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The Supply of Medical Radioisotopes

2016 Medical Isotope Supply Review: ⁹⁹Mo/^{99m}Tc Market Demand and Production Capacity Projection 2016-2021







Organisation de Coopération et de Développement Économiques Organisation for Economic Co-operation and Development

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NUCLEAR ENERGY AGENCY STEERING COMMITTEE FOR NUCLEAR ENERGY

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

2016 Medical Isotope Supply Review: 99Mo/99mTc Market Demand and Production Capacity Projection 2016-2021

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NEA/SEN/HLGMR(2016)2

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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 (99Mo)/technetium-99m (99mTc) production capacity situation to facilitate the creation of an updated demand and capacity projection for the 2016-2021 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 99Mo and its decay product, 99mTc.

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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Chapter 1. Introduction

Medical diagnostic imaging techniques using technetium-99m (99mTc) 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 (99Mo) and only 6 hours for 99mTc, 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 99Mo-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 <code>99Mo/99mTC</code>. 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 <code>99Mo</code> 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 ⁹⁹Mo 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 with a report, "2015 Medical Isotope Supply Review: ⁹⁹Mo/^{99m}Tc Market Demand and Production Capacity Projection 2015-2020" (NEA, 2015), which focused on the same period. This report¹ updates the 2015 report, and focuses on the important 2016-2021 period. At the end of 2015, the OSIRIS reactor in France permanently shut down operations and late in 2016 one of the largest irradiators, the National Research Universal (NRU) reactor in Canada, will cease routine ⁹⁹Mo production, while the associated processing capacity will be maintained and moved to a "hot standby" mode. New reactor- and non-reactor-based ⁹⁹Mo/^{99m}Tc projects are expected to be commissioned in various countries. It is important to analyse the overall impact and timing to understand how global production capacity might be affected.

This report presents global irradiation and processing capacity under the same three main capacity scenarios as set out in the 2015 report. As in that report, the projected demand and production capacities are presented in six-month intervals. It is intended that this report offers a high added value to the international community and the HLG-MR has 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.

^{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.

Chapter 2. Demand update

In 2011, the NEA released a study with the results of a global survey of future demand for ⁹⁹Mo/^{99m}Tc (NEA, 2011), based on an assessment by an expert advisory group. The study showed ⁹⁹Mo/^{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 ⁹⁹Mo demand at 10 000 6-day curies ⁹⁹Mo per week¹ at end of processing (EOP). This was lower than the previously estimated 12 000 6-day curies ⁹⁹Mo 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 shortage. Those changes included: better use of available ⁹⁹Mo/^{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 ⁹⁹Mo/^{99m}Tc Market, 2015-2020" (NEA, 2014) used as a starting point, the NEA 2012 estimate of 10 000 6-day curies ⁹⁹Mo 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 report adjusted the estimated demand down to 9 000 6-day curies ⁹⁹Mo EOP per week from processors, based on data collected from supply chain participants on capacity utilisation data during each operating quarter of 2012, 2013 and 2014. 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 for 2015.

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, as again, one processor was not able to provide data. The latest data reconfirms recent global demand for ⁹⁹Mo is close to 9 000 6-day curies ⁹⁹Mo EOP per week with some quarterly fluctuations. As the analysis period again included some periods of minor shortages, the actual long-term demand trend remains difficult to determine without full market data. Care must be taken when analysing this data set as periods of limited supply shortage could appear to suggest reduced market demand.

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

^{1.} A six-day curie is the measurement of the remaining radioactivity of ⁹⁹Mo 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.

For the purposes of this report, the market demand for ⁹⁹Mo activity has been held at 9 000 6-day curies ⁹⁹Mo 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 ⁹⁹Mo/^{99m}Tc, while emerging markets account for 16%. The latest NEA market demand analysis, made with the present available data does not fully confirm this level of projected market growth, but 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 99mTc at the nuclear pharmacy and in the clinic, combined with some reduction in average injected dose due to some gamma camera and protocol improvements may have played some role. Also in a market where full cost recovery (FCR) pricing is being implemented in steps along the supply chain, with the result of increasing materials prices, it would be understandable that efficiency of use continues to be a priority.

What capacity level is required to ensure that 99Mo/99mTc 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 unplanned outages at major ⁹⁹Mo producers occurring during those periods. These 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 this resulted in only a small number of limited supply shortages.

The capacity level required to ensure that ⁹⁹Mo/^{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 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 recent 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 as a reference.

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 99Mo/99mTc production capacity

The NEA regularly updates the list of current and planned new ⁹⁹Mo/^{99m}Tc irradiation and processing projects. The updates include: revisions to production start/end dates, additional "qualified" potential projects and anticipated impacts of some existing supply chain participants converting to using low-enriched uranium (LEU) targets. Appendix 1 provides a list of current and some potential new ⁹⁹Mo/^{99m}Tc producers, along with the status of "qualified" projects as of January 2016. It should be noted that not all 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 ⁹⁹Mo/^{99m}Tc supply will generally match demand. Therefore, the intent of this forecast is not to predict the actual level of ⁹⁹Mo/^{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.

In this report, the forecast horizon for ⁹⁹Mo/^{99m}Tc production capacity is the six-year period (2016-2021), a period that reflects important anticipated changes in global production capacity, including the planned exit from the supply chain of the NRU reactor and Canadian Nuclear Laboratories (CNL) and Nordion processing capacity (October 2016). The period also anticipates the commissioning of new reactor- and non-reactor-based projects in Europe, North and South America, Australia and the Far East. The capacity scenarios presented in this document are based on the data in Appendix 1, with some caveats ¹. Appendix 1 provides the current normal available capacity for producing reactors and processors.

This report explains the results obtained from three capacity scenarios for the 2016-2021 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 ⁹⁹Mo production capacity in some cases. New reactor-based projects, given their proven technology and direct access of product to the existing supply chain, are assumed to start production on their announced commissioning dates and are included in the analysis from their first full year of production. New alternative technology (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 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 ⁹⁹Mo/^{99m}Tc market by 2021, which is unsustainable 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 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. Two projects have been excluded as their likely commissioning dates have been delayed beyond 2021. This is not to suggest that these projects will not become operational, but that they are now not scheduled in the forecast horizon (2016-2021).

The approach for this report concerning the effects of LEU conversion is the same as that used in the August 2015 report and a simple blanket effect of a 10% level of efficiency loss has been applied in all cases where conversion will take place.

Chapter 4. Reference scenario: A

The reference scenario includes only current ⁹⁹Mo 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) is now included in the reference scenario, this raises the level of the baseline reference scenario slightly compared to the 2015 report.

Reference scenario: A - Irradiation and processing capacity

As discussed in previous NEA studies, most irradiators are ageing; the OSIRIS reactor has ceased operation (December 2015) and the NRU reactor will cease operation for ⁹⁹Mo production in October 2016. The planned exit of the NRU reactor will also take out of operation the processing capacity provided by CNL/Nordion. In response to this both irradiators and processors in the current fleet are in the process of adding substantial additional capacity through facility adjustments, which increases the baseline capacity projected in the reference scenario.

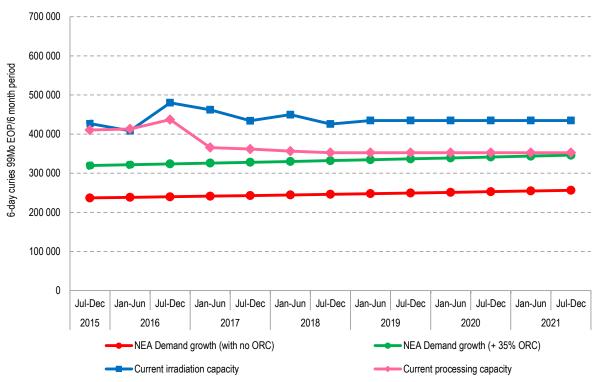


Figure 4.1. Demand (9 000 6-day Gi ⁹⁹Mo/week EOP) and demand +35% ORC vs. current irradiation and current processing capacity, 2016-2021: Scenario A

Figure 4.1 shows the projected 2016-2021 global NEA demand estimate for ⁹⁹Mo, the NEA demand estimate +35% ORC, and the projected current irradiation capacity and processing capacity based on the reference scenario of the present fleet of irradiators and processors, inclusive of planned additional capacity adjustments to those facilities. The NEA has added the preceding 6-month period (July-December 2015) to all graphs, a period that precedes the forecast horizon; this is to highlight the recent impact on irradiation capacity of the loss of the OSIRIS reactor.

In the reference scenario, the global irradiation capacity decreases in the January-June 2016 period due to the end of OSIRIS operation (December 2015). It then recovers in the July-December 2016 period with the return to service of the BR-2 reactor and with increases in existing Opal reactor capacity. Capacity then falls again through 2017 due to the end of routine ⁹⁹Mo production from the NRU reactor, but the scale of decrease is offset by further planned increases to capacity at other existing facilities. Capacity then stabilises for the rest of the period to 2021 well above the NEA demand + 35% ORC line. Irradiation capacity appears to be sufficient to assure supply throughout the projection period.

In the reference scenario, the global processing capacity increases through to the end of 2016 as current processors add capacity in preparation for LEU conversion and this includes increased transition capacity at ANSTO in preparation for the new processing facility. It then drops in the January-June 2017 period as the CNL/Nordion processing capacity moves to a "hot standby" mode and as some LEU conversion efficiency losses feed in. It then remains stable at a level just above the NEA demand +35% ORC line for the rest of the period to 2021.

Throughout the projection period, the global processing capacity should be sufficient, but from 2017 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 ⁹⁹Mo-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 additional irradiation capacity that exists in the European network can be seen by comparing the irradiation and processing capacity curves in Figure 4.1. The gap between irradiation and processing capacity is slightly negative in the first half of 2016, but following the return to service of the BR-2 the situation recovers from the July-December 2016 period onwards.

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 2021. 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 and 2015 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 around the world 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, where adequate levels of data have been provided to the NEA and where the operational timeline is within the 2016-2021 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 2021. 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 excluded projects will never materialise, but rather that they may not be commissioned within the forecast period. In the longer term, after 2021, the ⁹⁹Mo demand-supply schedule may look different with these projects operating.

Furthermore, all new alternative technology projects 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 ⁹⁹Mo/^{99m}Tc market. This has been translated as applying only 50% of the expected maximum capacity to the forward forecasts for each of those projects.

Appendix 1 (Tables A1.3 and A1.4) presents planned new "qualified" projects to be commissioned by 2021. The scenarios B and C (see also Chapter 6) include all but 2 of these projects. The two exclusions from the scenarios are:

- the Brazil MR project which is now scheduled to have its first full year of operation later than 2021,
- the China Advanced Research Reactor and associated ⁹⁹Mo processing facility where no firm project planning to achieve operation by 2021 could be ascertained (this is shown as 2021+ in the relevant tables).

The review of potential projects has indicated some further project timeline slippage since the 2015 report, and of at least one year in many cases. Further similar levels of timeline slippage can be assumed to continue for projects that have not yet finalised a detailed project build timetable, secured full funding and acquired relevant licence approvals.

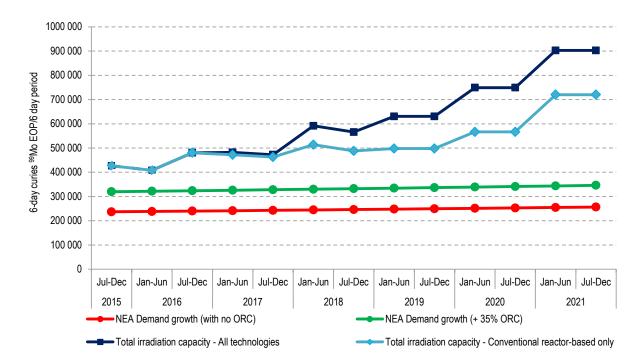
The only new project added to this analysis which may have the potential for becoming operational earlier than 2021, is the combined Nordion/General Atomics processing project that proposes to use the existing MURR reactor for irradiation capacity and to reutilise the existing Nordion processing facility in Canada.

In the timeframe beyond 2021, the proposed projects for ⁹⁹Mo/⁹⁹mTc 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, or consider the sustainability of potential "over-capacity" 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 exit from the market of the NRU reactor, planned new capacity in Asia, Australia, Europe and North and South America, should more than compensate for the capacity losses seen in the reference scenario A.

Figure 5.1. Current demand (9 000 6-day Ci ⁹⁹Mo/week EOP) and demand +35% ORC vs. irradiation capacity – total and conventional reactor-based only, 2016-2021: Scenario B



To compare the effect that alternative \$^99Mo/^99mTc production technologies may have upon irradiation capacity, Figure 5.1 separates out conventional (reactor-based) irradiation capacity from total irradiation capacity. These lines start to diverge as early as the January-June 2017 period as initial quantities of product from alternative technologies are expected to enter the market.

As in the reference scenario, the capacity drop in the January-June 2016 period is due to the loss of the OSIRIS reactor; capacity then recovers with the return to service of the BR-2 reactor in July-December 2016 and increases in existing Opal reactor capacity.

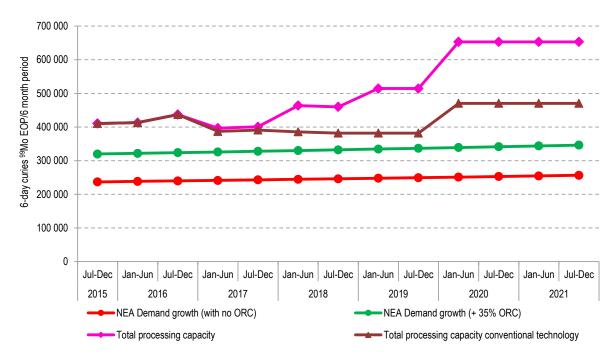
Irradiation capacity is then largely maintained in 2017 despite the exit of the NRU reactor through further increases in capacity in existing facilities. Through the course of the period 2017 until 2019 the conventional reactor-based capacity is projected to remain relatively flat, with some increased irradiation capacity added in Germany (2018) following LEU target conversion by processors. Additional new-build reactor-based capacity does not show any further influence until 2020 and 2021; this confirms the long lead-time associated with adding these facilities. The additional capacity in 2020 is due to the commissioning of new reactors in South America and Asia, the additional capacity in 2021 is in Europe.

From 2018, the additive irradiation capacity from "alternative technology" projects primarily in the United States and Canada is progressive and quite substantial throughout the period, indicating that the additive capacity of "alternative technology" will support overall security of supply from 2018 onwards.

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 Gi ⁹⁹Mo/week EOP) and demand +35% ORC vs. processing capacity – total and processing capacity – conventional only, 2016-2021: Scenario B



In line with the reference scenario, the "conventional technology" processing capacity is projected to increase slightly over the period until July-December 2016, in January-June 2017 it then decreases as the end of operation of the CNL/Nordion processing capacity feeds in. The capacity then remains relatively flat above the projected demand +35% ORC

line for a 3-year period, before increasing in 2020 with the planned commissioning of processing capacity mostly associated with reactor new-build programmes.

The processing capacity from alternative technologies in the technological challenges scenario in this report is projected to start later than in the equivalent scenario in the 2015 report. This is because alternative technologies have not yet been introduced, with some projects delayed by a further year. As a result, the first full year of addition of processing capacity from an alternative technology is in 2017 and the main addition from alternative technology projects, primarily in the United States and Canada, now begins in 2018. Addition is then projected to be progressive and quite substantial through the period until 2020, indicating that alternative technology will start to support security of supply from 2017.

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

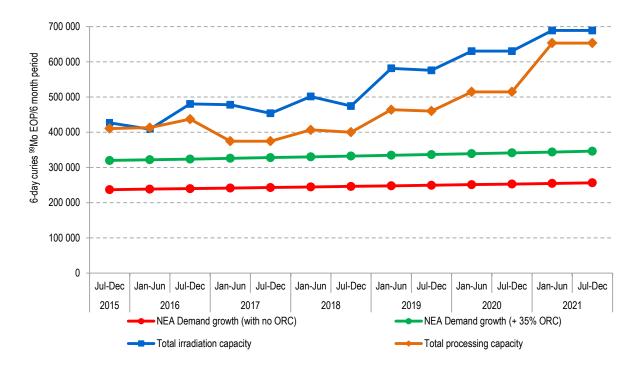
Chapter 6. Project delays scenario: C

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, where anticipated delays in projects that were modelled in those reports often materialised.

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 ⁹⁹Mo/week EOP) and demand +35% ORC vs. total irradiation capacity and total processing capacity – projects delayed, 2016 - 2021: Scenario C



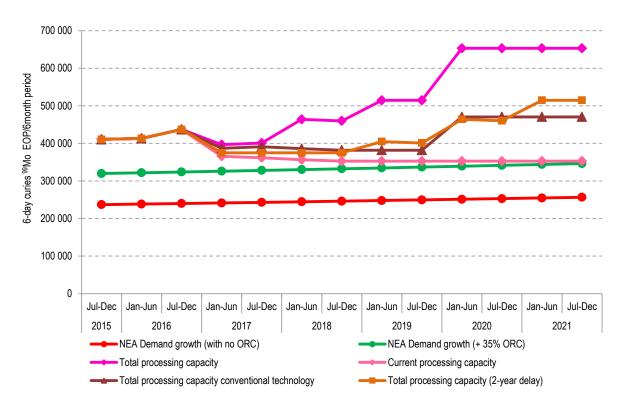
Compared to scenario B, irradiation and processing capacity under scenario C are almost identical in 2016. Both then decrease through 2017, but with processing capacity decreasing sooner and more significantly. This is because this scenario models the effect of a one-year commissioning delay of the additional Australian capacity. The total irradiation capacity holds up better as additional capacity from existing facilities is still added, but LEU conversion is assumed to be delayed. From 2018, irradiation and processing capacity then both increase generally in a number of steps, primarily due to the introduction of alternative technology that has been delayed. Total processing capacity in this scenario C only regrows to exceed the 2015 capacity levels from 2019 onwards.

The most important effect of scenario C is that the total processing capacity line drops and falls closer to the NEA demand +35% ORC line in 2017, indicating a lower level of reserve capacity. This dip underlines the importance of the on-time introduction of new capacity in Australia; this project is currently reported to be running on time.

The potential impact of project delays is relevant as history confirms that most projects experience some delays. Figure 6.2 looks at the potential impact of further delays and concentrates 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 ⁹⁹Mo/week EOP) and demand +35% ORC vs. processing capacity – current, total, total conventional only and total two-year delay, 2016 - 2021:

Scenarios A + B + C (two-year delay)



It is interesting that the impact of assuming only new processing capacity from conventional technologies has a similar pattern to assuming two years total delay in all processing projects. Both of the intermediate projections show processing capacity reductions starting in the January-July 2017 period, they then remain relatively flat at a level a little above the NEA demand +35% ORC line for periods of two to three years, before increasing again. Both of these intermediate projections confirm that a reduction in overall processing capacity occurs when projects are delayed and as a result the processing capacity levels remain close to the reference scenario levels until 2020.

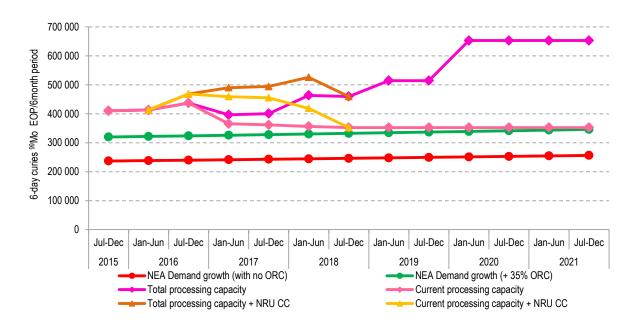
Chapter 7. Potential NRU contingency capacity

On 6 February 2015, Natural Resources Canada announced adjusted plans for the NRU reactor that affected the potential supply of ⁹⁹Mo, proposing a "supply of last resort" from the NRU reactor, supported by the CNL and Nordion processing capacity. Subject to licencing approvals it was proposed to operate the NRU reactor for the period from 31 October 2016 to 31 March 2018 for non-⁹⁹Mo purposes, with the effect of keeping the NRU reactor in "hot operation" for that time period. In addition the associated facilities required for ⁹⁹Mo production and processing would be kept in a "hot standby" mode for the same period.

The NRU reactor and the associated processing facilities could be made available under special conditions of market supply shortage, this contingency capacity would be used only in the unexpected circumstance of significant 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 on top of the ORC held within the rest of the supply chain. 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).

Figure 7.1. Current demand (9 000 6-day Ci ⁹⁹Mo/week EOP) and demand +35% ORC vs. processing capacity – current and total, with and without NRU CC, 2016-2021:

Scenarios A + B + A with NRU CC + B with NRU CC



The forecast 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 case of total processing capacity (from Scenario B), this is boosted to a very safe level for a two-year period before falling back to the total processing capacity line in the July-December 2018 period. In the case of current processing capacity only (from Scenario A), the processing capacity is kept well above the NEA demand +35% ORC line until dropping in the July-December 2018 period back to the reference scenario at a level just above the NEA demand +35% ORC line until 2021.

In the maximum case, it is unlikely that the contingency capacity would be required, while if the minimum processing capacity forecast is followed, the NRU contingency capacity would provide an important buffer period. It can be seen from the structure of the two sets of forecast lines, that in any of the alternative or intermediate scenarios, the scale of the potential contingency capacity would provide a useful additional buffer period, but in each case the processing capacity returns back to the original projection line in the July-December 2018 period.

Chapter 8. Conclusions

The global demand estimate has been maintained at a level of around 9 000 6-day Ci ⁹⁹Mo per week EOP. This demand level has been a factor in allowing the existing supply chain to continue to provide a near to full service level in the last 4 years, despite some significant operational problems.

Progress with increasing the levels of existing capacity and adding some new capacity in 2015 has raised the baseline reference scenario projections. 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 2021. From 2017, the level of capability to manage adverse events reduces in particular when considering current processing capacity.

The possible extension of the NRU operating period could be a useful stop-gap in 2017 and early 2018, with the potential provision of substantial contingency capacity. But in the event that slow progress is made with the introduction of alternative technologies, or when all processing projects are substantially delayed, then processing capacity could still fall back to levels only a little above the NEA demand +35% ORC in late 2018.

The need to add processing capacity by 2017 remains clear; in particular the on-time introduction of substantial conventional processing capacity in Australia and the introduction of alternative irradiation and processing technologies. If these are achieved, then both irradiation capacity and processing capacity should be fully secured for the rest of the period to 2021. However, alternative technologies have experienced some delays since the last report and further delays can lead to some weakness in the period from 2017

The supply situation will continue to require careful and well considered planning to minimise security of supply risks, with a high degree of cooperation 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:

- NEA (2011), "The Supply of Medical Radioisotopes: An Assessment of Long-term Global Demand for Technetium-99m", OECD, Paris.
- NEA (2012a), "A Supply and Demand Update of the Molybdenum-99 Market", OECD, Paris.
- NEA (2012b), The Supply of Medical Radioisotopes: Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production, OECD, Paris.
- NEA (2014), "The Supply of Medical Radioisotopes: Medical Isotope Supply in the Future: Production Capacity and Demand Forecast for the ⁹⁹Mo/^{99m}Tc Market, 2015-2020", OECD, Paris.
- NEA (2015), "The Supply of Medical Radioisotopes: 2015 Medical Isotope Supply Review: 99Mo/99mTc Market Demand and Production Capacity Projection 2015-2020", OECD, Paris.

Appendix 1.

| Reactor (Fuel) | Reactor (Fuel) Current targets ⁸ | Normal operating days/year | Anticipated 99Mo production weeks/year | Expected available capacity per week (6-day Ci 99Mo) | | Expected first full year Expected available capacity per of 99Mo production9 year (6-day Cl 99Mo) by 2021 | Estimated end of operation |
|-------------------------|---|----------------------------|---|--|------|---|----------------------------|
| BR-21 (HEU) | ΠËN | 190 | 27 | 7 800 | ΨV | 210 600 | 2026 |
| HFR ² (LEU) | HEU | 275 | 39 | 6 200 | ΨN | 241800 | 2024 |
| LVR-15 (LEU) | HEU/LEU | 210 | 30 | 2 4 00 | AN | 72 000 | 2028 |
| MARIA (LEU) | HEU | 200 | 36 | 2 7 0 0 | Ą | 95 000 | 2030 |
| OPAL (LEU) | LEU | 300 | 43 | 1 750 | ĄN | 75 250 | 2055 |
| RA-3 (LEU) | LEU | 230 | 46 | 400 | AN | 18 400 | 2027 |
| SAFARI-13 (LEU) | HEU/LEU | 305 | 44 | 3 000 | ĄN | 130 700 | 2030 |
| NRU⁴ (HEU) | HEU | 280 | 40 | 4 680 | Ą | 187.200 | Late 2016 |
| RIAR ⁵ (HEU) | HEU | 350 | 90 | 1 000 | ĄV | 20 000 | At least until 2025 |
| KARPOV⁵ (HEU) | HEU | 336 | 48 | 350 | ĄV | 16 800 | At least until 2025 |
| OPAL ⁶ (LEU) | LEU | 300 | 43 | +1 750 | 2017 | 75 250 | 2055 |
| FRM-II7 (HEU) | LEU | 240 | 32 | 2 100 | 2018 | 67 200 | 2054 |

Table 1. Current irradiators including those in transition by 2021

Notes: 1). BR2 Out of operation for parts of 2015 and 2016, 2). HFR capacity increases from 5 400 to 6 200 per week from 2017, 3). SAFARI capacity limited by temporary processing limits until end Q2/2016, 4). NRU will cease routine ⁹⁹Mo production after 31 October, 2016, but the reactor will follow a regular operating schedule and all ⁹⁹Mo capabilities will remain in "hot standby" until 31 March , 2018, 5). RIAR and KARPOV material requires licensing in some markets, the KARPOV facility will be relicensed in 2020, 6). OPAL extra irradiation capacity is additional and ready but market entry dependant on new ANSTO processing capacity, 7). FRM II market entry dependent upon conversion of processors to LEU targets, 8). HEU >20% enriched Uranium, LEU <20% enriched Uranium, 9). NA = Not Applicable

Table 2. Current processors including those in transition by 2021

| Processor | Targets ⁷ | Anticipated 99Mo production weeks/year | Available capacity per week (6-d Ci ⁹⁹ Mo) | Expected available capacity per year (6-d Ci ⁹⁹ Mo) by 2021 | Expected first full year of 99Mo production8 | Expected year of conversion to LEU targets | Estimated end of production |
|-------------------------------|----------------------|---|--|--|--|--|-----------------------------|
| ANSTO Health | LEU | 43 | 1750 | 75 250 | AN | LEU | 2055 |
| CNEA | LEU | 46 | 400 | 18 400 | ΑN | LEU | 2027 |
| IRE1 | HEU | 52 | 3 500 | 182 000 | AN | 2016 | At least until 2028 |
| Mallinckrodt ² | HEU | 52 | 2 000 | 260 000 | NA | 2017 | Not Known |
| NTP3 | HEU/LEU | 44 | 3 000 | 130 700 | AN | LEU | At least until 2030 |
| CNL/Nordion ⁴ | HEU | 48 | 4 680 | 187 200 | ΑN | No conversion | 2016 |
| RIAR5 | HEU | 90 | 1 000 | 20 000 | NA | No date | At least until 2025 |
| KARPOV Institute ⁵ | HEU | 48 | 350 | 16 800 | AN | No date | At least until 2025 |
| ANSTO Health ⁶ | LEU | 43 | +1 750 | 75 250 | 2017 | LEU | 2055 |

Notes: 1). IRE maximum capacity remains dependent upon regulator agreement, 2). Mallinckrodt capacity increase from current facilities introduced by 3Q 2016, 3). NTP capacity limited by temporary processing limits until end Q2/2016, 4). CNL/Nordion will cease routine ⁹⁹Mo processing of NRU material after 31 October, 2016, but all ⁹⁹Mo processing capabilities will remain in "hot standby" at all times for NRU material until March 31, 2018, 5). RIAR and KARPOV material requires licensing in some markets, the KARPOV facility will be relicensed in 2020, 6). ANSTO extra processing capacity is additional and is required to use OPAL additional irradiation capacity, 7). HEU >20% enriched Uranium, BLU <20% enriched Uranium, B. NA = Not Applicable

Table 3. Potential irradiators entering in period 2016 to 2021

| Irradiation source (Fuel) | Targets/technology ⁵ | Expected operating days/year | Anticipated Mo-99 production weeks/year | Expected available capacity per week (6-d cl ⁹⁹ Mo) by 2021 ⁶ | Potential annual production (6-day Ci ⁹⁹ Mo) by 2021 ⁶ | Expected first full year of production | Project status (Dec 2015) |
|---|------------------------------------|------------------------------|---|---|--|--|--|
| MURR/NorthStar (HEU) | Natural Mo in CRR | 339 | 52 | 750 | 39 000 | 2017 | Reactor capacity and irradiation facilities in place |
| MURR/NorthStar¹ (HEU) | Enriched Mo in CRR | 339 | 52 | +2 250 | +117 000 | 2018 | Transition to enriched Mo targets starts in 2016 |
| NorthStar | Non-fissile from LINACs | 352 | 52 | 3 000 | 156 000 | 2018 | Final design 2016 |
| MURR/GA(HEU) | Reusable LEU-SGE Assembly | 339 | 52 | 4 200 | 218 400 | 2019 | Preliminary design complete |
| SHINE (LEU) | LEU solution with DTAs and SAAs | 350 | 50 | 4 000 | 200 000 | 2020 | Construction not yet started |
| Korea (LEU) ² | LEU in CRR | 300 | 43 | 400 | 17 200 | 2020 | Construction permit in review by regulatory body |
| RA-10 (LEU) | LEU in CRR | 315 | 48 | 2 500 | 120 000 | 2020 | Preliminary design completed, construction starts 2016 |
| Jules Horowitz Reactor ³ (LEU) | LEU in CRR | 220 | 32 | 4 800 | 153 600 | 2021 | Under construction |
| Brazil MR (LEU) | LEU in CRR | 290 | 41 | 1 000 | 41 400 | 2021+ | Detailed design to be contracted in 2016. Construction depends on budget |
| China Advanced RR⁴ (LEU) | LEU in CRR | 240 | 34 | 1 000 | 34 000 | 2021+ | Existing reactor under modification |

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). JHR reactor begins active commissioning in 2019, but ³⁹Mo capacity not expected to be available until 2021, 4). CARR is already operational, but date of ³⁹Mo availability is unknown and is not before 2021, 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 2021

Table 4. Potential processors entering in period 2016 to 2021

| Processor | Targets ⁵ | Anticipated Mo-99 production weeks/year | Expected available capacity per week (6-day Ci) by 20216 | Expected available capacity per year (6-day Ci 99Mo) by 2021 ⁶ | Estimated first full year of production | Project status (Dec 2015) |
|--------------------------------|------------------------------|--|--|---|---|---|
| MURR/NorthStar | Natural Mo target | 52 | 750 | 39 000 | 2017 | Processing capacity in place (natural Mo targets) |
| MURR/NorthStar1 | Enriched Mo target | 52 | +2 250 | +117 000 | 2018 | Transition to enriched Mo targets starts in 2016 |
| NorthStar | Non-fissile | 52 | 3 000 | 156 000 | 2018 | Final design 2016 |
| Nordion | Reusable LEU-SGE Assembly | 52 | 4 200 | 218 400 | 2019 | Preliminary design completed |
| SHINE | LEU solution | 90 | 4 000 | 200 000 | 2020 | Construction not yet started |
| MARIA: Mo-99 2010 ² | LEU | 40 | 1 000 | 40 000 | 2020 | Financing – not yet agreed |
| Korea ³ | LEU | 43 | 400 | 17 200 | 2020 | Construction permit in review by regulatory body |
| CNEA | LEU | 48 | 2 500 | 120 000 | 2020 | Preliminary design completed 2016, start construction 2016 |
| Brazil MR | LEU | 41 | 1 000 | 41 400 | 2021+ | Detailed design still to be contracted. Construction depends on budget |
| China Advanced RR ⁴ | LEU | 34 | 1 000 | 34 000 | 2021+ | Financing decision after 2017 tests |

Notes: 1). MURR/NorthStar Enriched Mo capacity is additional to the Natural Mo capacity when introduced, 2). MARIA uses existing capacity at the MARIA Reactor, 3). Korea capacity is planned to increase further in stages after 2023, 4). CARR is already operational, but date of ⁹⁹Mo processing capacity availability is unknown and not before 2021, 5). Mo = inactive Molybdenum, either natural or enriched, LEU <20% enriched Uranium, 6). Numbers in italics indicate availability after 2021