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Guidance Document

Provision of Outage Reserve Capacity for Molybdenum-99 Irradiation Services: Methodology and Economic Analysis

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Introduction

In June 2011, the OECD Nuclear Energy Agency's (NEA) High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) released its policy approach for ensuring a long-term secure supply of molybdenum-99 (^{99}Mo) and its decay product technetium-99m (^{99m}Tc). This policy approach was developed after two years of extensive examination and analysis of the challenges facing the supply chain, and the provision of a reliable, secure supply of these important medical isotopes. The full policy approach can be found in the OECD/NEA report, *The Supply of Medical Radioisotopes: The Path to Reliability* (NEA, 2011).

One of the key principles in the policy approach relates to the provision of outage reserve capacity (ORC) in the ^{99}Mo/^{99m}Tc supply chain, as defined on page 7:

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

This Principle follows the findings of the OECD/NEA report, *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain* (NEA, 2010), which clearly demonstrated the need for excess ^{99}Mo production capacity, relative to demand, as some reactors may have to be shutdown unexpectedly or for extended periods. The Study also demonstrated that the pricing structure from reactors for ^{99}Mo irradiation services prior to the 2009-10 supply shortage was not economically sustainable, including the pricing of ORC, with the cost being subsidised by host nations. These nations have indicated a move away from subsidising production, which often benefits foreign nations or foreign companies, and therefore pricing for irradiation services must recover the full cost of production to ensure economic sustainability and a long-term secure supply. Appropriate pricing would also encourage more efficient use of the product, reducing inefficient use of ^{99}Mo/^{99m}Tc would reduce excess production and the associated radioactive waste.

Since the 2009-10 supply shortage, there has been a co-ordinated effort by ^{99}Mo/^{99m}Tc supply chain participants to improve communication and share information in a more timely and effective manner. This helps optimise operating reactor capacities and minimise the impact of potential future supply shortages. However, in addition to paying for operating capacity through a full-cost recovery methodology, the supply chain should also be responsible for maintaining adequate ORC and paying for it.

All ^{99}Mo producers that supply the global market should maintain and pay for ORC, otherwise there will be market distortions that could jeopardise the long-term economic sustainability of the irradiation providers and thus jeopardise the long-term supply security of ^{99}Mo/^{99m}Tc. In addition, it should be recognised by all consumers within the global market that the price increases expected by the application of full-cost recovery should flow through the supply chain and should be reflected in the costs of the final medical procedure, to be reimbursed appropriately by the health care system.

This guidance document provides a methodology for determining the necessary amount of ORC to be provided, an approach to valuing and paying for ORC, and the economic effects from ORC pricing.

Acknowledgements

This guidance document was developed as a result of the work of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) Working Group on Outage Reserve Capacity Sourcing and Paying Options (see Annex 2 for a full list of members). In addition, key supply chain participants and stakeholders reviewed the proposed methodology and made important comments.

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Chapter 1. Reserve capacity in the ^{99}Mo/^{99m}Tc supply chain

Research reactors do not operate 100% of the time and, when there is an unexpected or extended shutdown, reserve capacity in another reactor or production source is required to counter the lost production capacity. This reserve capacity was traditionally not paid for by the supply chain. In addition, the size of the reserve capacity needs to be determined and supported by effective co-ordination of the operating schedules of reactors to ensure efficient use and to support a sustainable market environment.

In addition to paying for production capacity through a full-cost recovery methodology, the supply chain should also be responsible for the appropriate use of that capacity, including ensuring adequate reserve capacity to cope with unexpected losses of supply. When one looks at all the available reactor and alternative technology capacity globally, this capacity should be more than 100% of demand for the year. This capacity, sometimes referred to as peak capacity, includes the capacity of all reactors without taking account of their operational schedules or availability for isotope production. As a result, the term peak capacity actually hides two different types of capacity: weekly reserve capacity (WRC) and ORC.

WRC is the capacity that exists within the system to account for the fact that research reactors do not operate 100% of the time. As a result, there has to be enough capacity so that over the year, the total fleet of reactors and ^{99}Mo/^{99m}Tc alternative production technologies can provide sufficient irradiation services to produce the required (demanded) amount of ^{99}Mo/^{99m}Tc.

ORC is the capacity that exists within the system to account for the fact that research reactors sometimes have unplanned or extended shutdowns. As a result, there needs to be on-call capacity that can be used during these events.

These two types of capacity and the policy option to address them will be discussed separately as they require different actions.

Weekly reserve capacity

Proper and effective co-ordination of reactor and alternative technology operation schedules should theoretically reduce WRC to zero on an annual basis – there should only be enough operating capacity in a year to meet the required demand, with no excess producing capacity. Any excess producing capacity is inefficient and could result in increased social and private costs (e.g. from over-investment).

Currently, reactor operators and processors participate in co-ordination efforts managed by the Association of Imaging Producers and Equipment Suppliers (AIPES). During the 2009-10 supply shortage, these co-ordination efforts reduced the impacts of the shortage by having reactors and processors work together to smooth out production over time. These efforts should continue and become more sophisticated to ensure more efficient scheduling. To make co-ordination more effective, increased information sharing related to production capacity should be made available to the co-ordination group. This would allow for an assessment of whether the capacity is in excess of what is required in the market and could be part of ORC.

In addition, “rules of engagement” could be developed that would describe the principles of co-ordination. These principles should recognise the need for a minimum level of production at all reactors. This minimum level is required to ensure that available ^{99}Mo/^{99m}Tc producers (reactors and alternative technologies) have the ability to produce, receive financial compensation for production, maintain the expertise to produce, and have the regulatory approval to produce and use their ^{99}Mo/^{99m}Tc. This volume sharing would be encouraged through the provision of ORC.

As part of these rules of engagement, reactors should agree to adjust operating programmes where feasible, working in good faith to ensure effective co-ordination. To support the efforts towards effective co-ordination and the ability to maintain flexibility in the system, contracts between reactors and processors should provide for open access, removing any contractual provisions that may prevent diversity of supply sources and thus security of supply. Open access has also been recommended by the Council of the European Union.

Given the role of demand management actions during the most recent (2009-10) shortage, it is essential to recognise the important role that these actions could play for short periods where co-ordination efforts still result in a shortage.

Recommendations

- *Supply chain participants, both public and private, should both continue and improve annual co-ordination efforts through AIPES or another similar mechanism to ensure the appropriate use of available capacity, recognising a minimum necessary volume level at all* ^{99}*Mo/*^{99m}*Tc producing facilities. New entrants to the supply chain should join these co-ordination efforts.*
- *To support effective co-ordination, contracts between* ^{99}*Mo/*^{99m}*Tc producing facilities and processors should allow for open access to* ^{99}*Mo irradiation services.*
- *Demand-management options should be encouraged as they could support effective co-ordination efforts.*

Outage reserve capacity

The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain (NEA, 2010) indicated that ORC should be funded by the supply chain via a "reliability price premium", with those stakeholders that do not pay the premium not receiving ^{99}Mo during any shortage situation. However, many stakeholders indicated that they did not see such a system as acceptable since they felt that distribution in times of a shortage should be "fair". They did, however, agree that it was the responsibility of the supply chain to source and pay for ORC.

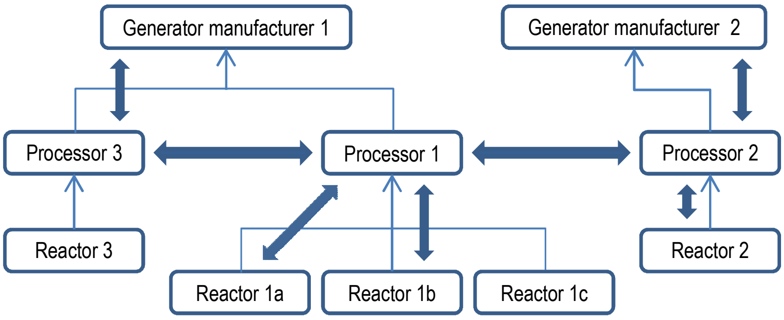
In order to recognise the need for fair distribution in times of shortage and still create the incentive for the supply chain to pay for the reserve capacity, it is necessary to set a minimum amount of ORC that needs to be maintained by the supply chain and increase end-users' prices accordingly. This would require transparency and some verification of the amount of reserve capacity being held within the supply chain to ensure that the payments received were used to increase reliability.

A capacity option is a contract that provides the opportunity, but not the obligation, for Party A to access product from capacity that Party B sets aside in case Party A requires it. Party A would pay Party B for the opportunity; when Party A exercises the option, requiring product from the capacity, they would pay Party B for the production.

After examining many options, the HLG-MR agreed that ORC should be provided through incremental capacity options. For ease of implementation, and recognising the pivotal role of processors in the supply chain, processors should be responsible for holding ORC options equal to at least the largest source in their supply chain at all times. This is referred to as the "n-1" criterion, where the supply chain should be able to absorb the loss of the largest unit in the chain. The HLG-MR Outage Reserve Capacity Working Group considered other levels of ORC, but determined that a level greater than n-1 would be too onerous and not necessary. It did recognise, however, that the n-1 level should be evaluated after some experience to determine if there was a need to change the recommended level (either to make it stricter or more lenient).

In order to be useful, ORC should be available in a short-time frame when needed – within 48 hours from the moment of requesting the irradiation service. This does not mean that processors should be the sole supply chain actors dealing with ORC. ORC can come from all levels of the supply chain and should be paid for in the price to the end-user. This reserve capacity can come from idle reactor capacity, but also from generator manufacturers and/or hospitals that provide a credible, reasonable and incremental demand management plan (e.g. schedule shifting, priority setting, etc), or other processors (who would be required to account for these responsibilities in their own n-1 calculations). As a result, options contracts would be offered by individual providers based on their availability, and through private contracts between parties. The figure below provides an illustrative example of how an ORC capacity option system could function, including in places where there are no multiple regional research reactors.

An example of how the ORC system could work



- P2, in a single-source supply chain, holds ORC options contracts with:
  - P1 to supply product if R2 is down; and
  - GM2 to implement demand-side management (DSM) downstream to address a shortage condition.
- P1 holds ORC options contracts with:
  - R1a, R1b and P2 in enough quantity to address a shortage if a reactor in the supply chain is down;
  - P2 then must hold ORC within R2 for the amount offered to P1.
- P3 holds ORC options contracts with:
  - GM1, which can implement DSM downstream to use supply from P1 more efficiently during a shortage; and
  - P1 to provide supply if R3 goes down;
  - P1 then must hold additional ORC to the amount offered to P3 from R1a and R1b.

ORC options would have to be based on credible, reasonable, incremental and available ORC. For example, reactors offering ORC should be producers of ^{99}Mo that leave some irradiation channels idle. This ensures that they have the experience and regulatory approval in place to fulfil ORC requirements when necessary. In order to ensure that reactor-based ORC options are credible and available, the reactor will have to have operated at some minimum level within the previous three- to four-month period.

As noted above, if a reactor does not provide some minimum level of ^{99}Mo irradiation services on a quarterly basis, they may not have the expertise, personnel, experience or ability to provide ORC, if it was required. Where a reactor had not provided this minimum level of irradiation services in a preceding three- to four-month period, they should not be considered to be a credible and available source of ORC.

This provision of credible and available ORC from a reactor, coupled with the n-1 criterion, supports the necessity to have some "volume-sharing" of production among reactors without dictating to processors which reactors they would have to buy from. The n-1 criterion would encourage volume- sharing, as a concentrated share of production at one reactor would increase the need for ORC within the system.

A further requirement to ensure that ORC options were credible, incremental, and available would be the need to include provisions for enforceability within the ORC options contracts. These provisions could come in the form of a penalty clause that would be triggered if the ORC was not available when required, or if it was determined that the same ORC was actually being sourced by two or more parties.

It must be noted, however, that the ORC system described in this document would not address very short outages – of less than 8-10 days. Such outages would not give reactors holding ORC enough time to load, irradiate targets and send the irradiated targets for processing, which poses a short-term risk to the security of supply of medical isotopes. This short-term risk is currently managed by an emergency communications protocol for ^{99}Mo distribution to ensure a fair access to product by all supply chain participants.

Valuing and paying for ORC

Processors would negotiate private ORC options contracts with their partners in the supply chain. The prices of the ORC options contracts would be settled in the market, recognising these prices should allow for full-cost recovery. This would result in clear price signals on the need for ORC capacity. If there is excess capacity in the market, above and beyond the ORC market needs, prices will fall and some players will be forced to leave the ORC market and use their capacity for other purposes; if there is not enough ORC supply, prices will rise and additional ORC will be offered.

In terms of full-cost recovery, the price paid for options contracts should logically cover the transaction costs and fixed costs (capital and operating) of ORC providers. When the option is exercised, the processor would have to pay additional variable costs based on the actual production capacity used. Governments should clearly indicate that they will not subsidise ORC at reactors and, therefore costs will have to be fully recovered through ORC contracts. How that pricing is designed should be up to the supplier of the ORC options contract (e.g. whether bundled with irradiation services or priced as a separate product from irradiation services).

However, it should be noted that options contract prices, even if determined by market forces, may not capture the actual full costs to the supply chain in the event of ORC use. If a reactor fails, hence activating ORC elsewhere in the supply chain, the processor(s) that are using this reactor as their main (or only) source of ^{99}Mo irradiation services will attempt to source capacity from another reactor/processor or further downstream. This alternative source is likely to be less efficient for the processor (e.g. located farther from their production facilities or irradiating targets that require different transportation containers), which will increase the processor's production costs and, consequently, the ^{99}Mo prices for downstream customers. This price increase will not be reflected in the ORC options contract and may not be significant, but should be taken into consideration in case of ORC activation/use.

While processors would be expected to pay for ORC options contracts, they would recuperate their costs through ^{99}Mo/^{99m}Tc prices to their customers and further downstream. In essence, downstream prices would include a non-optional “reliability premium”. End-users should be made aware of the need for reliability provisions and the fact that their payments include a portion to ensure a secure supply of these vital medical radioisotopes by supporting reserve capacity. End-users should also clearly include provisions in their contracts with suppliers related to reliability that would be triggered in the event of non-deliverability of product, encouraging upstream reliability measures.

A key feature of this recommended ORC system is that those processors that are currently dependent upon one single reactor for their supply will be able, and responsible for, sourcing and paying for ORC. This situation was demonstrated in the figure on page 9, where an isolated processor (P3) sourced ORC through an agreement with another processor (P1). In this manner, the approach recognises the global nature of the supply chain, while allowing for regional organisation and opportunities for the provision of ORC.

To increase trust and transparency within the system, an international expert panel could be set up to review the provision of ORC within the system to determine whether processors were holding the required (sufficient) level of ORC, and report on it. This would provide an additional incentive for processors to voluntarily hold ORC.

Recognising that time will be required within the supply chain to become informed and prepare for the ORC system being recommended by the HLG-MR, a transition period is recommended before full implementation. In addition, the health community will require some time to examine the effects of sourcing and paying for ORC within the supply chain. However, a transition period that is too long may mean that ORC is not made available in sufficient amounts, affecting the economic sustainability of ORC provision and thus the security of supply. The HLG-MR has recommended a target of June 2014 (three years from the release of the HLG-MR policy approach[1]) to fully implement the proposed ORC system.

Recommendations

- *Processors should voluntarily hold ORC equal to their largest supply (n-1 criterion) at all times, which can come from anywhere in the supply chain as long as it is credible, incremental and available on short notice.*
- *Reserve capacity options should be transparent and verifiable to ensure trust in the supply chain.*
- *Reactor operators, processors and generator manufacturers should review the current contracts to ensure that payment for reserve capacity is included in the price of* ^{99}*Mo.*

Co-ordination of reactor scheduling

As previously noted, market players should participate in efforts to co-ordinate scheduling of reactor operating times related to ^{99}Mo production. The benefits of this co-ordination include ensuring continuous reliable supply, efficiency, market transparency, reduced social and private costs (through reducing over-investment in production capacity) and promoting economic progress (by facilitating economic sustainability and reducing government subsidies), and improving the distribution of ^{99}Mo supply infrastructure/production. Recognising these benefits, governments should encourage producers (research reactors and ^{99}Mo/^{99m}Tc alternative production technologies) and processors operating in their jurisdiction to participate in good faith in the scheduling efforts undertaken by AIPES or other global co-ordination efforts.

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[1] The full HLG-MR policy approach is articulated in *The Supply of Medical Radioisotopes: The Path to Reliability* (NEA, 2011).

If reactor operators and processors in their jurisdiction do not participate in these scheduling efforts, governments could explore options to make participation mandatory. Currently, voluntary participation in scheduling efforts has been successful with all participants respecting (to the extent possible) their commitments; however, some jurisdictions may be interested in making participation mandatory by exploring tools for doing so, including enforcement. New producers and processors in the market should also participate in ongoing co-ordination efforts.

Recommendation

- *Governments should encourage continued supply chain participation in* ^{99}*Mo/*^{99m}*Tc production schedule co-ordination efforts, including making such participation mandatory, if voluntary participation decreases or commitments are not respected.*

Government role in ensuring sufficient ORC

Although the market should be solely responsible for sourcing and paying for ORC, governments should monitor the levels of ORC, based on the information received from the self-assessment by supply chain participants[2] or an international expert panel looking into this issue. It is possible, given historical involvement, that the supply chain will expect governments to intervene in shortage situations, thus reducing the incentive for supply chain participants to voluntarily maintain a set level of ORC. If this is the case, governments should consider addressing this free-rider problem by regulating minimum levels of ORC, as described in the *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain* (NEA, 2010).

Recommendation

- *Governments should monitor levels of ORC maintained by the market and, if found to be below the n-1 criterion, consider regulating minimum levels.*

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[2] The NEA is preparing a report, based on information provided by ^{99}Mo/^{99m}Tc supply chain participants, to evaluate the progress made towards implementing the HLG-MR policy approach. The report is expected to be published in the first half of 2013.

Chapter 2. Economic effects of valuing and paying for ORC

The approach to valuing and paying for ORC in this document is based on the premise that reactors holding ORC incur costs to provide this service and should be compensated appropriately for it. Otherwise, they would not have an incentive to hold ORC. Producers of ^{99}Mo who have access to ORC should pay for its share of overhead and capital costs, as well as fixed operating costs, when the ORC is not used. When the ORC is used, the price of irradiation services would cover the variable operating costs as well.

The results in this document present two cases of a new, multi-purpose (MP) reactor with 20% of its production capacity allocated to ^{99}Mo irradiations – one with capital costs and one without capital costs. The first case is consistent with the principle of full-cost recovery (i.e. includes sustainable pricing of normal irradiations and ORC), while the second case reflects the market situation in many cases, where major reactors have completely depreciated their capital costs. Two scenarios were developed for each case – with 33% ORC[3] and 47% ORC[4] in the reactor. The two scenarios were compared to a reference case with no ORC. It should be noted that these economic results describe a situation where ORC is provided on the supply side, i.e. in reactors, and exclude ORC that could be provided on the demand side, i.e. by generator manufacturers.

Valuing and paying for ORC *with* capital costs (new reactors with full-cost recovery)

Table 1 shows the levelised unit costs along the ^{99}Mo/^{99m}Tc supply chain in the two scenarios for the case with capital costs included in the ORC pricing, compared to the reference case. Table 2 presents the percentage increases in the levelised unit costs from holding ORC. These increases are calculated relative to the reference case. Table 3 shows the cost impact of holding ORC on the end-user, based on the model developed for the economic study of the ^{99}Mo/^{99m}Tc supply chain (NEA, 2010).

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[3] 33% is based on a derived model showing that a system with somewhat effective, but not perfectly ideal co-ordination, with a large reactor in the fleet, could maintain n-1 ORC levels if each reactor kept, on average, 33% of their capacity as ORC. A derived model with more perfect co-ordination and more equal-sized reactors had the ability to maintain n-1 ORC levels if each producing reactor kept 17% of its capacity as ORC. It should be noted that the "traditional five" reactors have in total about 37% of their maximum ^{99}Mo production capacity unused in normal times. This capacity is not necessarily set aside as ORC at present, but it is the difference between the maximum production capacity (setting aside other projects) and the normal production capacity.

[4] 47% is a conservative scenario based on a simple calculation of how much reserve capacity would have to be held at four of the "traditional five" reactors to account for the loss of the largest reactor in the system.

Table 1. Illustration of levelised unit costs for a MP reactor with 20% of its capacity allocated to ^{99}Mo production with capital costs, in EUR/6-day Ci EOP*

	From reactor	From processor	From generator	From radiopharmacy
Reference case: 20% MP, sustainable pricing no ORC	142	415	471	1 908
20% MP, sustainable pricing 33% ORC in reactor	207	480	537	1 974
20% MP, sustainable pricing 47% ORC in reactor	260	533	590	2 026

* Values are rounded and medians presented for all scenarios. Values should only be used for illustrative purposes and should not be construed as true market prices.

Table 2. Illustration of % increases in levelised unit costs for ORC*

	From reactor	From processor	From generator	From radiopharmacy
Reference case: 20% MP reactor with sustainable pricing, no ORC				
20% MP, sustainable pricing 33% ORC in reactor	46%	16%	14%	3%
20% MP, sustainable pricing 47% ORC in reactor	83%	28%	25%	6%

* The levelised unit costs are calculated in EUR/6-day Ci EOP.

Table 3. Illustration of the cost impact of ORC on the end-user

	Irradiation/ORC value in final radiopharmaceutical price	Final radiopharmaceutical price of ^{99m}Tc per procedure	Irradiation/ORC value as % of reimbursement rate	Radiopharmacy price of ^{99m}Tc as % of reimbursement rate
Reference case: 20% MP, sustainable pricing no ORC	EUR 0.85	EUR 11.44	0.35%	4.66%
20% MP, sustainable pricing 33% ORC in reactor	EUR 1.24	EUR 11.83	0.51%	4.82%
20% MP, sustainable pricing 47% ORC in reactor	EUR 1.56	EUR 12.15	0.63%	4.95%

* Values are rounded and medians presented for all scenarios. Values should only be used for illustrative purposes and should not be construed as true market prices.

Valuing and paying for ORC *without* capital costs (many existing reactors)

Table 4 shows the levelised unit costs along the ^{99}Mo/^{99m}Tc supply chain in the two scenarios for the case without capital costs in the ORC pricing, compared to the reference case. Table 5 presents the percentage increases in the levelised unit costs from holding ORC. These increases are calculated relative to the reference case. Table 6 shows the cost impact of holding ORC on the end-user.

Table 4. Illustration of levelised unit costs for a MP reactor with 20% of its capacity allocated to ^{99}Mo production and no capital costs, in EUR/6-day Ci EOP*

	From reactor	From processor	From generator	From radiopharmacy
Reference case: 20% MP, no capital costs, no ORC	56	329	385	1 822
20% MP, no capital costs 33% ORC in reactor	79	352	409	1 846
20% MP, no capital costs 47% ORC in reactor	98	371	427	1 864

* Values are rounded and medians presented for all scenarios. Values should only be used for illustrative purposes and should not be construed as true market prices.

Table 5. Illustration of % increases in levelised unit costs for ORC*

	From reactor	From processor	From generator	From radiopharmacy
Reference: 20% MP reactor with no capital costs, no ORC				
20% MP, no capital costs 33% ORC in reactor	41%	7%	6%	1%
20% MP, no capital costs 47% ORC in reactor	75%	13%	11%	2%

* The levelised unit costs are calculated in EUR/6-day Ci EOP.

Table 6. Illustration of the cost impact of ORC on the end-user

	Irradiation/ORC value in final radiopharmaceutical price	Final radiopharmaceutical price of ^{99m}Tc per procedure	Irradiation/ORC value as % of reimbursement rate	Radiopharmacy price of ^{99m}Tc as % of reimbursement rate
Reference case: 20% MP, no capital costs, no ORC	EUR 0.33	EUR 10.93	0.14%	4.45%
20% MP, no capital costs 33% ORC in reactor	EUR 0.47	EUR 11.06	0.19%	4.51%
20% MP, no capital costs 47% ORC in reactor	EUR 0.58	EUR 11.18	0.24%	4.55%

* Values are rounded and medians presented for all scenarios. Values should only be used for illustrative purposes and should not be construed as true market prices.

The difference in the cost impact between the two cases – new and old reactors – although not appreciable in *relative* terms (i.e. percentage increases), is significant in *absolute* terms. For example, for a new MP reactor holding 33% ORC, the cost increases by 65 EUR/6-day Ci EOP (compared to holding no ORC), while for an amortised old reactor, the corresponding cost increase is 23 EUR/6-day Ci EOP.

Conclusions

The provision of ORC is important to achieve long-term economic sustainability of the ^{99}Mo/^{99m}Tc supply chain and improve the global supply reliability of these key medical isotopes. To ensure that a sufficient level of ORC is maintained at all times, ORC should be appropriately priced and included in contracts between supply chain participants. This would compensate reactors for the capital and operational costs that they incur to hold it. Otherwise, reactors would have an incentive to use any reserve capacity for other missions.

Paying for ORC would increase ^{99}Mo prices throughout the supply chain, with the largest increases occurring upstream – at the reactor and processor levels. At the end-user level (radiopharmacies and hospitals), isotope prices are projected to increase only slightly, with the ORC irradiation value remaining below 1% of the final reimbursement rate.

The economic effects from valuing and paying for ORC presented in this document show that the *relative* ^{99}Mo price increases are not appreciably different in a case with new, multipurpose reactors (including their capital costs) and many existing reactors (excluding their capital costs). However, in *absolute* terms, the case with capital costs shows that maintaining ORC results in significantly higher costs for the supply chain than the case without capital costs.

References

OECD/NEA (2011), *The Supply of Medical Radioisotopes: The Path to Reliability*, OECD Publishing, Paris, France.

OECD/NEA (2010), *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain*, OECD Publishing, Paris, France.

Annex 1. Methodology for determining the required level of ORC

1. The probability of failure was developed for each reactor based on failure data from the past 16 years compared to normal expected operations. From there, a probability of one reactor failing in a year was developed. This probability of failure was calculated at 22.365% per year[5].
2. Using the model developed for the economic study of the ^{99}Mo/^{99m}Tc supply chain, adjustments were made to account for the provision of ORC and to determine the cost implications[6]. First, some production capacity was set aside as ORC. In addition, operating costs were identified as fixed and variable costs, based on a general understanding that fixed operating costs were a significant portion (80%) of operating costs. The model also assumes that ORC is charged at 80% of the value of normal irradiation services.
3. The net present value (NPV) of the costs under this adjusted scenario was calculated. The calculation accounted for the reduced variable operating costs, which would only be incurred under a situation of an unexpected/extended outage (i.e. when ORC is used). For full-cost recovery, the expected NPV of revenues under the ORC provision scenario would have to equal the expected NPV of costs.
4. The levelised unit cost was determined based on the following formula:

$$\frac{K + FOper + (Prod * VOper) + \rho * ORC * VOperProd}{Prod}$$

Where:

K = capital costs;

FOper = fixed operating costs (80% of operating costs);

Prod = production of irradiation services (measured in 6-day curies EOP);

VOper = variable operating costs (20% of operating costs);

ρ = probability of one reactor failing;

ORC = production capacity set aside as reserve capacity.

5. Percentage changes were derived by comparing the derived ORC scenarios with the reference case of a multipurpose reactor that allocates 20% of its capacity to ^{99}Mo irradiation services.

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[5] A probability of two reactors failing at the same time was also developed. Although this situation was seen in 2010, the actual probability of it happening is only 2.179%. A probability of three reactors failing at the same time was less than 0.001%.

[6] For simplicity, the scenario used is based on a multipurpose reactor that allocated 20% of its capacity to ^{99}Mo irradiation services, with a 20-year payback period required, a discount factor of 5%, and with/without capital costs. For the example used in this document, there were no additional processing facilities required.

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