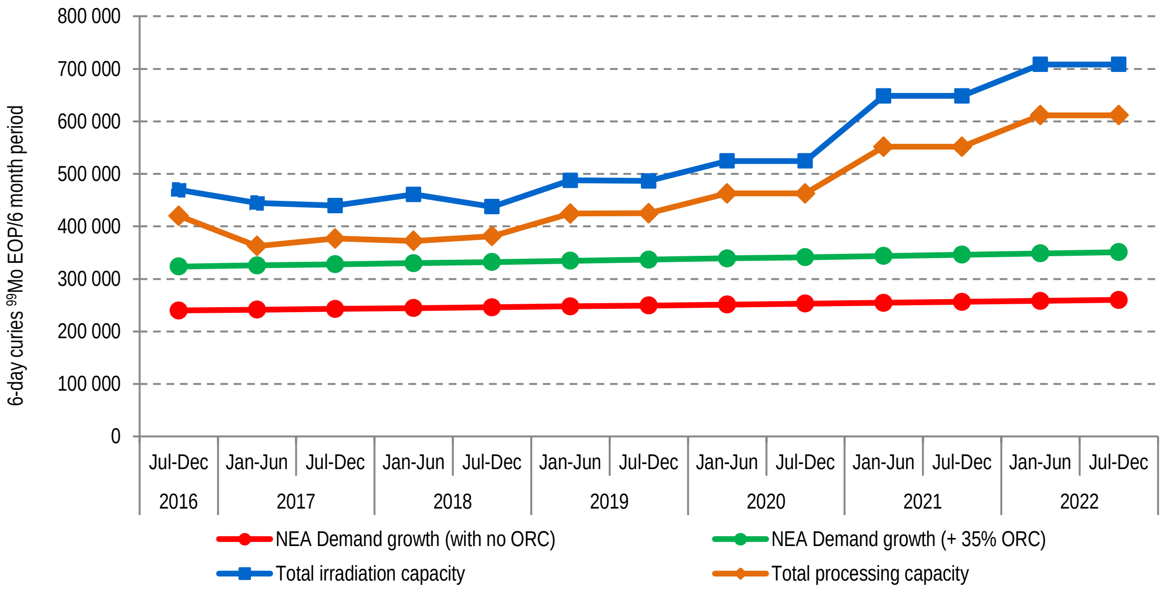
Chapter 6. Project delays scenario: C

The project delays scenario C has been developed from the technological challenges scenario B by modelling a delay of all new projects and LEU conversion by one year. This scenario considers the theoretical impact to future capacity when considering the technical complexity of new reactor-based projects and the often ground-breaking efforts in reaching large scale, commercial production by alternative technologies. Experience has shown that large projects often take longer to complete than originally envisaged. This has already been clearly demonstrated during the review of the previous reports and in the analysis of scenario B in this report. As further project delays can be anticipated, the projects delays scenario C is probably the scenario most likely to reflect future events.

Project delays scenario: C – Irradiation and processing capacity

Figure 6.1 shows the projected global irradiation and processing capacity under the project delays scenario C. Under this scenario, delayed new capacity will have a negative effect on both irradiation and processing capacity, but at the same time, delayed LEU conversion will have some opposite effect in the early years, provided that sufficient inventories of high enriched uranium (HEU) for targets are available for the period of any delay.

Figure 6.1: Current demand (9 000 6-day Ci ^{99}Mo/week EOP) and demand +35% ORC vs. total irradiation capacity and total processing capacity – projects delayed, 2017 - 2022: Scenario C

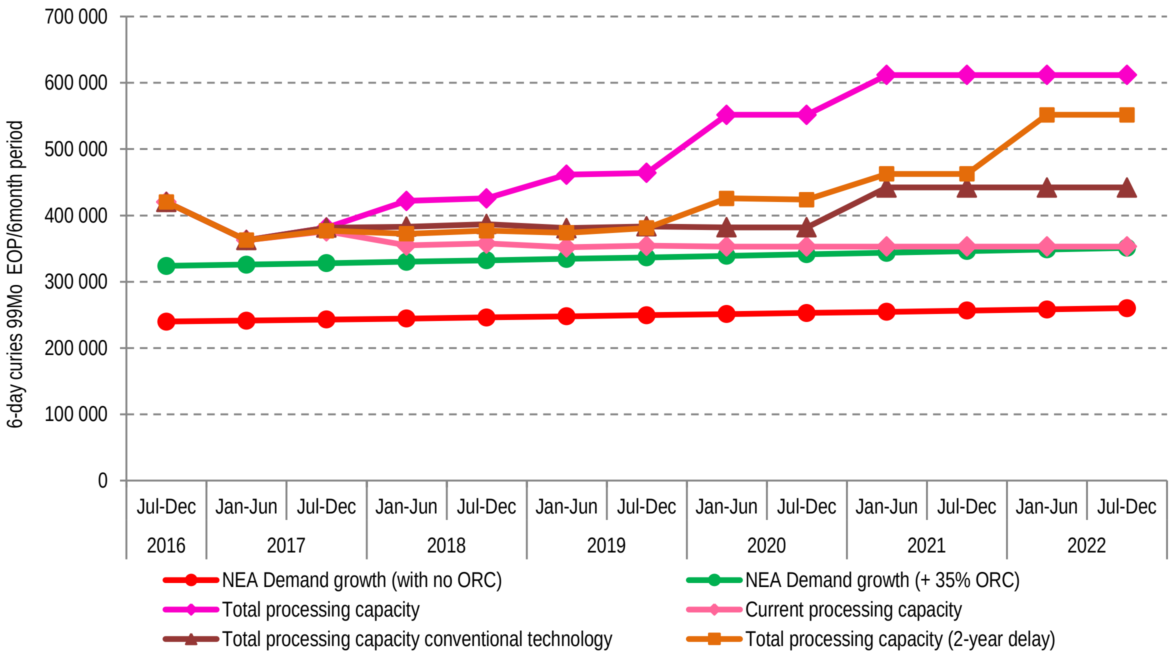


Compared to scenario B, irradiation and processing capacity under scenario C are almost identical in 2017. Both then remain relatively flat through 2018, increasing a little in 2019 and 2020 and then more significantly in 2021. In this report, the effects of scenario C are less marked than in the 2016 report, because a substantial amount of the additional irradiation and processing capacity coming from Australia has already been locked into the reference scenario A and a relatively lower proportion of the additional capacity is now planned from the new ANM facility. So the effect of a projected one-year delay in commissioning of the additional ANM capacity in this scenario while noticeable, it does not appear as critical as in the 2016 report. Total irradiation and processing capacity in the 2017 scenario C recovers to be above the July-December 2016 capacity level that included some Canadian capacity contribution from 2019 onwards.

The 2017 scenario C projection for both total irradiation capacity and total processing capacity stay well above the NEA demand +35% ORC line throughout the reference period. This improvement has been achieved because of the on-time introduction of additional capacity in Australia utilising existing facilities.

The potential impact of even more extended project delays is relevant as history confirms that most projects experience some delays and sometimes multiple year delays. Figure 6.2 looks at the potential impact of further delays and concentrates only on processing capacity, because it has lower levels of reserve capacity. It shows the projected demand and projected demand +35% ORC lines compared to the current processing capacity, the total processing capacity and the conventional technologies only capacity (all with no project delay), and with a total processing capacity line with a two-year total project delay. The graph lines therefore represent the minimum, the maximum and two potential intermediary lines for processing capacity that represent different types of challenge.

Figure 6.2: Current demand (9 000 6-day Ci ^{99}Mo/week EOP) and demand +35% ORC vs. processing capacity – current, total, total conventional only and total two-year delay, 2017 - 2022: Scenarios A + B + C (two-year delay)



The impact of assuming two years total delay in all processing projects has a similar pattern to assuming only new processing capacity from conventional technologies. In both cases the divergence in the two intermediate projections start in 2018 and in both cases the projections show processing capacity remaining relatively stable. They remain above the reference scenario A level through the period 2018 to 2019 before increasing at varying rates from 2020.

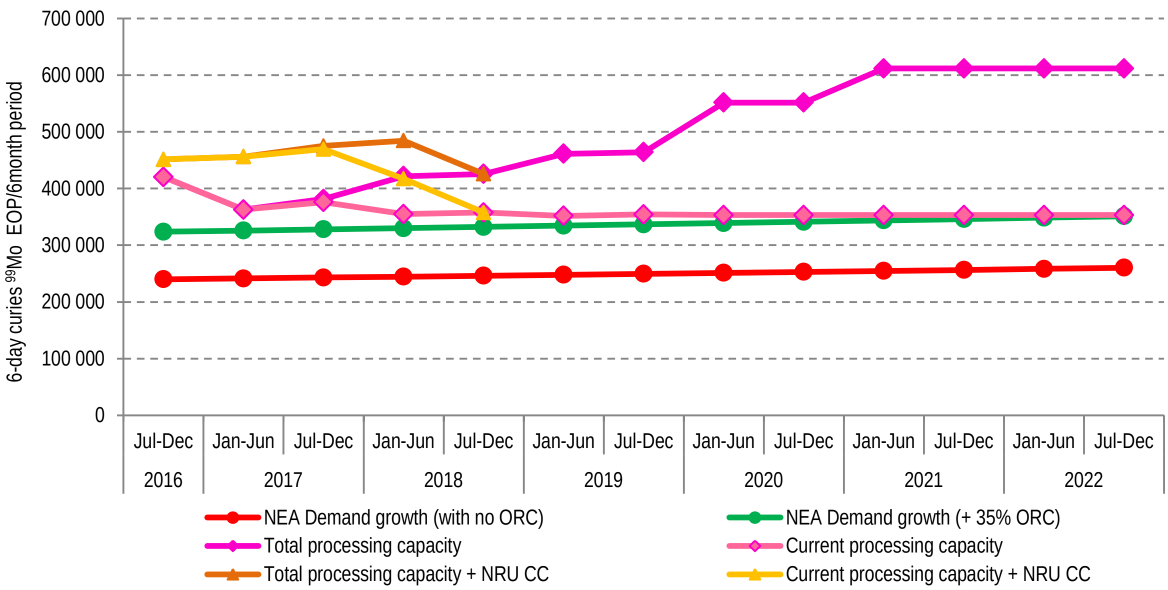
In both cases, the capacity lines stay well above the NEA demand +35% ORC line throughout the reference period. This is an improvement compared to the 2016 report and has been achieved because of the on-time introduction in 2016 of the additional transitional capacity in Australia utilising existing facilities and also partially reflects the delay in LEU conversion losses in the delayed scenarios. Both of these intermediate projections confirm that a substantial reduction in overall processing capacity occurs when projects are severely delayed, but that the resulting processing capacity levels remain stable and above the reference scenario levels throughout the whole projection period.

Chapter 7. Potential NRU contingency capacity

On 6 February 2015, the Government of Canada announced adjusted plans for the NRU reactor that affected the potential future supply of ^{99}Mo, proposing to operate the NRU reactor as a "supplier of last resort" from 1 November 2016 to 31 March 2018, with contingency capacity provided by Atomic Energy of Canada Limited, CNL and Nordion. As per this announcement, the NRU will operate during this period for non-^{99}Mo purposes, with the effect of keeping the NRU reactor in "hot operation" and associated facilities required for ^{99}Mo production and processing in "hot standby" mode.

While the NRU reactor and associated processing facilities can be made available under special conditions of market supply shortage, this contingency capacity would be used only in the unexpected circumstance of significant global shortages and only if alternative technologies or other sources of supply were not available to meet demand. In this way, a form of additional contingency capacity could be available through the NRU on top of the ORC held within the rest of the supply chain.

Figure 7.1. Current demand (9 000 6-day Ci ^{99}Mo/week EOP) and demand +35% ORC vs. processing capacity – current and total, with and without NRU CC, 2017-2022: Scenarios A + B + A with NRU CC + B with NRU CC



The NEA considered that it would be useful to continue to model the effect of this contingency capacity. Figure 7.1 concentrates upon the effect that the potential NRU contingency capacity (NRU CC) could have upon total available processing capacity, as this has lower levels of reserve capacity in all scenarios. It shows the demand and demand +35% ORC lines compared to current processing capacity only – Scenario A (both with and without NRU CC) and the total processing capacity – Scenario B (with and without NRU CC).

The projection lines represent the maximum and minimum processing capacity lines from the earlier scenarios and show that the effect of potential NRU CC is substantial in the period to January-June 2018. As the impact of additional processing capacity from alternative technologies has now moved out to 2018 (from 2017 in the previous report), the maximum and minimum capacity lines in this NRU CC scenario are essentially the same throughout 2017, so the impact of the potential NRU CC only has a difference in character in early 2018.

In both cases total processing capacity including NRU CC is boosted to a very safe level for the period before falling back to the reference scenarios, so the potential NRU CC provides an important buffer in the period until the end of March 2018.

Chapter 8. Conclusions

The global demand estimate has been maintained at a level of 9 000 6-day Ci ^{99}Mo per week EOP. This demand level has been a factor in allowing the existing supply chain to be able to continue to provide a near to full service level in the last five years, despite some operational and scheduling problems.

Good progress with increasing the level of existing capacity in 2016 has raised the baseline reference scenario A projections for the second year in a row. The successful introduction of substantial conventional irradiation and processing capacity in Australia from existing facilities has made the baseline capacity more robust, but the addition of further processing capacity from the new ANM facility and from alternative technologies by 2018 remains important.

The decision to extend the NRU operating period to potentially provide contingency capacity will be a useful stop-gap until early 2018.

There have been delays in the introduction of alternative irradiation and processing technologies, with some projects suffering multi-year delays. Some delays to large conventional technology projects have now pushed them beyond the time scope of this review, reducing the projected capacity available by 2022. The multiple and extended character of the delays experienced by some projects is a concern.

Overall, the current irradiator and processor supply chain capacity should be sufficient and if well maintained, planned and scheduled, be able to manage an unplanned outage of a reactor, or a processor throughout the whole period to 2022. When no additional capacity is added, then from mid-2018, the level of capability to manage adverse events reduces, in particular when considering processing capacity.

The supply situation will continue to require careful and well considered planning to minimise security of supply risks, with a high degree of co-operation between the supply chain participants being essential for the foreseeable future. The market situation will require regular monitoring, along with periodic review of the progress in bringing proposed new production capacity to market.

References/further reading

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

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

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NEA (2015), "The Supply of Medical Radioisotopes: 2015 Medical Isotope Supply Review: ^{99}Mo/^{99m}Tc Market Demand and Production Capacity Projection 2015-2020", OECD, Paris.

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Appendix 1.

Table 1. Current irradiators including those in transition by 2022

Reactor (Fuel)	Current targets[7]	Normal operating days/year	Anticipated ^{99}Mo production weeks/year	Expected available capacity per week (6-day Ci ^{99}Mo)	Expected first full year of ^{99}Mo production[8]	Expected available capacity per year (6-day Ci ^{99}Mo) by 2022	Estimated end of operation
BR-2 (HEU)	HEU	147	21	7 800	NA	163 800	At least until 2026
HFR[1] (LEU)	HEU	275	39	6 200	NA	241 800	2024
LVR-15 (LEU)	HEU/LEU	210	30	3 000	NA	90 000	2028
MARIA (LEU)	HEU	200	36	2 700	NA	95 000	2030
OPAL (LEU)[2]	LEU	300	43	2 150	NA	92 450	2057
RA-3 (LEU)	LEU	230	46	400	NA	18 400	2027
SAFARI-1 (LEU)	HEU/LEU	305	44	3 000	NA	130 700	2030
RIAR[3] (HEU)	HEU	350	50	1 000	NA	50 000	At least until 2025
KARPOV[3] (HEU)	HEU	336	48	350	NA	16 800	At least until 2025
OPAL[4] (LEU)	LEU	300	43	+1 350	2018	58 050	2057
FRM-II[5] (HEU)	LEU	240	32	2 100	2020	67 200	2054
NRU (HEU)[6]	*HEU*	*280*	*None scheduled*	*Up to 4 680*	*NA*	*NA*	*2018*

Notes: 1). HFR capacity increases from 5 400 to 6 200 per week from 2017, 2). OPAL extra irradiation capacity now operating at 12 plates, 3). RIAR and KARPOV material needs to comply with specific requirements to be available in some markets, the KARPOV facility will be relicensed in 2020 to continue its operation, 4). OPAL extra irradiation capacity at 12 plates in the new ANM ^{99}Mo facility starting late 2017, first full year 2018, 5). FRM II market entry dependent upon conversion of processors to LEU targets, full capacity will be available from Q3 2019, 6). NRU will remain in operation until 31 March 2018 for non ^{99}Mo purposes and is capable of providing ^{99}Mo contingency capacity at the discretion of the Canadian government in the event of significant shortage that cannot otherwise be mitigated, 7). HEU >20% enriched Uranium, LEU <20% enriched Uranium, 8). NA = Not Applicable

Table 2. Current processors including those in transition by 2022

Processor	Targets[6]	Anticipated ^{99}Mo production weeks/year	Available capacity per week (6-d Ci ^{99}Mo)	Expected available capacity per year (6-d Ci ^{99}Mo) by 2022	Expected first full year of ^{99}Mo production[7]	Expected year of conversion to LEU targets	Estimated end of production
ANSTO Health	LEU	43	2 150	92 450	NA	LEU	2057
CNEA	LEU	46	400	18 400	NA	LEU	2027
IRE	HEU	52	3 500	182 000	NA	2017	At least until 2028
Mallinckrodt[1]	HEU	52	5 000	260 000	NA	2017	Not Known
NTP[2]	HEU/LEU	44	3 000	130 700	NA	LEU	At least until 2030
RIAR[3]	HEU	50	1 000	50 000	NA	2018	At least until 2025
KARPOV Institute[3]	HEU	48	350	16 800	NA	2018	At least until 2025
ANSTO Nuclear Medicine (ANM)[4]	LEU	43	+1 350	58 050	2018	LEU	2057
CNL/Nordion[5]	*HEU*	*None scheduled*	*Up to 4 680*	*NA*	*NA*	*No Conversion*	*2018*

Notes: 1) Mallinckrodt capacity increase from current facilities introduced by 3Q 2016; 2) NTP capacity limited by temporary processing limits until end Q3/2017; 3) RIAR and KARPOV material needs to comply with specific requirements to be available in some markets, the KARPOV facility will be relicensed in 2020 to continue its operation; 4) ANM extra processing capacity is additional and will use OPAL additional irradiation capacity; 5) NRU will remain in operation until 31 March 2018 for non 99Mo purposes, CNL/Nordion will remain capable of providing 99Mo contingency capacity if NRU irradiations are performed; 6) HEU >20% enriched Uranium, LEU <20% enriched Uranium; 7) NA = Not Applicable

Table 3. Potential irradiators entering in period 2017 to 2022

Irradiation source (Fuel)	Targets/technology[5]	Expected operating days/year	Anticipated Mo-99 production weeks/year	Expected available capacity per week (6-d Ci ^{99}Mo) by 2022[6]	Potential annual production (6-day Ci ^{99}Mo) by 2022[6]	Expected first full year of production	Project status (January 2017)
MURR/NorthStar (HEU)	Natural Mo in CRR	339	52	750	39 000	2018	Capacity and irradiation facilities ready for FDA inspection
MURR/NorthStar[1] (HEU)	Enriched Mo in CRR	339	52	+2 250	+117 000	2018	Transition to enriched Mo targets starts in 2017
NorthStar (non U)	Non-fissile from LINACs	352	52	3 000	156 000	2020	Accelerator selected
MURR/GA(HEU)	LEU-SGE	339	52	3 200	166 400	2019	Phase 1 complete
SHINE (LEU)	LEU solution with DTAs and SAAs	350	50	4 000	200 000	2020	Construction not yet started
RA-10 (LEU)	LEU in CRR	315	48	2 500	120 000	2021	Groundworks started, construction starts 2017
Jules Horowitz Reactor[2] (LEU)	LEU in CRR	220	24	4 800	115 200	2022	Under construction
Korea (LEU)[3]	LEU in CRR	300	43	*400*	*17 200*	2020+	Construction permit pending due to earthquake
Brazil MR (LEU)	LEU in CRR	290	41	*1 000*	*41 400*	2022+	Detailed design to be contracted in 2017. Construction depends on budget
China Advanced RR[4] (LEU)	LEU in CRR	240	34	*1 000*	*34 000*	2022+	Existing reactor under modification

Notes: 1). MURR/NorthStar Enriched Mo capacity is additional to the Natural Mo capacity when introduced, 2). JHR reactor begins active commissioning in 2021, but 99Mo capacity not expected to be available until 2022, 3). Korea capacity is planned to increase further in stages after 2023 4). CARR is already operational, but date of 99Mo availability is unknown and is not before 2022, 5). Mo = inactive Molybdenum, either natural or enriched, CRR = Conventional Research Reactor, LINACs = multiple linear accelerators, LEU <20% enriched Uranium, DTAs = multiple deuterium-tritium accelerators, SAAs = multiple subcritical aqueous assemblies, 6). Numbers in italics indicate availability after 2022

Table 4. Potential processors entering in period 2017 to 2022

Processor	Targets[5]	Anticipated Mo-99 production weeks/year	Expected available capacity per week (6-day Ci) by 2022[6]	Expected available capacity per year (6-day Ci ^{99}Mo) by 2022[6]	Estimated first full year of production	Project status (January 2017)
MURR/NorthStar	Natural Mo target	52	750	39 000	2018	Processing capacity in place ready for FDA inspection
MURR/NorthStar[1]	Enriched Mo target	52	+2 250	+117 000	2018	Transition to enriched Mo targets starts in 2017
NorthStar	Non-fissile	52	3 000	156 000	2020	Accelerator selected
Nordion	LEU-SGE	52	3 200	166 400	2019	Phase 1 complete
SHINE	LEU solution	50	4 000	200 000	2020	Construction not yet started
CNEA	LEU	48	2 500	120 000	2021	Preliminary design completed start construction 2018
Korea[2]	LEU	43	*400*	*17 200*	2020+	Construction permit pending due to earthquake
MARIA: Mo-99 2010[3]	LEU	40	*300*	*12 000*	2022+	Financing – not yet agreed
Brazil MR	LEU	41	*1 000*	*41 400*	2022+	Detailed design still to be contracted. Construction depends on budget
China Advanced RR[4]	LEU	34	*1 000*	*34 000*	2022+	Financing decision after 2017 tests

Notes: 1). MURR/NorthStar Enriched Mo capacity is additional to the Natural Mo capacity when introduced, 2). Korea capacity is planned to increase further in stages after 2023, 3). MARIA uses existing capacity at the MARIA reactor, 4). CARR is already operational, but date of 99Mo processing capacity availability is unknown and not before 2022, 5). Mo = inactive Molybdenum, either natural or enriched, LEU <20% enriched Uranium, 6). Numbers in italics indicate availability after 2022