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The Supply of Medical Radioisotopes

An Economic Study of the Molybdenum-99 Supply Chain

NEA No. 6967

NUCLEAR ENERGY AGENCY
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FOREWORD

At the request of its member countries, the OECD Nuclear Energy Agency (NEA) has become involved in global efforts to ensure a reliable supply of molybdenum-99 (^{99}Mo) and its decay product, technetium-99m (^{99m}Tc), the most widely used medical radioisotope. The NEA Steering Committee for Nuclear Energy established the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) in April 2009. The main objective of the HLG-MR is to strengthen the reliability of ^{99}Mo and ^{99m}Tc supply in the short, medium and long term. In order to reach this objective, the group has been reviewing the ^{99}Mo supply chain, working to identify the key areas of vulnerability, the issues that need to be addressed and the mechanisms that could be used to help resolve them.

Recognising that there could be a market failure in the ^{99}Mo supply chain, the HLG-MR asked the NEA Secretariat to undertake an economic study of the full supply chain. The goal of the study was to analyse the economics of the supply chain from the reactors to the end users (the patients), to develop a solid factual base of the supply chain and the various costs, to assess whether there is a market failure and to suggest options to encourage sufficient investment in ^{99}Mo production capacity to ensure a long-term, reliable supply of ^{99}Mo and ^{99m}Tc.

This report provides comprehensive information on the supply chain and possible changes needed. The historical development of the market has an impact on the present economic situation, which is currently unsustainable. The supply chain's economic structure therefore needs to be changed to attract additional investment in production capacity as well as the necessary reserve capacity. This report presents options that could be considered in that regard.

This report was prepared by the NEA Secretariat at the request of the HLG-MR. It does not necessarily represent a consensus view of the HLG-MR but is presented to enable discussions and further analysis among the members of the HLG-MR, other stakeholders and decision-makers. The individuals and organisations that contributed to the study are not responsible for the opinions or judgements it contains.

Acknowledgements

This report would not have been possible without input from a significant number of supply chain participants and stakeholders including all major reactor operators, all major processors, generator manufacturers, representatives from radiopharmacies and nuclear medicine practitioners (identified in Annex 1). The input from the supply chain participants was essential for completing this study, and the NEA greatly appreciates the information provided by interviewees.

Drafts of this report were reviewed by members of the HLG-MR and supply chain participants who provided initial input. In addition, valuable comments were received during the presentation of the findings at the Third Meeting of the HLG-MR.

This report was written by Chad Westmacott of the NEA Nuclear Development Division. Detailed review and comments were provided by Ron Cameron, with other reviews and input from Jan Horst Keppler and Alexey Lokhov of the NEA Nuclear Development Division.

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Introduction

The NEA Steering Committee established the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) in April 2009 to examine the problems and suggest possible solutions for ensuring a long-term reliable supply of molybdenum-99 (^{99}Mo) and technetium-99m (^{99m}Tc).

During early discussions, the HLG-MR discussed the possibility of there being a market failure in the ^{99}Mo supply chain, given that it was (and is) not economically viable for current reactor operators to produce irradiated targets containing ^{99}Mo, and that there are not sufficient financial incentives based on the current economic structure to develop additional infrastructure to produce ^{99}Mo. This means that recent ^{99}Mo supply shortages were a symptom of the longer-term problem related to insufficient capital investment for a reliable supply. In order to determine if there is a market failure in the supply chain, the HLG-MR requested that the NEA Secretariat undertake an economic study on the ^{99}Mo supply chain.

The study is based on input from supply chain participants, including all major reactor operators, all major processors, generator manufacturers, representatives from radiopharmacies and nuclear medicine practitioners. It examines the current situation, identifies the economic problems and suggests options to address those problems. The report is not intended to recommend a single solution but to present the full analysis of options. This recognises that economic considerations are only one factor that will affect the final decisions being taken about the future of this supply chain; policy, medical and technological factors are also important for decision makers to consider.

In order to be able to describe the current economic structure, and to do so in terms of the commonly used unit of curies, six days after the end of the processing stage of the supply chain (EOP), detailed analysis was performed on the costs and prices at all stages of the process, based on information provided by supply chain participants and using a range of assumptions. It is recognised that these calculations are only as good as the data from which they were derived but various checks were undertaken to verify that the results reflected the realities of the market, as determined from the interviews with participants. The data is presented as averages of the input provided to protect confidentiality. The reader should not see the averaged data as representative of any one individual supplier or region.

Sensitivity analysis shows that the uncertainties and variability in the data do not affect the final results relating to the overall magnitude of the changes required. Importantly, the final conclusions of the study are robust.

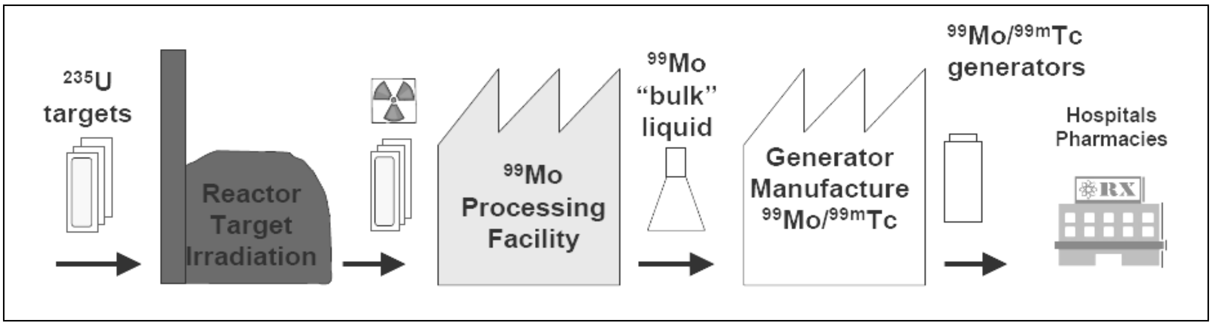
While the report focuses on existing production technologies, which mainly use highly enriched uranium (HEU) targets, the NEA notes the agreement among governments to move toward using low enriched uranium (LEU) targets for medical isotope production. The economic conclusions drawn in the report apply equally to ^{99}Mo production using LEU targets, either from conversion or from the development of new LEU-based production capacity.

Description of the supply chain and its historical development

Given the short half-lives of ^{99}Mo (66 hours) and ^{99m}Tc (6 hours), the logistical arrangements in the supply chain have to move very quickly and predictably to get the product delivered to the end user in its usable form – a prepared dose containing ^{99m}Tc for injection into the patient. ^{99}Mo cannot be efficiently stored over extended periods. For practical purposes, the economics and medical utility of ^{99}Mo/^{99m}Tc are dependent on minimising decay losses. Logistical efficiency and just in time delivery are essential to the realisation of the economic sustainability of the global supply chain.

The supply chain consists of target manufacturers, reactor operators who irradiate the targets to create ^{99}Mo, processors who extract the ^{99}Mo from the irradiated targets and produce bulk ^{99}Mo, generator manufacturers who produce generators with the bulk ^{99}Mo, and radiopharmacies and hospital radiopharmacy departments who elute ^{99m}Tc from the generator and couple it with "cold kits" to prepare radiopharmaceutical doses for nuclear medical imaging of patients (Figure E.1).

Figure E.1: ^{99}Mo supply chain



Source: Ponsard, 2010.

Historically, there were only five reactors that produced 90 to 95% of global ^{99}Mo supply, all of which are over 43 years old. In the past, other reactors produced ^{99}Mo but they have been shut down. The way that these reactors operate contractually with the processors is quite varied. There are three different market structures that have emerged based on the degree of responsibilities of the reactor and the vertical integration between the processor and reactor (described in Chapter 2). Each of these structures can provide different challenges related to the economics, including the ability to have flexible pricing for services rendered as circumstances change.

All of the major producers of ^{99}Mo use multipurpose research reactors for target irradiation, which were originally constructed and operated with 100% government funding for research and materials testing purposes. When ^{99}Mo production started, the reactors' original capital costs had been paid or fully justified for other purposes. It was reported by interviewees that the production was seen as a by-product that helped provide another mission for the reactor and that could bring in extra revenue to the reactor to support its research. As a result, reactor operators reportedly originally only required reimbursement of *direct* short-run marginal costs; there was no consideration that ^{99}Mo should cover a share of marginal costs related to the overall reactor operations and maintenance. Further, there was no share of any capital costs included in the price of the ^{99}Mo, nor was there any allowance for replacement or refurbishment costs of the reactor facility.

The importance of ^{99}Mo production in these reactors increased over the years to the point where most of the major reactor operators indicated that it is now a significant factor behind reactor operating decisions. Even with this increased importance, the by-product status remained and there were no substantive changes to the pricing structure to reflect the larger share of the general operating and maintenance costs of the reactor that should be borne by ^{99}Mo production.

This market structure for the reactor stage of the supply chain poses some challenges for the reliable production of ^{99}Mo:

- The current fleet of ageing reactors is subject to longer and more frequent planned and unplanned shutdowns.

- The proposed conversions from targets normally containing between 45 and 98% ^{235}U (HEU) to targets containing less than 20% ^{235}U (LEU) may have impacts on reactor and processor economics based on additional conversion and operating costs.

- The current economic structure does not support the investments required for new production infrastructure, regional balance and the reserve capacity necessary for a reliable supply chain.

The processing component (i.e. extraction and purification of ^{99}Mo) of the supply chain was originally funded by governments as part of their efforts to develop the use of nuclear radioisotopes for medicine, recognising the significant health benefits of nuclear imaging techniques. In the 1980s and 1990s these components were separated from the reactors and commercialised. Although the commercialisation process was originally thought to be beneficial to all parties, reactor operators did not receive the benefits expected. Interviewees indicated that governments created the commercial contracts based on historical perceptions of costs and pricing structures and their interest in developing the nuclear medicine sector. This resulted in long-term contracts with favourable terms for the commercial processing firm; the separation of activities did not lead to a change to the commercial prices for the irradiation part of the supply chain. Once these contracts were established, they set the standard for new processors and reactors that entered the market.

In addition, the historical processing market was reported as being characterised by significant barriers to entry. Along with natural barriers to entry (being a knowledge and capital intensive industry), there were actions undertaken by existing firms that interviews indicated created barriers to entry. These actions, such as aggressive pricing strategies and exclusivity contracts, had the effect in many cases of convincing new entrants that they would not be able to compete profitably and thus they did not enter the market.

During the most recent supply shortage situation, much attention has been focussed on reactor capacity and reliability, but there are also limitations on processing capacity. These limitations predominately relate to the geographical location of processing facilities and the need for them to have reserve capacity.

Waste management is another important issue for the processing stage. A general economic model that incorporates the final treatment and disposal costs of the liquid radioactive waste is not available. It is generally accepted that the full final waste disposal costs are not included in the pricing. The conversion to LEU may increase this concern as more targets may need to be processed to obtain the ^{99}Mo, resulting in increased waste volumes and related in costs.

Generator manufacturers and radiopharmacies or hospital radiopharmacy departments represent the further downstream components. The principal challenge for the downstream actors is related to changes in reimbursement rates for SPECT[1] procedures, which could potentially affect the funds available to pay for the medical isotopes.

Overall, the ^{99}Mo/^{99m}Tc supply chain is very complex and faces a number of significant challenges, both short and long term. An ever-present factor in the supply chain is the need to get the product to the patient while minimising the decay of the product and related losses of its economic value.

Impacts of historical market development on current economic sustainability

The historical foundations have had, and continue to have, a significant impact on the current market structure, its economics and the ability to adjust the market to ensure economic sustainability.

Reactor irradiation prices set too low to support infrastructure development

As a result of ^{99}Mo production being seen as a by-product and reactor capital costs that were already paid off or fully justified, historical pricing of reactor irradiation services reportedly included very limited direct marginal costs and did not included replacement costs and full direct and indirect marginal costs. The non-inclusion of these costs has resulted in prices for target irradiation that are too low to sustainably support the portion of reactor operations that could be attributed to ^{99}Mo production and do not provide enough financial incentive to cover the attributable portion of costs for replacing or refurbishing ageing reactors. In some cases, the pricing does not even cover short-run marginal costs.

Commercialisation reinforced low prices and created market power

The current supply chain economics was pivotally impacted by the commercialisation of the major processors in the supply chain. Apart from contracts not providing for the economic sustainability of ^{99}Mo irradiation services, they also resulted in some perverse economic effects, including encouraging some cases of potentially inefficient production of ^{99}Mo. For example, interviewees indicated that some contracts allowed for the processor to stockpile the rapidly decaying ^{99}Mo in order to smooth out customer supply. This type of behaviour greatly affected the economic return to the reactor and resulted in overproduction and an increase in related radioactive waste volumes.

Another effect of the commercialisation process was the establishment of a situation of market power for processors. The contracts, in some cases, provided for an exclusive relationship between the reactor and the processor, creating a situation of monopsony/oligopsony [a market dominated by one/few buyer(s)] whereby the reactor had only one avenue for selling its ^{99}Mo related irradiation services. This market power has contributed to maintaining low prices for irradiation services.

A further complicating factor was the historical existence of excess capacity of irradiation services. While some excess capacity is necessary for reliable supply, it is difficult to determine the difference between reserve capacity and overcapacity when services are not properly valued. This overcapacity coupled with an incomplete accounting for costs on the part of suppliers meant that the reactors would supply irradiation services even if prices were low. It was reported that purchasers could thus pay low prices for the irradiation services and look elsewhere for irradiation suppliers if prices were to increase.

1. SPECT stands for single photon emission computed topography – the nuclear imaging technique which uses gamma rays produced by ^{99m}Tc.

The market power that existed and the related barriers to entry resulted in lower prices at the bulk ^{99}Mo stage than were necessary to encourage new entrants and created a situation of limiting the number of buyers of irradiation services. This maintained the buyer market power and perpetuated the pricing structure that was insufficient to cover full operational and replacement costs of reactors.

Downstream pricing perpetuated low prices

Interviewees indicated that generator manufacturers used low-margin selling models for ^{99}Mo generators, pricing them low to encourage sales of their cold kits. In addition, patent protection that allowed generator manufacturers to obtain a return for the upfront research and development costs also allowed them to obtain economic returns for the combined product of the ^{99}Mo and the cold kits. This pricing model resulted in the companies making profits on the cold kits and not on the generators.

This undervaluation of the ^{99}Mo in the generator pricing had a feedback effect on upstream prices. Since the generator manufacturers captured the economic value of the ^{99}Mo through their sales of cold kits, the profits they made did not flow back up through the ^{99}Mo supply chain and limited the flexibility to absorb upstream price increases within *generator* prices.

These low prices for ^{99}Mo led to unsustainably low prices for the ^{99m}Tc, which were one factor, among many, that contributed to reimbursement rates for SPECT imaging procedures being set low. This has had a feedback effect on maintaining low prices in the upstream supply chain; as these reimbursement rates fell, some hospitals reportedly have negotiated even lower rates for the ^{99m}Tc.

Government support sustained the industry

The question that obviously arises at this point is: *If the supply chain pricing structure was such that the irradiation services were unable to be offered on an economically sustainable basis, why did reactors continue to irradiate targets?*

The answer to this question is related to the social contract that governments had established with the medical imaging community (whether implicitly or explicitly). Governments would subsidise the development of research reactors and related infrastructure and the operation of that infrastructure, including radioactive waste management. Using part of this funding, reactor operators irradiated targets to produce ^{99}Mo. In return for this use of taxpayer funds, citizens would receive an important medical isotope for nuclear medicine diagnostic procedures.

Although reactor operators were aware the government financial support was increasingly used for ^{99}Mo production, this change may not have been transparent to governments. In some cases, the magnitude of the change did not become evident until there were requests to refurbish a reactor or construct a new reactor. These subsidies were also supporting the production of ^{99}Mo that was exported to other countries. Recently, some governments have started to question their social contract with the medical community and with the reactor operators.

Result: Historical foundations created an economically unsustainable industry

The overall impact of the historical market development on the current situation is that there is currently not enough reliable reactor capacity and there are constraints on processing capacity. As explained above, this has been caused by a market structure that developed around an unsustainable economic model that did not remunerate reactor operators and processors sufficiently well to provide incentives to invest in new infrastructure to meet growing demand or to maintain reserve capacity.

This lack of investment has resulted in a system reliant on older reactors that have had reliability concerns over the last decade. The shortage seen in 2009 and 2010 is a **symptom** of this economic problem. Once the shutdown reactors return to operation and the short-term supply becomes stable again, it is important to stress that although the symptom has been addressed, the underlying problem – the unsustainable economic structure – has not.

Analysis of current economic situation

Calculations confirm that the industry is unsustainable

Based on information received during interviews with market participants at all stages of the supply chain, the cost and pricing structure of the ^{99}Mo supply chain were analysed to confirm the assessment that historical market development has resulted in an economically unsustainable supply chain.

Using the models developed and described in the report, the calculated prices of a six-day curie EOP are presented in the Table E.1. These prices are indicative of those seen before the supply shortage period of 2009-2010. During the shortage period, many market participants observed price increases, in some cases quite significant (upwards of 200% increases). These prices are not presented in this report as their longevity is not guaranteed and could be misleading as to the long-term economic sustainability of the supply chain.

From the values calculated using the model of the current economic situation, and the information provided on costs at the reactor stage, the analysis finds that the marginal revenue from production was lower than the marginal costs, with reactors facing a loss on average of EUR 26 on each ^{99}Mo six-day curie EOP produced (USD 36).

Table E.1: Selling price of six-day curie EOP pre-shortage*

	Selling price EUR/six-day curie EOP	Selling price USD/six-day curie EOP**
Reactor	45	60
Processor	315	445
Generator	375	520
Radiopharmacy	1 810	2 525

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value seen in the market.

** An exchange rate of EUR 1 = USD 1.395, which is the average exchange rate for 2009 taken from www.ecb.int (European Central Bank). Exchange rates for other currencies are discussed in Annex 2.

To better understand the significance of the pre-shortage prices, it is necessary to look at the net value of each stage of the supply chain as a proportion of the final ^{99m}Tc dose price provided to the hospital for the patient procedure. Based on a median value of about EUR 11 (USD 15) for the ^{99m}Tc dose, the calculated net price of a six-day curie EOP at each supply stage is presented in the Table E.2.

Table E.2: Net revenue of each stage based on selling prices at the hospital stage – pre-shortage*

	Revenue of ^{99}Mo/^{99m}Tc within the radiopharmaceutical price		Share of revenue of ^{99}Mo/^{99m}Tc of each supply stage within the final reimbursement rate**
	EUR/dose	USD/dose	Per cent
Reactor	0.26	0.37	0.11
Processor	1.64	2.29	0.67
Generator	0.34	0.47	0.14
Radiopharmacy	8.62	12.02	3.51

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

** The total does not equal 100% as the reimbursement rate also pays the hospital for its facilities, the doctors and nuclear clinicians, etc. used during the nuclear medicine diagnostic procedures.

More important is the proportion of these prices within the final reimbursement rates[2]. Based on a representative reimbursement rate for a SPECT imaging procedure (calculated to be about EUR 245/USD 340 using a weighted median of reported values) the net share of that reimbursement rate that goes to each stage of the supply chain is also presented in the table above. As shown, the irradiation price from the reactor is less than one-fifth of one percent of the total reimbursement rate (calculated as 0.11%).

This low value for irradiation should not be interpreted as implying that significant profits are being made at any of the downstream stages or by the hospital itself. There is no reason in principle that the reactor should get any more than 0.11% of the final reimbursement rate, provided that production was economically sustainable, but this is not the case. The price increases at each subsequent stage are expected given other input costs at that level, such as labour and capital investments, as well as value added in terms of making the ^{99}Mo usable for the patient procedure and delivering the product to the next supply stage.

The values demonstrate that the economic structure is inadequate

The values presented in the report clearly show that there is neither sufficient financial incentive for the development of new capital infrastructure nor even for the maintenance of capital to ensure continued operation. The current pricing does not reportedly include any significant value for general overhead or full operating costs, or for capital maintenance or replacement of reactors. As a result, the costs presented here are less than what is required to be economically sustainable. The inclusion of these costs in the calculations would have increased the calculated losses in the current pricing structure for reactor operators.

In addition, the current economic structure does not provide any financial recognition of reserve capacity. Reserve capacity is back-up capacity to be used in two cases: 1) to account for operational

2. Reimbursement rates are the amounts paid to hospitals or clinics via public or private health insurance for the medical procedure undertaken and include the cost of the medical radioisotope.

down times of research reactors as they do not operate 100% of the time – weekly reserve capacity (WRC); and 2) in the event of unscheduled or extended maintenance outages – outage reserve capacity (ORC). Traditionally this meant that when one reactor was not operating, another could fill the void and irradiate targets for ^{99}Mo production.

Historically, WRC was the principal reason for reserve capacity development as the reactors were generally reliable. However, as the reactors (and processing facilities) have aged, there has been an increase in the incidences of unexpected or extended repair shutdowns and the ORC has become of paramount importance in the short term.

Overall, the effect of these poor economic conditions is that the ^{99}Mo supply chain currently relies on older reactors, new reactors are struggling to cover ^{99}Mo production investments, and there is not sufficient reserve capacity to ensure a reliable supply of ^{99}Mo. However, the demonstrated small share of the irradiation prices within the final reimbursement rate provides some hope for reaching a better economic structure, as any changes to upstream prices would be expected to have only small impacts on the end user.

Other issues increase the pressure on the unsustainable economic situation

There are a number of other issues within the industry that increase the impact of the current uneconomical supply chain. Industry stakeholders are being faced with possible additional economic pressures as a result of the conversion to LEU targets[3] and changing levels of government financial support for overall and reserve capacity. In addition, the pricing structure has resulted in examples of suboptimal use of ^{99m}Tc; however, this provides opportunities for demand management actions.

LEU conversion is necessary, but currently not supported by the market

Conversion to LEU targets for the production of ^{99}Mo has been agreed by most governments for security and non-proliferation reasons. In fact one major producer (NTP Radioisotopes) expects to have converted their reactor and processing facilities to use LEU targets in 2010. However, at this time there is not yet an established body of knowledge as to the comparative yield, waste management costs, development costs, capital requirements and the related economic impacts that would be observed for a major ^{99}Mo producer wishing to undertake conversion.

The main technical issue is the obvious fact that LEU targets contain less ^{235}U compared to the HEU targets currently being used. Since ^{99}Mo is a fission product of the ^{235}U in the targets irradiated in the reactor, there is an impact on the yield of product from a target with less ^{235}U. Two ways to compensate for this are to increase the density of total uranium in the targets and to increase the number of targets irradiated. The former action is a source of much current research, as is the development of new technologies and targets to increase yields. The latter may affect other missions within the research reactor or may require more irradiation positions within the reactor.

Without these changes, an increase in costs per curie produced will occur, as there will be a need for some degree of additional irradiation and processing capacity to continue to produce the same quantity of ^{99}Mo globally, depending on the uranium density that can be achieved in the target. There may also be an increase in waste management costs (capital and operational) since more total uranium waste and liquid wastes will need to be managed. However, until final disposal strategies are implemented, it is difficult to quantify the cost increases. Reduced physical protection costs as a result

3. As discussed more fully in the report, some reactors have already made this change.

of dealing with LEU instead of HEU may help to offset any potential cost increases of using LEU targets.

However, even with the uncertainty on the costs of conversion, the conclusion that the current pricing provides insufficient financial incentives is expected to be equally applicable to LEU, as the costs of ^{99}Mo production are generally expected to increase as the industry moves forward with LEU conversion, although the magnitude of any increase will depend upon the specifics of a particular situation.

Governments are re-examining their level of subsidies to reactors

There are indications that the traditional social contract that supported ^{99}Mo production has started to change. Governments from all of the current major global producers' countries have indicated that they are no longer interested in subsidising the ongoing production of ^{99}Mo at the reactor level at historical levels (or at all), some more formally than others.

This changing social contract is also relevant when looking at the possible development of new multipurpose research reactor projects that are being discussed to replace ageing reactors, as well as efforts to encourage the development of other production options. In most of these projects there has been an indication that ^{99}Mo production will have to be undertaken on an economically sustainable basis, including accounting for an attributable portion of the capital investment.

This change in the social contract has come about due to governments questioning whether it is still in the public interest, based on a number of reasons:

- Increased awareness by governments of the amount that they were subsidising ^{99}Mo production and the related waste management (with all its responsibilities).
- The growing proportion of reactor use for ^{99}Mo production brings with it questions of the government's role in a commercial activity, not only from a philosophical perspective but also a regulatory one.
- The taxpayer-funded subsidisation was mostly supporting the health care system of other countries, since much of the product was exported.
- The taxpayer may not benefit from the subsidisation when the irradiated targets or bulk ^{99}Mo are exported and the generators are then imported back into the country.

The historical social contract model also meant that reserve capacity was traditionally provided by governments – they paid for the capital costs for the capacity to exist and production was only done when required. Governments questioning whether to continue subsidising ^{99}Mo production would also impact their level of financial support for reserve capacity.

Any change in the social contract, with a move away from the traditional government role in subsidising the upstream industry, will have a significant impact on supply chain economics. With a changed social contract, the economics have to become sustainable on a full-cost basis or the availability of a long-term reliable supply of ^{99}Mo will be threatened.

Historical suboptimal use of ^{99m}Tc means there are demand management options

As with all products, when the price of ^{99m}Tc is low, people tend to use more or use it less efficiently. In some cases, this "use" meant letting the product decay without being used for a patient procedure, just to ensure its availability. During the current supply shortage, there have been many examples of better use of the ^{99m}Tc that confirm previous inefficient use. In many cases the reduced supply is not affecting the number of patients being tested or the quality of those tests.

Historically, there have been some preparation and delivery practices at radiopharmacies/hospital departments that may have been suboptimal, such as elution patterns that did not maximise the use of the ^{99m}Tc produced within the generator. Radiopharmacies, hospitals and physicians have been changing these historic practices during the current shortage period to deal with a reduced supply. As well, there are a number of recent studies on SPECT procedures and advances in software that indicate the possibility of reducing the required dose of ^{99m}Tc for current practices without sacrificing the quality of the diagnostic test.

These changes, or potential for changes, from traditional practices indicate that there are significant demand-side management options that could be exercised that may not have been considered before. Suboptimal practices result in the overproduction of ^{99}Mo, with the related waste and safety concerns. With accurate pricing, the supply chain players could make a more appropriate assessment on the best way to supply and use ^{99}Mo/^{99m}Tc.

Additional capacity can increase supply, but it is not an economic panacea

Over the past year there has been much discussion and some action related to possible new projects that have or could come on line to support ^{99}Mo production. The use of the MARIA and LVR-15 reactors and the possible future use of other reactors are encouraging for addressing the short- to medium-term supply shortages.

However, it is important to note that these possible new projects could have a negative effect on the current economic situation. Depending on the remuneration provided to reactor operators and the related social contract with the host government, these projects could potentially be detrimental to the long-term economic sustainability of ^{99}Mo provision. If any new projects follow the historical remuneration model, paying only for the direct costs of irradiation with no or partial payment for the reactor investment costs directly related to ^{99}Mo production, it will be the responsibility of the host government to cover those costs not included. As a result, the continued production of ^{99}Mo will depend on the maintenance of the previous social contract with the host government.

This continuation of the historical unsustainable pricing structure could have important effects in the broader market. Those reactors that are required to operate commercially may not be able to sustain their operations in the long term, threatening the long-term reliability of the supply chain. As a result, these new sources of irradiation, given that they are mostly older reactors, could just serve to postpone the pending supply shortage. If the pricing structure perpetuates the current economic situation where new LEU-based ^{99}Mo production infrastructure cannot be constructed or maintained without government assistance, the issue will not be solved in the long term.

That being said, these projects are important for helping to alleviate the short- to medium-term shortages. If they implement pricing that encourages the economic sustainability of the industry, they will not only be crucial in setting the industry on the right price path but will also provide additional flexibility in the supply chain to give time for market changes to occur and new infrastructure to be developed.

Required changes for economic sustainability

Changes are needed to address market, policy and technological failures

Overall, the current economic situation points to the need for changes in the economic structure, and especially so if governments reduce their financial support for the industry. Before discussing how to make those changes, it is important to discuss what type of failures are occurring and then determine the proper action to address the failure.

A market failure exists if there is an inherent value of a product that is not being realised in the prices observed in the market as a result of some form of market operation barrier, including transactions costs from imperfect or asymmetric information, institutional failure, historical circumstances and/or market power. A policy failure exists where government initiatives to address concerns regarding market operations result in outcomes that create their own problems – at times resulting in an overall situation that is worse and leading to inefficient allocation of resources in the economy. A technology failure exists when a technology does not work and creates a significant disturbance in the market. The ^{99}Mo/^{99m}Tc market is subject to all of these types of failures.

- **Market failure**: Patients benefit from there being a reliable supply of ^{99m}Tc through having access to timely medical diagnostic imaging. Since the benefits may not be fully accounted for in the pricing structure, a positive externality exists. This positive externality should be addressed at the health care system level through reimbursement rates, not at the research reactor level.

- **Market failure**: Imperfect information related to the full costs of waste management, reactor operations, fuel consumption, etc. not being known or included in the price structure provides a significant deficiency in the pricing mechanism. In many cases the full costs for ^{99}Mo provision were not transparent to or appreciated by governments who were subsidising the production.

- **Market failure**: The existence of significant market power creates a barrier to developing a proper pricing mechanism for the efficient allocation of resources.

- **Policy failure**: The historical commercialisation route of the processing industry set the industry on the path toward unsustainable pricing and reinforced market power, resulting in the perpetuation of an uneconomical pricing structure and potentially inefficient use of ^{99}Mo.

- **Technology failure**: The development of new ^{99}Mo production capacity was stalled for a decade or more given the development of the MAPLES project in Canada, which was expected to have production capacity in excess of 100% of world demand. However, this project was cancelled by the Government of Canada in 2008. If this project had proceeded[4] there theoretically would have been sufficient capacity at the moment to meet global needs. However, the project could have created some other market failures if it had proceeded, including market power and reliability concerns as a result of the possibility of a single point of failure.

4. Note that this paper is not presenting a view on the technology of the MAPLES project and its cancellation. This paper is only interested in the effect on the market.

Prices must increase, but the impact on end users is small

Pricing for ^{99}Mo must reflect the full costs of production, the benefits of the product and the transportation and logistics. To do so, the pricing structure must change to include remuneration for necessary repairs, maintenance and finally replacement of the infrastructure. Without continued government support, the only way to make the industry economically sustainable is for it to operate on commercial terms.

To determine the magnitude of the price changes needed and their impact, levelised unit cost of ^{99}Mo (LUCM) calculations, based on information received from industry participants, were done to approximate the prices required for economic sustainability. The magnitude of these price increases were then applied to the supply chain to find the effect on the end user (the patient and/or the health insurance system). A number of capital investment scenarios were developed to compare different options available to the industry, with sensitivity analysis undertaken on discount rates, payback periods and the amount of ^{99}Mo produced per week. The investment scenarios were based on the construction of a:

- Fully dedicated isotope reactor (FDIR).
- A multipurpose reactor where 20% of operations are for ^{99}Mo production (MP 20%).
- A multipurpose reactor where 50% of operations are for ^{99}Mo production (MP 50%).
- An existing multipurpose reactor (no capital costs) with 20 and 50% of operations for ^{99}Mo production.
- The above scenarios with processing facilities (Proc).

A separate scenario was not undertaken to determine the LUCM produced from a reactor that converted to using LEU targets because there is not yet a body of knowledge concerning costs and impacts of conversion on production, waste and the related economics at a major producer. New LEU-based reactors and processing facilities (Greenfield) would likely have similar capital costs to HEU production facilities, but may have increased operating costs per ^{99}Mo curie produced based on current target design. It is reasonable to assume that the conclusions related to the need for economically sustainable pricing and the impacts on the end user for production from HEU would continue to hold for production from LEU (either Greenfield or conversion).

It is not the role of the NEA to state what the price of ^{99}Mo should actually be within the supply chain. The calculated values should only be considered indicative of the pricing that would provide for economic sustainability relative to the prices calculated in the previous section and of the magnitude of changes necessary. They should not be construed as representing the situation exactly in any particular region or jurisdiction.

Calculating the LUCM values and applying these through the supply chain indicates that significant price increases are necessary in the upstream supply chain to be able to arrive at a situation of economic sustainability.

Even though the price increases are significant in the upstream supply chain, the analysis finds that there is very little effect on the prices that the end user would see, even assuming a full pass through of all cost increases. Irradiation services require a price increase from about EUR 45 (USD 60) per six-day curie EOP to a range of approximately EUR 55 to 400 (USD 75 to 555) depending on the investment scenario, which is a maximum factor increase of about nine. In terms of the end user, the Table E.3 shows that the reactor share in the final reimbursement rates would increase from approximately EUR 0.26 per procedure at pre-shortage prices to between EUR 0.33 and EUR 2.39 under a situation of economic sustainability (with the lowest value related to an existing multipurpose reactor with no capital cost requirements and the highest value relating to the FDIR scenario).

Even at the most extreme price increase at the reactor level the value of irradiation would only be 0.97% of the final reimbursement rate for the procedure. When compared to the original 0.11% this is a substantial increase but when compared to the overall reimbursement rate of the procedure it is not very significant. In terms of the final impact of the price pass-through for the supply chain (including the required price increases at processing facilities), the impact of the increased radiopharmacy price on the final reimbursement rate is minimal, increasing from 4.42% of the reimbursement rate to a maximum of 5.69%.[5] This, of course, assumes that the *absolute cost increases* are passed through, not percentage increases.

Table E.3: Impact of price increases at hospital level*

	Irradiation value within final radiopharmaceutical price EUR	Irradiation value within final radiopharmaceutical price USD	Irradiation value as % of reimbursement rate
Current situation pre-shortage	0.26	0.37	0.11
FDIR	2.39	3.33	0.97
MP 20%	0.85	1.18	0.35
MP 50%	2.12	2.96	0.86
MP 20% – no capital costs	0.33	0.47	0.14
MP 50% – no capital costs	0.84	1.16	0.34

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value. The scenarios with processing capacity are not presented here as they do not impact the irradiation values within the final prices. Table 5.7 in the report provides the impact of investment scenarios that include new processing capacity.

The demonstrated small impacts indicate that the downstream components should be able to absorb these price increases. However, this issue may require further study and possible assessment by hospitals and medical insurance plans, especially in the context of continued downward pressure on reimbursement rates or where the health system provides fixed budgets to hospitals for radioisotope purchases.

The impact on the end user of converting to LEU targets is also quite small, even through the price impact upstream could be quite significant. Simulating conversion under a situation where the density of the uranium in the targets cannot be increased significantly can be done by looking at the difference in the calculated LUCM between the investment scenarios for the 20 and 50% ^{99}Mo-attributed multipurpose reactors. The end result on the patient is quite small, with the radiopharmacy

5. Not shown in Table E.3 but presented in Table 5.7.

price going from 5.06% to 5.58% of the final reimbursement rates and with the share of the irradiation services in the final reimbursement rate going from 0.35% to 0.86%.[6]

There was concern raised by some market participants that if irradiation prices increased substantially, there would be too much of a financial strain on companies further downstream. The analysis shows that while the required price increases throughout the supply chain could be considered significant, the end effect on the end user is very small and thus the supply chain should be able to absorb the price increases.

Creating a pricing system that covers the full costs of production should also reimburse for the local impacts of production for the global market, including radioactive waste management, that are currently being subsidised by the domestic taxpayer.

Reserve capacity needs to be funded

With effective coordination of reactor and processing production schedules that allows for the optimal use of operating reactor capacities, one would expect that the WRC component of total reserve capacity would result in an annual supply capacity equal to the annual amount of product demanded. However, a lack of effective coordination could result in excess capacity. Historically, this has been the case and has resulted in prices being driven below economically sustainable levels, especially given the situation of processor buying market power that existed.

For ORC there would need to be some annual excess capacity as one or more reactors may have to be shut down for an extended period. In order to have ORC available, there has to be a mechanism to recognise its value and financially support its capacity development, its availability and the action of *not* using the capacity when it is not necessary. The level of remuneration to reactor operators for holding reserve capacity should be less than the actual amount received for production since variable costs of production would not need to be covered. However, there would have to be sufficient reimbursement to cover the attributable portion of capital costs and overhead costs of the facility.

If this value is not recognised and remunerated, there will be a tendency for reactor operators to use the capacity to gain revenue rather than leaving it idle (i.e. as empty channels when the reactor is operating). The consequence of this would be to drive down the prices of irradiation services and perpetuate the market power at the processor level (since they would be able to go elsewhere for irradiation services without another customer stepping in to take their place).

Without WRC and ORC, the supply chain would not be reliable, creating ongoing supply uncertainties that greatly affect the ability to deliver quality health care. This reserve capacity must be available when required, with the full supply chain ready and able to respond, including having all regulatory approvals in place for operation, transportation and use of the ^{99}Mo/^{99m}Tc. As a result, the best option to ensure technical readiness would be spread reserve capacity among research reactors and processors by not using their maximum ^{99}Mo irradiation and processing capacity. In all cases, the provision of reserve capacity and the appropriate use of the capacity (i.e. not using it when not required and using it if required) must be enforceable through contractual agreements, and the coordination of the reserve capacity must respect all appropriate competition regulations.

As new reactors and processors enter the market they will have to voluntarily join these coordination efforts in order to avoid the situation of creating excess capacity and the resulting

6. Again, not shown in Table E.3 but presented in Table 5.7.

depression of prices. If this voluntary coordination does not work, governments may have to consider requiring those supply chain participants that operate in their jurisdiction to participate in coordination efforts. Of course, this coordination role should by no means be used to restrict available production to levels below expected demand in order to increase prices beyond what is commercially required.

Recognition of the value of reserve capacity does not necessarily have to be at the reactor level; it could also include demand management practices. Demand management, including demand shifting, can provide an additional source of "supply" and reduce the need to develop capacity.

There has been experience gained from the structuring of liberalised electricity markets to ensure the existence of reserve capacity and to pay for that reserve capacity (such as through energy-only markets or capacity measures). However, the ^{99}Mo and electricity markets are not identical, so although common lessons may be learned, identical replication of mechanisms is not necessarily feasible.

Things are starting to change

The current shortage has disrupted the market and provides an opportunity to correct historical problems, moving toward a more economically sustainable market structure. For example, some of the barriers to entry at the processor stage discussed previously have been effectively reduced or removed, allowing others to enter the market and reduce the market power (although these have not been completely eliminated given existing contracts). The shortages have also convinced bulk ^{99}Mo clients that they should be multisourcing so that their supply is not subject to a single point of failure.

In addition, with the revived interest in nuclear energy there is an increase in demand for irradiation services for material and fuel testing at the major research reactors, reducing the market power of ^{99}Mo irradiation service purchasers (the processors).

The overall effect of the reduction of market power has resulted in reactor operators and other processors being able to gradually increase prices of ^{99}Mo toward more commercially sustainable levels. The shortages have reportedly stopped the price wars (at least temporarily) and diversification strategies have allowed for prices to increase.

There has also been an increase in downstream prices, partly as a result of the low margin pricing models being replaced by more appropriate pricing of ^{99}Mo at the generator stage of the supply chain, an effect that had already started before the present shortages. These price increases have not necessarily resulted in increased remuneration to reactor operators but have increased awareness of the value of ^{99}Mo, with supply chain participants indicating that there is greater acceptance of rising prices.

However, it is not clear whether the price increases that are starting to happen will be able to be maintained once the technical issues related to short-term supply reliability are resolved and short-term capacity increased. In order to ensure that these changes are sufficient and continuous there are actions that still need to be taken.

Recommendations and options

Defining government role in financially supporting the industry

The first thing that needs to be done is for governments to assess their role in respect of the industry, especially related to the level of subsidisation provided to the upstream ^{99}Mo supply chain (reactors and in some cases the processors). This is predominately a policy decision rather than an economic one. As a result, this study is not recommending what a government should define as its social contract but only that the government should define their position and should ideally harmonise their approach with that of other producing nations. When industry has the impression that governments will continue to subsidise the ^{99}Mo supply chain, they will be less accepting of a change in the price structure and may delay possible investments as they wait to see the final government direction.

The options for defining the social contract are based on the expected role of the government and the degree of financial support that they are willing to provide to the industry. The three options available are based on the traditional model, a modified traditional model and a commercial model:

- **Traditional model**: government would build the required reactors and would irradiate targets for the processing component of the supply chain; the reactor operator would continue to charge only for direct marginal costs. This social contract would require continued government dedicated funding, including replacement costs when necessary.
- **Modified traditional model**: government would again build the reactor and irradiate the targets for the processing stage of the supply chain and not charge for any significant capital replacement costs. However, market pricing would include remuneration for costs related to maintenance, upgrades, share of total reactor operating costs/overheads and waste. The government would be required to fund the infrastructure development but the reactor should be able to *operate* on a commercial basis.
- **Commercial model**: the portion of the reactor facility that is attributed to ^{99}Mo production would be funded on a completely commercial basis, with all costs covered by market prices, including the attributed portion of the capital costs (or replacement costs) of the reactor. The government would not have to commit significant resources to capital development or continued operation of the reactor for ^{99}Mo production, removing concern about subsidising production and waste management through taxes. However, governments would still have to fund the other non-commercial uses of the reactor.

The commercial model does not result in the government abdicating any responsibilities it has to providing health care to its citizens. Governments may decide to continue to pay for the use of ^{99m}Tc through increasing health insurance reimbursement rates (which are currently falling in many jurisdictions). This is a more appropriate place to subsidise the supply chain as it ensures the continued supply of ^{99m}Tc without specifying how it is produced, thus avoiding governments needing to pick technology winners. This would enable alternative technologies, if they are economical and efficient, to enter the market freely while recognising the positive externalities of nuclear medicine.

Once defined, governments should demonstrate their social contract through a strong, clear signal and committed actions such as removing subsidies, defining a transition period for removal of financial support or committing specific funding to the ongoing operation and capital development of reactors for ^{99}Mo production. This signal must include an ongoing political commitment to *not* intervene in the market even if there is public pressure to do so. In all cases, producing nations should make every effort to harmonise their approaches to avoid creating distortions between regional markets and to ensure that commercial-based production can continue to exist.

Paying for the full costs of ^{99}Mo production and capacity

Regardless of the definition of the social contract, the reactor operator must be remunerated for the full costs of ^{99}Mo production. These full costs include a share of common reactor costs and a reasonable share of the capital costs of the production facility or replacement costs. Where this remuneration will come from – through government direct support to reactors or from downstream supply chain participants through the pricing structure – will depend on the definition of the social contract in each country.

If the social contract is defined such that governments will continue to support ^{99}Mo production, they need to be willing and able to increase *ongoing* remuneration to reactor operators. In the current supply chain, additional LEU-based supply capacity and any related processing capacity is needed to account for ageing reactors and international commitments. As a result, governments would be required to provide funds for this capital investment.

Government funding could take the form of unilateral or international funding arrangements. The latter could be subdivided into directly funding a specific project through multilateral efforts or creating an internationally managed "fund". All of these arrangements would need to support ^{99}Mo production either through the traditional model or the modified traditional model.

The internationally managed fund could be supported by consuming nations paying a fee proportional to consumption. This option avoids potential free-riders as the support to the fund is based on consumption, not production. The problem of this option will be its enforceability – ensuring that consuming nations provide the funding required for the fund. In addition, It is recognised that implementation of any international funding mechanism would be extremely difficult.

If the social contract is redefined such that ^{99}Mo production infrastructure would be developed and operated under a commercial model, then more appropriate market prices will be required to cover the full costs. The pricing structure that will need to be demanded by reactors will require a substantial increase in prices and the maintenance of these higher prices once the current shortage situation is resolved. Such a move towards commercial-based pricing would have to be reflected in industry contracts over time, providing for a better operating market.

Various options exist on how to deliver the revised pricing, including: levelised cost pricing; levelised cost pricing with a fixed component; and access fee and service fee. These methods differ in delivery, but should be equal in terms of the present value of the remuneration to the reactor:

- **Levelised cost pricing**: price is based on expected production and full costs, including capital costs, with no guarantee of minimum funding as remuneration would be based entirely on the amount of the product produced and sold.

- **Levelised cost pricing with a fixed component**: pricing structure contains remuneration through a fixed component for service provision and then a variable cost for production. This would provide the reactor operator with a guaranteed minimum price covering fixed costs.

- **Access fee and service fee**: pricing structure would require customers of irradiation services to provide upfront funding to the portion of the capital investment that is related to ^{99}Mo production. This funding would guarantee the customer access to the services provided by the infrastructure, with some guaranteed minimum amount of irradiation service. A service fee would be paid for units of ^{99}Mo actually produced, based on the full variable costs of production.

In some discussions, stakeholders have suggested that regulating prices is another option for increasing prices for irradiation services and processing. This option is less appealing and would be much more complicated than moving towards full-cost pricing. If pricing was commercially set at a level that would be economically sustainable – based on a clearly defined social contract – pricing regulation would not be necessary. In addition, the regulation of prices across international borders presents its own difficulties that would likely be prohibitive to undertaking such regulation.

The challenge will be to develop a harmonised framework that will allow transition to full-cost remuneration in a period when there are both old and new reactors, some with HEU and some with LEU targets and where there will be a number of operators of older reactors that have the incentive to maximise revenue before closure of these reactors. One option to address harmonisation under these conditions would be to develop a panel of experts from producing countries (or an international body) to review the market and provide a view on whether producers are applying the agreed upon social contract (e.g. full-cost pricing) or have clear plans to do so.

It is clear that if there is not ongoing financial support from governments, commercial pricing is necessary for the continued supply of reactor-based ^{99}Mo in the medium to longer term and the conversion to LEU-based production. A commercial-based pricing structure would have the added advantage of allowing for the accurate assessment of the value of ^{99}Mo and its production by research reactors in the health community. It is likely that the benefit of ^{99m}Tc based nuclear imaging testing would allow for the absorption of cost increases downstream and a move to encourage medical insurers to increase reimbursement rates for these types of procedures. However, another possible outcome would be the increased development and use of alternative imaging techniques; increased demand-side management to use the product more efficiently; and increased development and use of alternative means of producing ^{99m}Tc, all where economically viable.

Paying for reserve capacity

It is clear that reserve capacity is required for a reliable supply of ^{99}Mo/^{99m}Tc and that coordination and effective communication through the supply chain is essential to ensure the appropriate use of reserve capacity and to reduce impacts of unplanned outages or longer-term planned outages. However, these efforts do not respond to the need to pay for reserve capacity. Funding is principally important for the provision of reserve capacity that serves the purpose of dealing with unplanned outages (ORC).

If governments decide to maintain their historical role of supporting the development and maintenance of reserve capacity, given the desire for security of supply, then they would have to commit to funding the provision of ORC at reactors and any related processing facilities. As with the overall capacity, government funding could be provided unilaterally by the national government responsible for the reactor or through a form of international government funding.

Under both of these options, funding for reserve capacity could be supported through general taxes. Under unilateral actions, a government would support reserve capacity in their jurisdiction, but this capacity also provides *global* supply security. An export tax on exported ^{99}Mo could potentially be used to help reduce the amount of funds required from the general tax base. Under international funding, countries could support an international reserve capacity fund through their general tax revenues. This international fund would then provide support to the ORC that is deemed necessary to ensure reliable supply.

Another option would be to fund reserve capacity through a flat charge applied to the ^{99}Mo/^{99m}Tc supply chain. Under this option, a levy would be charged on each curie of bulk ^{99}Mo sold or each curie of ^{99m}Tc used in a nuclear medicine procedure. This could be collected by each country's government to pay for reserve capacity in their country, to support reserve capacity at reactors in other countries or to support the "international reserve capacity fund". Again, it is recognised that implementation of any international funding mechanism would be extremely difficult.

Under any of the above scenarios, if a government determines that their social contract includes financially supporting reserve capacity they have to be able to commit to *long-term ongoing* funding for that capacity. In addition, government must be aware that they will have entered into a social contract with the global supply chain to ensure that the capacity is available, operational, has regulatory approval and will not be used except in situations where it is necessary.

If the government defines a social contract that does not include any obligation to fund reserve capacity, the capacity would need to be supported through commercial funding. Since it is theoretically possible to exclude any non-paying party from receiving product from reserve capacity that they did not support, it should be the clear role of the private sector to ensure that they have secured access to a reliable supply network and sufficient outage reserve capacity. In this case, the end users should demand reliable supply and be willing to support it through a "reliability premium". This demand and the remuneration should flow back up the supply chain, resulting in the upstream providing reserve capacity and being paid for it.

However, it is possible that the positive externalities of having a reliable supply would not be fully captured in the market and there may be a role for government intervention. If this occurred, governments could require that generator manufacturers and processors have access to ORC. Such a requirement could be delivered through a reserve capacity credit system.

Conclusion: Changes must occur for supply to be secure over the long term

The current economic structure of the ^{99}Mo supply chain does not provide for sufficient financial incentive to economically support ^{99}Mo production at existing research reactors or development of new LEU-based production and processing capacity. The historical market development and current pricing structure has other undesirable effects on the current economic situation, such as the potential inefficient use of ^{99}Mo and ^{99m}Tc and no recognition of the economic value of reserve capacity to deal with operational realities of reactors and unplanned outage situations.

It is clear that there is no single silver bullet that will set the supply chain on an economically sustainable path to reliability. It is highly unlikely that all governments and supply chain participants will be able to quickly decide on the social contract in a harmonised fashion and take the required steps to alter the market to reflect that contract. However, the long-term goal should be to arrive at a supply chain that is economically sustainable and not reliant upon the use of HEU.

A number of incremental changes could be taken to move toward realising that long-term goal. Governments could set a transitional period where they would continue to subsidise ^{99}Mo production and capacity development, gradually increasing the required amount of private sector contribution to these costs until full-cost pricing is achieved. This process would provide time to allow for the market to adjust to the new pricing paradigm but would require committed government funding through the period.

At the same time, governments could undertake a review of reimbursement rates for nuclear medicine diagnostic tests, focusing on the final impacts of a transition to full-cost pricing and how to manage the communication during and post the transition. It is understandable that increasing reimbursement rates or hospital-specific isotope budgets takes time and, in some countries, requires the co-operation of multiple jurisdictions. As a result, the transition period to full-cost pricing is even more important to ensure continued financial support.

Supply chain participants need to realise that it is unlikely that the current economic model can support ^{99}Mo production in the medium to long term. Pricing models and contracts need to reflect the principles of economic sustainability. Supply chain participants need to support, not hinder, the required changes with the goal of sustaining the industry and benefiting patients.

It is clear that the changes discussed in this report are necessary for the economic sustainability of the ^{99}Mo/^{99m}Tc supply chain. There are a number of decisions that governments and industry players need to take, decisions that could have a long-term impact on the supply chain. If no actions are undertaken, the supply chain will remain fragile and require significant, ongoing government financial support. Harmonised action is required and it seems that the supply chain and decision makers are becoming aware of the issues and are willing to take action.

The NEA can help

The NEA will support these efforts by playing an ongoing role in encouraging a reliable supply chain during and after the transition period. Its role is to provide important and relevant information, economic analysis and options/recommendations on the market situation. It will also continue to serve as a forum for producing nations to discuss the issues and work towards solutions through the HLG-MR.

Following up on the findings of this economic study, the NEA will undertake further study to support the HLG-MR in discussing policy options. Through a series of background papers, the NEA will examine different market models and approaches to ensure sufficient capacity, including reserve capacity.

Chapter 1

INTRODUCTION

1.1 NEA involvement in ensuring supply reliability

At the request of member countries, the OECD Nuclear Energy Agency (NEA) has become involved in global efforts to ensure a reliable supply of molybdenum-99 (^{99}Mo) and its decay product, technetium-99m (^{99m}Tc), the most widely used medical radioisotope. These isotopes are used in diagnostic imaging techniques that enable precise and accurate, early detection and management of diseases such as heart conditions and cancer, all in a non-invasive manner. Disruptions in the supply chain of these isotopes – which have half lives of 66 hours and 6 hours, respectively, and thus must be produced continually – can interrupt the availability of this important medical testing.

Historically, 5 reactors that were commissioned between 43 and 53 years ago have been producing, along with 4 processing facilities, 90 to 95% of the total global supply of ^{99}Mo. Given the age of these reactors, there are issues related to their longevity and reliability, with unexpected shutdowns occurring more often. For example, the Canadian National Research Universal (NRU) reactor was shut down in May 2009 as a result of a leak in the reactor vessel and only expects to return to service at the end of July 2010. In addition, the High Flux Reactor in the Netherlands and the OSIRIS reactor in France have extended maintenance periods in 2010. Some of the five reactors are expected to reach their end of life in the next six years. There have also been failures at processing facilities that have negatively affected the reliable provision of ^{99}Mo.

At the request of member countries, the NEA Steering Committee established the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) in April 2009 to oversee and assist, where necessary, efforts of the international community to address the challenges of medical isotope supply reliability. The NEA Secretariat supports the group and brings its expertise to the issue.

1.2 Goals and methodology of the economic study

During discussions at HLG-MR meetings and other initiatives, a key issue that was raised was the possibility of a market failure in the ^{99}Mo supply chain. This was hypothesised given the situation where it was (and is) not economically viable for current reactors to produce ^{99}Mo, nor is there sufficient incentive based on the current economic structure to develop additional reactor and processing infrastructure to produce ^{99}Mo. This lack of investment capability means that the short-term problems facing the supply chain are really a symptom of a longer-term problem, that of insufficient capital investment for a reliable supply. In order to determine if there is a market failure in the supply chain, the HLG-MR requested that the NEA Secretariat undertake an economic study on the ^{99}Mo supply chain.

The study was originally supposed to only focus on the upstream component of the supply chain (the reactor and processing components). However, it became clear early on that understanding the downstream components (generators to patients) was essential to fully understand the market, the changes that may be required, and the impact of those changes. As a result, the study was expanded to include the entire supply chain.

The intention of the economic study is to develop a solid factual base on the supply chain and to determine if there has been a market failure. From there, it would provide options on how to address any existing market failure and how to create a sustainable economic environment that would encourage additional ^{99}Mo production, additional capital investment in non-HEU ^{99}Mo production capacity and the development of the necessary reserve capacity required for a reliable supply system without depressing ^{99}Mo prices beyond economically sustainable levels. It would look at the appropriate balance between benefits and costs of ^{99}Mo provision and a better allocation of responsibilities for costs between public and private stakeholders. In addition, the economic study is meant to increase understanding of the supply chain and its economics to provide input to governments and other decision makers so that they can make informed decisions on the appropriate steps forward. One further goal of the study is to provide a better understanding amongst end users of the costs of supplying ^{99}Mo in order to support a better functioning market.

In the course of the study, the NEA Secretariat interviewed and obtained input from supply chain participants, including all major reactor operators, all major processors, generator manufacturers and representatives from radiopharmacies and nuclear medicine practitioners. A full list of individuals consulted is presented in Annex 1. In order to have access to as complete information as possible, the NEA Secretariat assured interviewees that information that may be of a commercial nature or that may have implications for relations with commercial partners would be kept confidential. As a result, the paper does not provide attribution of comments, values or statements to any specific interviewee where it may affect commercial undertakings. The input of the supply chain participants was essential to being able to complete this study and the NEA Secretariat greatly appreciates the information provided by interviewees.

The focus of the study is the economics of the supply chain and not an assessment of the full issues and barriers facing the industry. These other issues (e.g. transportation issues, alternative production methods) will be covered in the HLG-MR Interim Report.

In addition, it has to be recognised that economic considerations are only one factor that will affect the final decisions being taken about the future of this supply chain. Other factors that are important for decision makers are policy, medical and technological in nature. The prioritisation of these factors in the decision making process is up to governments; depending on how governments set their priorities, different solutions may be better suited for different governments. This study is only focused on the economic issues, the implications for the supply chain of those economic issues and how they could be dealt with by governments and the industry.

This report seeks to address the goals assigned to the economic study and is the result of the interviews with supply chain participants, economic research, analysis of the industry and comparisons with other industries where lessons could be learned (e.g. electricity, water supply). It starts from the central premise that there is a value to ^{99m}Tc procedures and the reactor based supply chain is the method best suited to deliver ^{99}Mo and ^{99m}Tc to the end user. As a result, the study sets out to recommend improvements to the economics to ensure the economic sustainability of this supply chain path. However, this central premise would be tested by any change to the underlying economics and pricing structure of the industry that would result in increased prices.

While the report focuses on existing production technologies, which mainly use HEU targets[1], the NEA notes the agreement among governments to move toward using LEU targets for medical isotope production. Unfortunately, there is not sufficient experience at this time to undertake a full economic analysis on such a conversion, but the report makes an attempt to simulate the economic impact. Regardless, the economic conclusions drawn in the report will apply to ^{99}Mo production using LEU targets, either from conversion or the development of new LEU-based production capacity.

The report provides comprehensive information on the supply chain to ensure a complete picture of the supply chain and any needed changes. In Chapter 2, the report describes the current supply chain and its historical development in order to increase the understanding of this complex market. Chapter 3 discusses the impacts of the historical market development on the current supply chain economics. The intention of this discussion is not to lay blame for the current economic situation but to understand how the situation came about so that the supply chain can move forward on a sound economic footing. Chapter 4 presents the economic analysis of the current economic situation of the supply chain, providing a description of the current pricing structure and the issues facing the supply chain related to that pricing structure. Chapter 5 discusses the changes to the economic structure of the supply chain that are necessary if economic sustainability is expected to be obtained. Chapter 6 provides the options to consider when determining how to move forward to addressing the economic issues of this supply chain.

1. Targets are classified as either LEU, containing less than 20% of ^{235}U, or HEU, which contains greater than 20% ^{235}U (in some cases greater than 95%).

Chapter 2

THE SUPPLY CHAIN – A DESCRIPTION

2.1 Introduction

^{99}Mo has a half-life of 66 hours, meaning that after 66 hours only half of the original product is remaining. As a result, the logistical arrangements in the supply chain have to move very quickly and predictably to get the product delivered to the end user in its usable form – a prepared dose containing ^{99m}Tc for injection into the patient. The prepared ^{99m}Tc is further constrained in that it has a half-life of only six hours. Given its short half-life, ^{99}Mo cannot be efficiently stored over extended periods. For practical purposes, the economics and medical utility of ^{99}Mo/^{99m}Tc are dependent on minimising decay losses. Logistical efficiency and just in time delivery are essential attributes to the realisation of economic sustainability within the global supply chain.

Figure 2.1 provides an overview of the supply chain.[1] Basically, the process is as follows, with some estimated times for each stage, recognising that times can vary greatly between supply chain participants and distances to customers:

- Targets containing uranium-235 (^{235}U) are shipped to nuclear research reactors and are irradiated in the reactor to create the fission product ^{99}Mo along with other fission products. **Six to seven days for irradiation.**

- After irradiation, the targets are cooled and then prepared for transportation to the processing facility and placed in a large, secure transportation container. **Approximately 12 hours for cooling; 4 hours for transportation preparation.**

- The irradiated targets are transported from the reactor to the processing facility, which should be located no further than 1 000 km (on land) from the reactor to minimise the decay of ^{99}Mo. The time taken for transportation depends on the location of the reactor compared to the processing facility. Transportation is constrained to land-based methods given the size, weight, and licence restrictions of the shipping containers. **Up to a number of hours**.

- Once the containers are unloaded at the processing facility, the ^{99}Mo is separated from the irradiated target through dissolution and then purified. The bulk ^{99}Mo radiochemical is transported to generator manufacturers; the duration of the transportation depends on the location of the generator manufacturing facility. Distribution can be done via all transport methods. **Twelve hours for processing; up to 36 hours for transportation.**

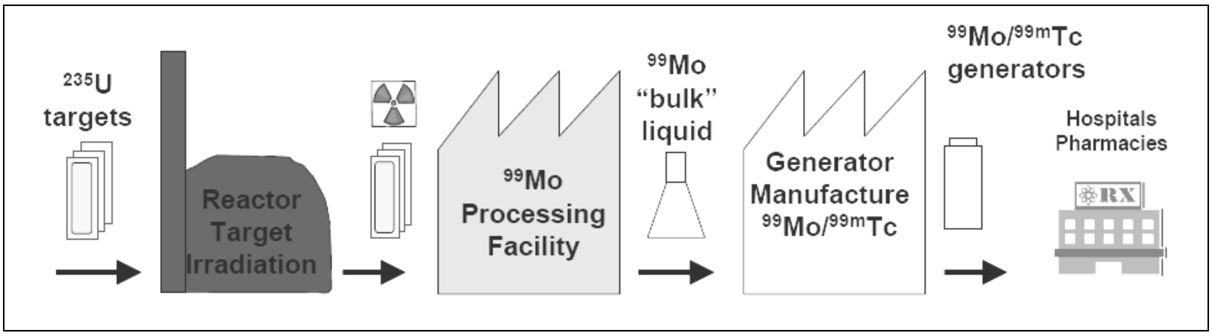
1. This report focuses on a supply chain based on existing reactor based production of ^{99}Mo, which is responsible for more than 95% of ^{99}Mo production. Alternative technologies are discussed in the NEA's forthcoming review of ^{99}Mo production technologies and only discussed in this report in so far as they may affect the economics of the currently supply chain.

- At the generator manufacturing facility, the bulk ^{99}Mo is absorbed onto an alumina column which is placed in a ^{99m}Tc generator. **Eighteen to 24 hours for the preparation of the generator.**

- This generator is then shipped to radiopharmacies or directly to hospitals. **Up to 24 hours for transportation.**

- Radiopharmacists elute ^{99m}Tc (pass a saline solution over the column to extract the ^{99m}Tc) and prepare the patient dose using a cold kit (a non-radioactive solution that is specifically designed for specific medical diagnostic procedures). This dose is then shipped to local hospitals for use in SPECT[2] nuclear medicine diagnostic imaging procedures. A ^{99m}Tc generator can be eluted for a period of up to two weeks under normal circumstances. In many cases, hospitals have their own radiopharmacy department, which undertakes the same preparation and then provides the dose to the imaging department in the hospital.

Figure 2.1: ^{99}Mo supply chain



Source: Ponsard, 2010.

This section will describe the current supply chain at each step, highlighting some issues that affect reliable supply and economic sustainability. In addition, the historical foundation of that step will be discussed; however, the implications on the current supply chain economics will be discussed in Chapter 3. It is important to understand the market structure of the supply chain to be able to discuss the economic issues affecting the supply chain. The nature of the product, the history of the market development and the challenges faced by the industry are all key factors affecting the economic sustainability of the ^{99}Mo supply chain.

2.2 Reactor component of the supply chain

Historically, there were only five reactors that produced 90 to 95% of global ^{99}Mo supply: three in Europe (BR-2 in Belgium, HFR in the Netherlands and OSIRIS in France), one in Canada (NRU), and one in South Africa (SAFARI-1). All these reactors are over 43 years old. In the past, the SILOE reactor in France, the Cintichem reactor in the United States, the NRX in Canada and the FRJ-2 reactor in Germany also produced ^{99}Mo for the global supply chain. However, all of these reactors have been shut down: Cintichem in 1989, NRX in 1992, SILOE in 1997 and the FRJ-2 in 2006.

2. SPECT stands for single photon emission computed topography – the nuclear imaging technique which uses gamma rays produced by ^{99m}Tc.

There are also the OPAL reactor in Australia and the RA-3 reactor in Argentina that predominately produce for their local markets but have recently been exporting small quantities of ^{99}Mo (IAEA, 2010). The OPAL reactor has the potential to increase production substantially but is currently limited by the local processing capacity (this issue will be discussed further in Section 2.3).

The newest additions to the ^{99}Mo global supply chain are the MARIA reactor in Poland that started producing ^{99}Mo for global distribution in February 2010 and the LVR-15 reactor in the Czech Republic that started producing ^{99}Mo for global distribution in May 2010. There are also various reactors and accelerators around the world that produce small quantities of ^{99}Mo for domestic use; these are not discussed in this report. Table 2.1 provides further information on the major ^{99}Mo producing reactors.

Table 2.1: Major current ^{99}Mo producing reactors

Reactor name	Location	Annual operating days	Normal production per week[a]	Weekly % of world demand	Fuel/targets[b]	Date of first commissioning
BR-2	Belgium	140	5 200[c]	25-65	HEU/HEU	1961
HFR	Netherlands	300	4 680	35-70	LEU/HEU	1961
LVR-15[d]	Czech Rep.	–	>600	–	HEU[e]/HEU	1957
MARIA[d]	Poland	–	700-1 500	–	HEU/HEU	1974
NRU	Canada	300	4 680	35-70	LEU/HEU	1957
OPAL	Australia	290	1 000-1 500	–[f]	LEU/LEU	2007
OSIRIS	France	180	1 200	10-20	LEU/HEU	1966
SAFARI-1	South Africa	305	2 500	10-30	LEU/HEU[g]	1965
RA-3	Argentina	230	200	< 2	LEU/LEU	1967

a. Six-day curies end of processing. In some cases, maximum production can be substantially higher that the values listed here for normal production.

b. Fuel elements and targets are classified as either LEU, containing less than 20% of ^{235}U, or HEU, which contains greater than 20% ^{235}U (in some cases greater than 95%).

c. Does not account for increase in capacity since April 2010 with the installation of additional irradiation capacity. This increases BR-2 available capacity to approximately 7 800 six-day curies EOP; however it is not yet clear what "normal" production will be at the facility.

d. These reactors started production in 2010 so some data is not yet available.

e. The LVR-15 reactor uses fuel elements that are enriched to 36% ^{235}U.

f. The OPAL reactor started production in 2007 for domestic use but has not yet exported significant amounts.

g. SAFARI-1 is in the process of converting to using LEU targets and expects to have completed conversion in 2010.

Market structure

There are three different market structures that have emerged in this component of the supply chain in regards to irradiating targets for the production of ^{99}Mo. Each of these structures can provide different challenges related to the economics, including the ability to change prices for services rendered.

The first, and most common, is that a reactor provides irradiation services to the ^{99}Mo processor. In this case, the reactor and processor have a contract whereby the processor arranges for the targets to be sent to the reactor and, once irradiated, to be shipped to their facility. The reactor is responsible for the storage of the targets, their installation in the reactor, their irradiation and their preparation for transportation. The payment structure of this transaction is normally based on a multiyear contract for these irradiation services.

The second market structure is similar to the first model, except that the reactor operator takes on additional responsibilities. In this second structure, the reactor operator is responsible for obtaining the targets, storing and then irradiating them and then undertaking the initial extraction of the ^{99}Mo from the irradiated targets before transportation to the processor. This structure does not have a direct charge for these services based on quantity per se, but rather a revenue sharing agreement based on the final product sold by the processor.

The third market structure is more vertically integrated, where the reactor operator and the processor are structurally linked. In this case, the reactor operator may source the targets for an external source or may produce their own targets. The irradiation services may not have a direct charge to the processor for the irradiation; however, the processor supports the costs of irradiation through its arrangements with the broader company. In this structure, the vertically integrated company may also produce some generators for domestic purposes.

All of the major producers of ^{99}Mo use irradiation in multipurpose research reactors. When these research reactors were constructed their purpose was research and materials testing; the production of ^{99}Mo was not a consideration. With the advent of the ^{99m}Tc generator in the 1960s and the related growth of nuclear diagnostic technology, ^{99}Mo was seen as a by-product of the irradiation processes already ongoing that could bring in additional revenue to these research reactors. This viewpoint has had implications for the economics of ^{99}Mo that will be discussed further in Chapter 3.

Another key factor in the market structure is that all the reactors were originally constructed and operated with 100% government funding (this is changing, however, as will be discussed further in Chapter 4). As a result, when ^{99}Mo production became a marketable by-product, the reactor capital costs were not considered to be relevant in the costing and pricing of the final product. The maintenance and periodic capital updates (which can be quite substantial) were also not considered to be relevant to the final pricing; these costs were seen to be necessary for the general operation of the reactor and thus would be incurred regardless of the ^{99}Mo production. At that time, the separation and purification of the ^{99}Mo were also performed by government operated facilities.

Over the years, the importance of ^{99}Mo production has increased in these reactors to the point where most of the major reactor operators have indicated that it is now a significant factor behind reactor operating decisions, in some cases the main short-term driving force. That being said, they are still research reactors and must balance the demands between irradiation services for ^{99}Mo production and research programmes (which often have to be established more than 12 months in advance).

Challenges

The current reactor market structure poses some challenges for the reliable production of ^{99}Mo. The challenges are related to: the age of the reactors; the conversion from targets normally containing greater than 90% ^{235}U (HEU) to targets containing less than 20% (LEU); and the requirement for reserve capacity. These challenges are discussed briefly below and form the basis for some of the key economic problems that are discussed in this report.

As mentioned above, the five main reactors were commissioned between 43 and 53 years ago. As the reactors age there is the requirement for longer downtime periods between production cycles to repair or replace ageing parts or to undertake additional inspections to determine the effects of ageing on the reactor. This requirement follows the increased likelihood of failures as many components are not observable or serviceable without extended maintenance shutdowns (AECL, 2009). During these extended downtimes the reactor is not producing any ^{99}Mo.

In the past, the supply impacts of the regular planned maintenance periods of each reactor could be smoothed out by other reactors. However, in recent years the duration of some planned maintenance periods have been extended, creating the need for longer term expanded production at other reactors. This has created logistical issues including increased difficulty in balancing reactor operations for ^{99}Mo production with other research projects. In addition, these extended periods are becoming more frequent whereby there are situations where more than one reactor is shut down at the same time. For example, in summer 2010 the HFR, the NRU and the OSIRIS reactor were all down for extended periods. As a result, the impacts of these extended periods are not always able to be smoothed out, greatly affecting the downstream component of the supply chain, especially the final user – the patient.

A consequence of ageing reactors that is even more important for the reliable supply of ^{99}Mo is the increased occurrences of unexpected shutdowns at producing reactors. Between 2000 and 2010, there have been six unexpected shutdowns related to reactor safety concerns (Ponsard, 2010). Most recently the NRU was shut down in May 2009 as a result of a leak in the reactor vessel and only expects to return to service at the end of July 2010.

These unexpected shutdowns can create turmoil in the supply chain especially when it occurs at one of the two largest producers (HFR and NRU), because it is very difficult for the other reactors to respond at very short notice to add or change a production cycle or to increase production greatly. In addition, the increasing length and frequency of periods where only one reactor is supplying a significant portion of world demand reduces reliability in the supply chain. These periods are high risk periods for supply continuity since there is no immediate backup capacity available in the event of an unexpected stop at that one reactor.

Not all these reactors have aged at the same pace given specific operating schedules and maintenance programmes. Both the SAFARI-1 reactor and the BR-2 expect to continue operations into the 2020s and possibly beyond; The former partly as a result of its low usage between 1977 and 1993 and the later as a result of a major refurbishment that occurred between 1995 and 1997. However, the OSIRIS reactor is planning to be retired from service in 2015, the Government of Canada has indicated that it will only seek to extend the NRU reactor license to 2016 and the HFR reactor is expected to be shut down before 2020.

The implications of these ageing reactors for reliable ^{99}Mo supply are created by economic factors that need to be addressed. As will be discussed later in the report, the current economic return on producing ^{99}Mo at the reactor is not sufficient to support the development of new infrastructure for the production of ^{99}Mo; a new research reactor costs greater than EUR 400 million.

An additional challenge that will affect the reactor component of the supply chain is the move to replace the usage of current HEU targets with LEU targets. As is noted Table 2.1, most of the five major research reactors are currently using HEU targets to produce ^{99}Mo. HEU targets contain weapons-grade uranium. Given efforts related to the non-proliferation of nuclear weapons, there is a global agreement to convert to LEU targets. The technical challenges of this conversion will not be discussed in this report at any depth; however the economic challenges will be covered.

Economically, the conversion may be expected to increase costs for irradiation on a per curie basis. Given the lower ^{235}U content, additional targets may have to be irradiated to produce the same amount of ^{99}Mo or the density of the uranium in the target will have to be increased to compensate for the lower ^{235}U content. The amount of increased irradiation is up for debate until more practical experience with conversion and increasing target density has been completed, recognising that current conversion efforts are focusing on ways to increase target density. If density cannot be increased to completely compensate for the lower ^{235}U content, conversion may require anywhere from a doubling to quadrupling of target irradiation to produce the same amount of ^{99}Mo. Such an increase, if necessary, would require additional infrastructure to produce the same amount of ^{99}Mo.

An additional challenge facing the reactor component of the supply chain is related to the need for reserve capacity. This capacity is need for two reasons: 1) to account for operational realities of research reactors (explained below); and 2) to serve as a backup in the event of unscheduled outages. However, the need for, and existence of, reserve capacity raises some interesting economic challenges that will be addressed later in this report, including:

- How can reserve capacity be guaranteed to be available and ready to operate?
- How can reserve capacity be financially supported in order to ensure its availability?
- How can reserve capacity be financially supported to ensure that it is **not used** when it is not necessary (whose use could be expected to drive down prices to unsustainable levels)?

The first reason for the need for reserve capacity results from the operational nature of research reactors and the extreme inefficiencies in stockpiling ^{99}Mo with its 66-hour half-life. Research reactors do not operate 100% of the time; they operate on the basis of cycles, with a number of days of operating and then a period where the reactor is shut down for refueling, changing research project set-ups, regular maintenance, etc. In addition, some reactors do not operate the full year depending on their research demands and available funding (Table 2.1 provides the approximate operating days of the main ^{99}Mo producing reactors). The duration of the cycles and shutdown periods varies between reactors but the important point is that when a reactor is not operating it is not producing ^{99}Mo. Other reactors need to be able to irradiate targets during these shutdown periods, especially for those of longer duration, to ensure a smooth supply of ^{99}Mo in the market.

The second reason for reserve capacity results from the unreliability of producing reactors. When a reactor is unexpectedly shut down as a result of a technical problem or a safety concern that requires an extended repair period, the remaining reactors need to increase production of ^{99}Mo if the market supply is to be sustained at normal levels so that patients can continue to have access to this medical nuclear imaging technique. This second component of reserve capacity has become more important as the reactors age and face unexpected or extended repair shutdowns more often, the number of producing reactors has decreased and the market demand has continued to increase.

As a result of the two issues above, if one were to merely add up the irradiation capacity at the producing reactors it should significantly exceed 100% of demand. However, at any one moment in time the producing capacity should be just sufficient to meet demand.

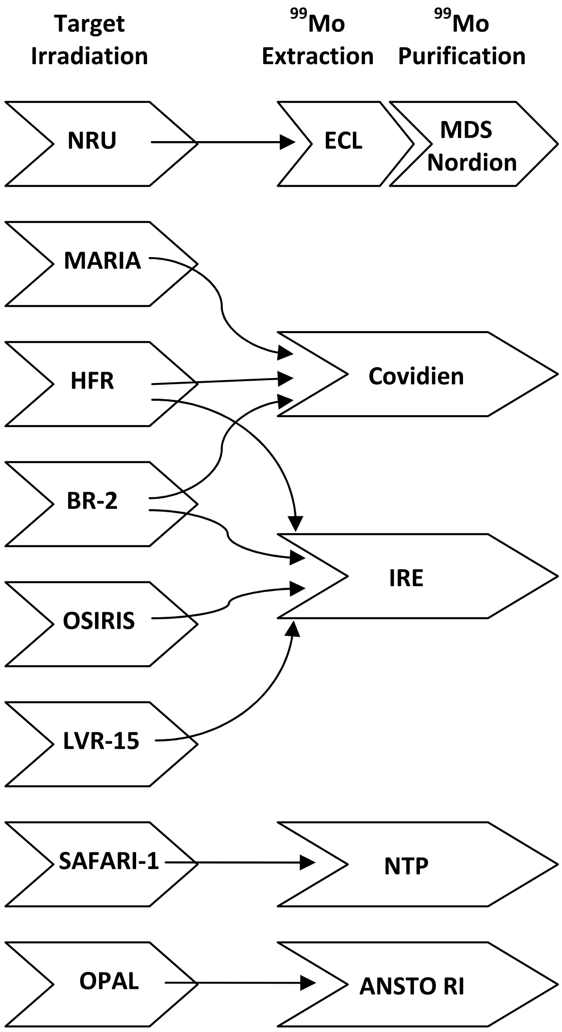
Overall, these issues in the reactor component create significant challenges for the overall supply chain. There are a few significant reactors that are expected to come online within the next decade that could address some of the above issues. However, there are still economic hurdles to overcome related to their production of ^{99}Mo. These projects and the economic issues will be discussed in Chapter 4 of this report.

2.3 Processing component of the supply chain

As mentioned above, the processing component of the supply chain generally involves the transportation of the irradiated targets from the reactor to the processing facility, the extraction of ^{99}Mo from the target and the purification of the ^{99}Mo. This process is required to obtain the bulk ^{99}Mo and to ensure that it meets or exceeds the minimum levels of impurities that are required for its medical application. Once purified, the bulk ^{99}Mo is transported around the world from the processing facility to generator manufacturing facilities, predominately on roads and commercial airlines.

There are four main processors that supply the global market: MDS Nordion (Canada); Covidien (The Netherlands); The Institute for RadioElements (IRE, Belgium); and NTP Radioisotopes (South Africa). In addition, ANSTO (Australia) and CNEA (Argentina) currently process bulk ^{99}Mo for their domestic market and expect to be or is already exporting small amounts. The unique situation in Canada must be pointed out here; AECL irradiates the targets and also does the initial extraction of the ^{99}Mo from the irradiated target. This extracted ^{99}Mo is then shipped to MDS Nordion for purification. Figure 2.2 provides additional detail on the supply chain from the reactors to the processors.

Figure 2.2: Reactor to processor supply chain



Prior to the NRU shutdown, MDS Nordion supplied approximately 40% of the world market; Covidien, 29%; NTP, 18%; IRE, 12%; and ANSTO about 1% (Vanderhofstadt, 2009). After the shutdown of the NRU, MDS Nordion's supply was not available and the other processors stepped in to partially fill the gap. Although estimates vary on actual percentages, it is safe to say that Covidien, NTP and IRE have all increased their market share during the shortage period, albeit of a smaller total supply.

The processing component of the supply chain was originally funded by governments as part of their efforts to develop the use of nuclear radioisotopes for medicine, with the processor originally associated with the reactor. In the 1980s and 1990s this component was separated from the reactors and either sold to private companies or charged by their government shareholders to operate in an economically sustainable manner (but not necessarily for profit). However, the agreements made between the processors and reactors during the commercialisation process provided for beneficial terms to the processors that were not completely on commercial terms, based partially on the notion that ^{99}Mo was a by-product.

It is a market characterised by significant barriers to entry. Extracting and processing the ^{99}Mo is a very capital intensive process, with a new processing facility costing over EUR 100 million. In addition, it is a knowledge intensive industry, with each processor having their method for extracting and purifying the ^{99}Mo.

The two issues (historical agreements and barriers to entry) have a significant impact on the economics of the ^{99}Mo supply chain. Both have contributed to the development of market power in this component of the supply chain and will be discussed further in Chapter 3.

Challenges

As with the reactor component of the supply chain, the processing component faces some challenges and limitations that could affect the reliable supply of ^{99}Mo and the related economics. These limitations and challenges being faced by the processing component of the supply chain will be the subject of a chapter in the NEA HLG-MR Interim Report. As a result, the issues will be discussed here and in future chapters only in so far as they impact the economics but will not be discussed in depth.

During this period of increased interest in the reliability of ^{99}Mo supply, there has been much coverage on the situation of reactors but very little attention dedicated to processing capacity. If one were to add up the global processing capacity as presented in Table 2.2 it would appear that there would be sufficient supply to readily meet the world's demand for approximately 12 000 six-day curies per week.[3] However, processing capacity is limited by its location.

As noted in the introduction, processing facilities should be located close to the reactor. Interviewees indicated that approximately 1 000 km (on land) from the reactor was the maximum acceptable distance. This is because irradiated targets have to be shipped to the processing facility in secure containers that weigh approximately four tonnes. These containers can only be transported via road transportation due to costs and container licensing limitations and therefore the decay rate of the ^{99}Mo dictates that the processor would ideally be located as close to the reactor as possible.

Table 2.2: Processing capacity

Processing facility	Location	Processing capacity six-day curies EOP/wk
ANSTO	Australia	> 1 000
Covidien	Netherlands	> 3 500
CNEA Ezeiza Atomic Centre	Argentina	> 600
IRE	Belgium	> 3 000
MDS Nordion	Canada	> 7 200[a]
NTP	South Africa	> 3 000
NTP – In development	South Africa	2 625[b]
Total		> 21 425[a]

a. Adjusted from Vanderhofstadt, 2010, based on MDS Nordion's ability to process AECL production, that can reach a maximum of 60% of global demand or 7 200 six-day curies per week.

b. The capacity is meant to serve as backup and not to be used immediately for production. Capacity value is estimated by NEA and represents a modification from Vanderhofstadt, 2010.

Source: Vanderhofstadt, 2010 with modifications.

3. A commonly used unit of measure in the industry is the six-day curie, defined as the radioactivity of ^{99}Mo six days after the end of processing component of the supply chain EOP, when the bulk ^{99}Mo leaves the processing facility.

Given this location constraint, regional processing capacity is more relevant in determining the ability to meet world demand. This has an impact on the economics of the supply chain and it limits the ability of the market players to fill in the supply gaps as required. For example, the processing capacity in Europe is not sufficient to process irradiated targets from the four European reactors if they were all producing at the same time; in Australia, the OPAL reactor could theoretically produce half of the world's demand of ^{99}Mo (about 6 000 six-day curies/week) but the limiting factor is its processing facility, which has the capacity to handle a maximum of 1 500 six-day curies per week. During some weeks of the shortage periods in 2009 and 2010, the European reactors had capacity to increase production but the processing capabilities presented a limiting factor.

This processing capacity limit implies that even if the economics encouraged the development of new ^{99}Mo production, it would be imperative to ensure that there was sufficient processing capacity in the region. This has been one of the limiting factors to developing ^{99}Mo production in the United States in the short term by adapting one of their existing research reactors.

In the processing sector, there is also the need for reserve capacity. This need is based on the same principles as in the reactor component: 1) to account for operational realities of research reactors; and 2) to serve as a backup in the event of unscheduled outages. Both instances apply most directly to processors that are served by a single reactor; when the reactor is down for operational reasons or as a result of an unscheduled event, the processor does not have access to their principal input – the irradiated targets. The processor can either not serve their clients during these periods or they have to seek alternative source of bulk ^{99}Mo to supply their clients. Some processors have developed various backup supply agreements with each other in order to try to ensure a continuous supply to clients.

There is also the possibility that the processor can face an unexpected shutdown, as occurred from August to November 2008 at the IRE facility, for example. In such a case, the reserve capacity would again have to come from another processor as the entire facility would be closed. However, there could also exist a situation where one production line of hot-cells became unavailable due to some mechanical failure. In this case, redundant capacity within the facility is necessary, which could also serve as a basis to increase production to fill market supply gaps if other facilities were to go offline unexpectedly.

Although bulk ^{99}Mo can be transported around the globe, there are important logistic considerations that can greatly affect the economics. A key value addition of the processor component of the supply chain is the handling of the complicated logistics to get the bulk ^{99}Mo to generator manufacturers in as short a time as possible; for every hour of shipment approximately 1% of the remaining ^{99}Mo is lost to due to decay.

The issue of delays is again dealt with in more detail in the HLG-MR Interim Report but there is one major point that needs to be raised for its implications on the economics. The decay of the ^{99}Mo during the transportation and various production processes can greatly affect the final economics of the supply chain. For example, if a shipment of bulk ^{99}Mo sits at an airport for 24 hours or there is a 24 hour delay in the processing chain, approximately 22% of the ^{99}Mo will be lost. It should be self-evident that a loss of 22% of product would greatly affect the financial returns on the product and could make the supply chain economically unviable.

Another issue that raises challenges for the economics of the processing component is the management of the liquid radioactive waste that is produced during the extraction, and to a lesser extent, the purification of ^{99}Mo. Currently, the cost of the waste management is not completely accounted for in the cost of the bulk ^{99}Mo. This is because the final disposal path of the waste has not been determined in most cases. In addition, some waste management facilities are nearing their maximum capacity and new storage facilities will have to be developed if production is expected to continue. Progress is being made on dealing with the radioactive waste, but these costs will likely have an impact on ^{99}Mo prices moving forward, the degree of which will need to be determined once the cost of the waste management is clear.

Related to the waste management challenge is the conversion to LEU for the production of ^{99}Mo. As discussed in the last section, in order to produce the same amount of ^{99}Mo with LEU there may need to be an increase in the ^{235}U density in the targets or an increase in the number of targets irradiated. If more targets require processing, this would translate to an increase in processing activity. In addition, processing of additional uranium (to account for the lower ^{235}U content) will mean an increase in waste volumes.

The conversion to LEU may require an increase in processing facility capacity as more targets may need to pass through the facility in the same amount of time to meet customer demand, if the uranium density within the targets cannot be increased sufficiently. The processing of the LEU targets may also require a different process. These two impacts may result in the need to develop new processing infrastructure, which is a significant cost.

Again, these challenges in the processing component of the supply chain raise issues for the long-term reliability of the supply chain, having an impact on the ability of the industry to respond to such events as unplanned outages.

2.4 Generator manufacture component of the supply chain

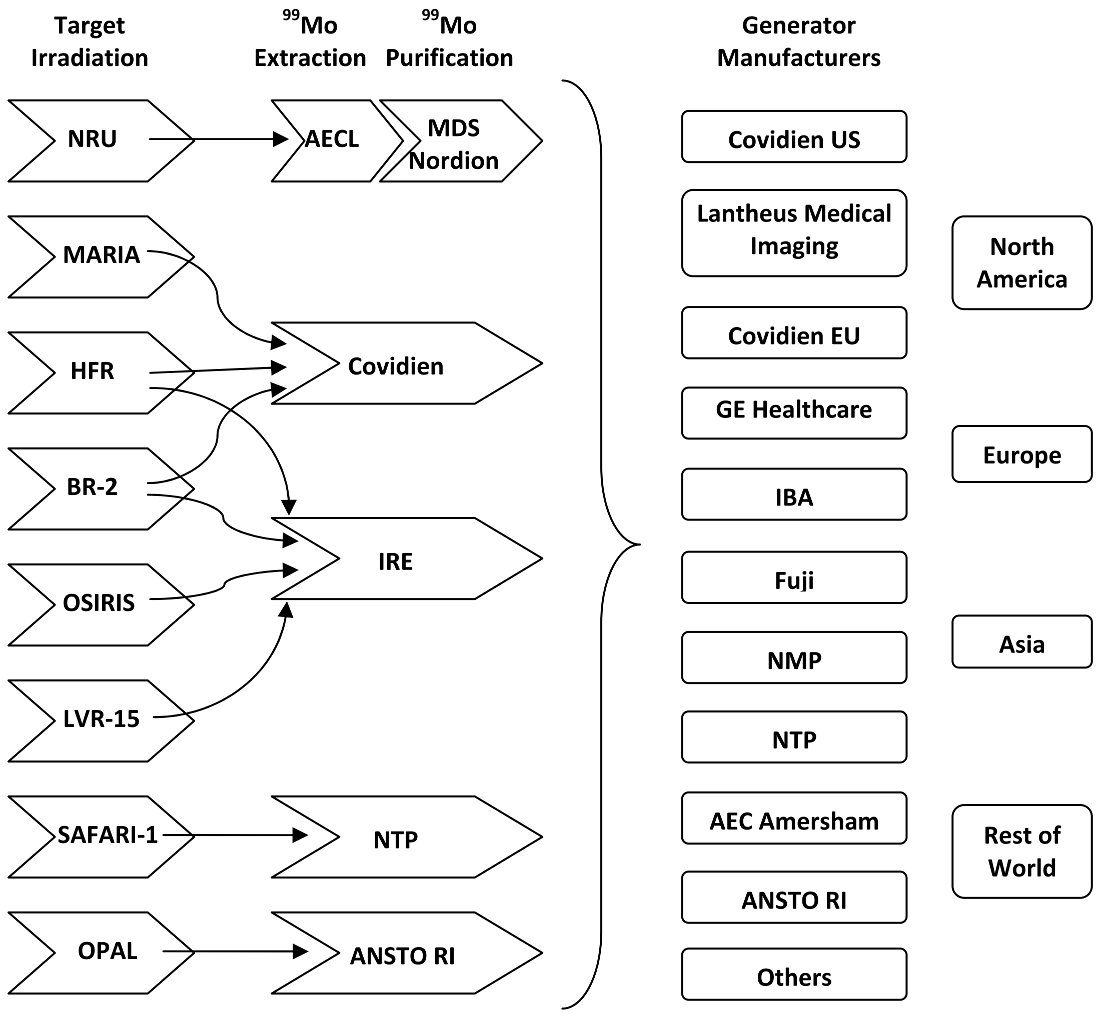
At the generator manufacturer stage, the manufacturers take the bulk ^{99}Mo and place it into a ^{99m}Tc generator. This generator is shipped to radiopharmacies or directly to hospitals, where the extraction of ^{99m}Tc for the use in nuclear medical imaging procedures occurs. Generator manufacturers also produce "cold kits" for use with the ^{99m}Tc generators. These kits contain non-radioactive (and hence "cold") solutions or powders that the radiopharmacist mixes with the ^{99m}Tc for the preparation of the patient dose for the procedure. Each cold kit is specially designed to focus on one type of scan (e.g. heart, bone, etc.).

The major generator manufacturers are: in Europe, Covidien, GE Healthcare and IBA Cis Bio; in North America, Covidien and Lantheus Medical Imaging; and in Japan, FUJI and NMP. There are a number of other generator manufacturers that serve their domestic markets and possibly surrounding areas. As with the processors, much of the generator manufacturing was started by governments. However, today the major generator manufacturers are all commercial enterprises without government ownership or interest. Many (but not all) of the smaller manufacturers are still government agencies. This smaller segment of the market is not the focus of this economic study. Figure 2.3 provides an overview of the full supply chain, including the generator manufacturers.

Historically, many of the manufacturers had a commercial relationship with one processor. However, during the current shortage situation, many have started to develop commercial relationships with other bulk ^{99}Mo suppliers to reduce supply risk. For example, Lantheus has announced that it is diversifying is sources of bulk ^{99}Mo (Lantheus, 2009). This recent direction to multi-sourcing is positively affecting the economics of the market supply chain and will be discussed later in the report.

This supply chain is becoming much more complicated as generator manufacturers are diversifying their sources of bulk ^{99}Mo and therefore most processors are supplying many generator manufacturers. The "others" box in Figure 2.3 is to indicated that most of the producers sell bulk ^{99}Mo to other smaller generator manufacturers that supply their local markets (such as in Brazil, China, Israel, Poland, Turkey, etc.).

Figure 2.3: ^{99}Mo supply chain participants and distribution channels



Challenges

As with the processors, the generator manufacturers add significant value to the supply chain through the logistical organisation of the supply of generators to radiopharmacies and hospitals around the world. The loss of ^{99}Mo can still occur if the decay product, ^{99m}Tc, is wasted by not being eluted from the generator on an optimal basis (since ^{99m}Tc has a half-life of six hours). If the logistics are not effectively operated, the economic consequences of the loss of product can be important.

The major challenges affecting the economic sustainability of the generator manufactures at this time is the changes in reimbursement rate structures for SPECT procedures, which affects the buying capacity of the generator manufacturers' clients. In addition, the development of generic options for the previously patent protected cold kits could reduce the revenue received from those products by generator manufacturers. Both of these challenges affect the profitability of generator manufacturers and will be discussed further in Chapter 3, with a more fulsome discussion on the product pricing model historically used in this sector.

2.5 Radiopharmacy/hospital component of the supply chain

The Radiopharmacist elutes ^{99m}Tc from the generator and prepares the patient dose using the cold kit. Once prepared, they send the dose to the hospital (if it is a centralised radiopharmacy) or to the nuclear medicine department (if prepared in the hospital).

Challenges

As with the further upstream components of the supply chain, the radiopharmacy component adds important value to the supply chain. Once the radiopharmaceutical is prepared it must be delivered for the patient procedure within the specified time for which the dose is prepared to ensure the appropriate quantity of ^{99m}Tc (which has a half-life of only six hours).

Again, as with the generator component of the supply chain, the major challenge affecting the radiopharmacy component is the changes in reimbursement rate structures for SPECT procedures, which affect the ability and willingness of hospitals to cover increasing costs of radiopharmaceuticals. These changes may result in clinics substituting other diagnostic techniques for the SPECT procedures.

2.6 Conclusions

As is clear from this chapter, the supply chain for the production and delivery of ^{99}Mo and ^{99m}Tc is complex and faces a number of significant challenges – both on a daily basis and looming in the future. Time is a significant challenge for this supply chain and the logistics have to be very well managed at all stages to minimise the amount of decay of the product. The full supply chain contains a variety of market structures and issues that affect current and future economic sustainability. These issues will be discussed in the following chapters.

Chapter 3

IMPACTS OF HISTORICAL MARKET DEVELOPMENT ON CURRENT ECONOMIC SUSTAINABILITY

3.1 Introduction

The previous chapter presented the supply chain and the historical foundations upon which the current market rests. As alluded to, these foundations have had, and continue to have, a significant impact on the current market structure, its economics and the ability to adjust the market to ensure economic sustainability.

This chapter will discuss the impact of the historical development on the current economics. The discussion will set the stage for Chapters 4 and 5 that will discuss the current economic situation in more detail and the changes that need to be made to the current economic structure to ensure a more sustainable economic footing.

3.2 Product development as a by-product

In the 1950s and 1960s governments developed research reactors for a variety of research related purposes. It was not until the later part of the 1970s that the production of ^{99}Mo from these reactors was more fully developed (and for some other reactors, later than that). At that time, ^{99}Mo production was not a principal driving factor of the reactor's operations; rather, it was considered a by-product of the reactors' other activities.

Reactor operators and decision makers saw the production of ^{99}Mo as another mission for the reactor and a way to bring in extra revenue for the reactor to support research projects and the reactors' operations. This was partly as a result of changing demand for research reactor services, where the 1980s and 1990s saw a decrease in interest for these services. This decline was the result of a reduced interest in nuclear energy by governments during these decades and a related decline in government funding levels to research reactors.

In terms of remuneration for the production of ^{99}Mo, interviewees indicated that reactor operators only originally required reimbursement of *direct* short-run marginal costs.[1] The reason for this form of pricing comes from the timing of the product development, the "status" as a by-product and the related incomplete accounting of the costs of expanded production.

1. A marginal cost is an incremental cost incurred as a result of an action. It does not imply that a cost is small or "marginal" in a quantity sense; in many cases, marginal costs can be quite significant.

In regards to the first issue, by the time ^{99}Mo production started to be undertaken by the major reactors, the reactor assets had been either almost or completely written off, or the capital fully justified for other purposes. This meant that there was no share of any spent capital costs included in the price of the ^{99}Mo; the prevailing attitude being that since the infrastructure existed there was no need to include it in prices. This is referred to in economic theory as "sunk costs". However, there was also no inclusion in the traditional pricing model of infrastructure replacement costs, which are future costs related to necessary refurbishment or replacement of capital and are relevant for pricing decisions.

A sunk cost is an expense that has already been incurred and cannot be recuperated. Therefore, it has no economic opportunity cost and should not impact production and pricing decisions.

Box 1: Marginal cost pricing

In economics, the marginal cost is an important concept for determining production and pricing decisions. Marginal costs are defined as the costs of increasing production by one additional unit or the costs saved by reducing production by one unit. Production decisions are based on the interaction of marginal costs and marginal revenues from producing an additional unit, with profit-maximising behaviour resulting in production occurring at the point where marginal revenue equals marginal costs, which would also be the price in the market under competitive market conditions.

However, for production that requires large capital investment, such as in the case of ^{99}Mo, long-run costs are the most relevant in order to minimise short-run instability in prices and capacity (Marsden, 2004). In the long-run time period, all input costs can be changed and therefore the relevant cost is the average cost with full cost recovery. Where average cost recovery is not realised, the financial sustainability of the industry is threatened; where pricing levels are less than long-run average costs there will be a need for a subsidy if the desire is to continue to operate (Majumdar, 1990).

To determine the average cost, all the relevant costs have to be known and included in the calculations. This means that the producer has to have a proper definition of its production function, which defines the quantity to be produced based on the input factors labour (l), capital (k), and other raw inputs (m), such that the production function is $f(q) = f(l,k,m)$.

Where the production function does not include the full input costs of capital [thus the production function $f(q) = f(l,m)$] the cost function will be underestimated and an inappropriate production decision and pricing structure will be established. In this case, average cost recovery will not be realised since the average costs will be undervalued.

In the case of ^{99}Mo production, the full cost impact was not well understood or communicated and the production function did not fully encompass all the relevant inputs. As a result, the prices set for irradiation services were too low to remunerate the costs actually incurred.

For the second issue, as a by-product there was no perception that ^{99}Mo should cover additional costs beyond direct marginal costs. Its initial small share of overall reactor operations meant that most of the reactors' variable costs were not considered to be impacted by the ^{99}Mo production; staff was already on site, electricity was already being used, fuel for the reactor was already being used, waste was already being dealt with and maintenance and other "overhead" costs were not attributed to ^{99}Mo production. Given this perception, these broader marginal costs were not included in pricing considerations.

As the production of ^{99}Mo increased and it became less a by-product and more an important component of the reactor operations, reactor operators (and the full market supply chain) did not re-evaluate this by-product status and its impact on pricing. During the early years, there was not a reflection on whether these broader marginal costs should be considered as input costs in the pricing of the ^{99}Mo given the increased production, even though the increase pointed to a need to attribute at least a portion of these costs to ^{99}Mo production. In some cases, the full marginal costs are still not considered as input costs for ^{99}Mo production when new pricing decisions are made.

Another impact of the increase in ^{99}Mo production and the lack of inclusion of full marginal costs has been on the amount of time that reactors are available for production. Many reactors have the potential to increase their operational days within the year but currently there is not sufficient financial justification to do so. The demand from research projects is not always there to add additional cycles. Although there is interest by the nuclear medicine industry in operating additional cycles, the traditional pricing structure does not provide for sufficient funds to economically justify operating the reactor specifically for ^{99}Mo production.

A complicating factor in attributing costs to ^{99}Mo production is that it is inherently difficult to determine the cost divisions between various activities in a multipurpose reactor. How much of the fuel and the associate waste is linked to ^{99}Mo production? How much of the staffing time? How much of the refurbishment costs? Many reactor operators are currently determining attribution based on an estimate of the share of total operational effort/attention required to produce the ^{99}Mo (e.g. staff time, priority in reactor operation).

As a result of the above factors, historical pricing of reactor irradiation services reportedly included very limited direct marginal costs and did not include replacement costs and full direct and indirect marginal costs. The non-inclusion of these costs has resulted in prices for target irradiation that are too low to sustainably support reactor ^{99}Mo operations. Without the inclusion of these costs, there is not sufficient revenue provided to the reactor to fully pay for the irradiation of targets or enough incentive to invest the capital for new production infrastructure, address regional imbalances, and support the reserve capacity necessary for a reliable supply chain.

3.3 Commercialisation of processing

Another historical event in the supply chain that has pivotally impacted the current supply chain economics is the commercialisation of the major processors. As noted in Chapter 2, governments were originally the principal agents throughout the full supply chain. However, efforts were undertaken to commercialise the processing component of the supply chain. In some cases, the choice was to completely privatise the processing by selling the government operation to a private company; in others, the processing component was hived off from the reactor organisation but the government remained the principal shareholder.

Interviewees indicated that during the commercialisation process governments based commercial contracts on historical pricing structures and on their interest in developing the nuclear medicine sector, as they recognised the significant health benefits of nuclear medicine. This resulted in the development of long-term contracts with favourable terms for the commercial processing firm. At the time of commercialisation, the reactors often felt that it was a win-win situation; they would have a confirmed customer bringing in revenue to the reactor and the commercial firm would take care of the commercial side of the ^{99}Mo production.

However, the reactor operators did not receive the benefits expected from the commercialisation process. The contracts with the commercialised firms were based on the historical perception of costs, with the result that the separation of activities did not lead to a substantive change to the commercial prices for the irradiation part of the supply chain.

These contracts, once developed, set the standard for the industry. When a new processor entered the market, it was offered a similar contract by the reactors. The reason for this treatment was to ensure a fair and transparent treatment of all market players. Given that the reactor was a government funded operation, there was a desire (and in some cases an obligation) to avoid unfair competition practices and the favouritism of one firm over another. As already explained, this pricing structure did not provide for the economic sustainability of the reactor operations.

The contracts of some processors also allowed for the *potential* inefficient production of ^{99}Mo, greatly affecting the return to the reactor. One form of commercialisation contract was based on a revenue-sharing arrangement, where the reactor received a share of the revenue earned on the sold bulk ^{99}Mo, irrespective of the reactor services and costs. Although there is a relationship between the reactor services and the final bulk ^{99}Mo sold, it is not necessarily a linear or consistent relationship and the differences can be substantial.

It was reported that within this commercial contract the processor was able to request that the reactor continue to provide irradiated targets during reactor shutdown periods. In this situation, the processor was able to provide a smooth supply to its customers even when the reactor was not operating. In practice it meant that the irradiated targets were supplying a reduced amount of ^{99}Mo since the ^{99}Mo was decaying while the irradiated targets were sitting idle. For example, in a situation where the irradiated target sat for five days, the extraction process would yield only about 28% of the ^{99}Mo that would have been extracted without the delay. This type of behaviour results in overproduction and an increase in related radioactive waste management requirements.

This behaviour is considered only *potentially* inefficient given the pricing structure that was established. The reactor received remuneration based only on the revenue of the final product. Thus, on a per curie basis the reactor's cost of production was more than three times higher for this ^{99}Mo since costs for the reactor were the same, including for the waste produced, but the amount of final curies produced and sold was less than one-third of normal quantities. If the contract rewarded the reactor operator based on irradiation services, the pricing structure would have indicated whether the value of supply smoothing was sufficient to pay for decay and related waste. If the processor continued to request this irradiation under a situation of proper remuneration, it would indicate that this was an economically efficient action. Without proper remuneration we can only speculate as to whether such an action is economically efficient within the supply chain.

Another effect of the commercialisation process and its contracts was the establishment of a situation of market power for processors. The contracts, in some cases, provided for an exclusive relationship between the reactor and the processor. As a result, the reactor had only one avenue for selling its ^{99}Mo related irradiation services. In addition, until the late 1990s there were only two major processors supplying the global ^{99}Mo market, creating an oligopsony in some markets and a monopsony in others. Some markets had the two processors purchasing irradiation services for that market while other regions only had one processor purchasing the services.

An oligopsony is defined as a market dominated by a few buyers. A monopsony is a market dominated by one buyer. These situations create market power on the part of the buyer, resulting in prices lower than would be seen with competitive markets.

According to interviewees, this buyer market power had the effect of contributing to the establishment of low prices for irradiation services and the perpetuation of these low prices. In general, there are two factors which influence the price offered to producers by a firm: competition from rival purchasing firms and the price-elasticity of the total input product supply (Mérel, 2009). In a monopsonist situation, the first factor is not relevant with the only consideration being the sensitivity of the supply of the input product to the price.

For the ^{99}Mo supply chain, the irradiation services are the input product. As a result, in the monopsonist situation the question becomes whether the supply of irradiation services has been historically sensitive to the price offered. As mentioned in Chapter 2, in the past there was a reserve capacity of irradiation services, which can be considered an overcapacity if not properly valued. This overcapacity coupled with an incomplete accounting for costs on the part of suppliers meant that the suppliers of irradiation services were not able to be sensitive to price changes; they would supply irradiation services even if prices were low. As a result of these factors, the purchasers could offer low prices for the irradiation services. In fact, it was reported by interviewees that when reactors tried to increase prices for their ^{99}Mo irradiation services, their customers indicated that they would obtain these services from other reactors instead.

As a result, the end effect of the reported buyer market power on the ^{99}Mo supply chain was an undervaluation of irradiation services and a perpetuation of this undervaluation when compared to what would have been expected under more competitive markets. Given the market power, there were downward pricing pressures that maintained the low market prices.

In reality, the fact that there were few buyers for ^{99}Mo irradiation services does not necessary indicated that an oligopsony existed if there had been many other users for irradiation services in general. However, as noted above, the demand for irradiation services from research reactors was on the decline in the 1980s and 1990s. This reinforced the potential market power of the ^{99}Mo irradiation service buyers.

Overall, the commercialisation process resulted in a market structure at the reactor level of the supply chain that did not historically provide for the economic sustainability of ^{99}Mo irradiation services. This was because of the industry being established by a series of contracts more favourable for the processors and that, coupled with the need for reserve reactor capacity, created buyer market power. In cases where the market structure is vertically integrated between the reactor operator and processor, the reactor-processor contract (or agreement) did not have any direct negative effects on the operation of the reactor since in general there was revenue *and expense* sharing and not a direct pricing structure.

3.4 Barriers to entry

Although the contracts established during commercialisation did not have any direct effects on the reactor-processing pricing structure for upstream vertically integrated players, it did have an impact on the pricing structure at the processing level through the creation of barriers to entry.

As noted above, in the 1990s there were only two processors for the world market.[2] This in turn meant that there were only two sellers of bulk ^{99}Mo for the world market, creating a situation of seller market power from the processing stage. This monopolistic/oligopolistic market power has had a significant impact on the current market as a result of the apparent ability to create barriers to entry. These actions, as will be explained below, have had the effect of perpetuating the effects of the low prices described in the previous section.

2. There were other processors of ^{99}Mo for domestic markets, but these were not supplying the world market and therefore did not affect the larger supply chain.

The ^{99}Mo processing process has some natural barriers that create significant hurdles to new entry; it is a complicated and radioactive waste-producing process and it is very capital intensive. However, there were also some other hurdles that were even more significant based upon the apparent market power that was exerted.

First a few words on the natural barriers. As noted in Chapter 2, the processing process is complicated, requiring the separation and purification of ^{99}Mo from the irradiated uranium targets. This process results in significant amounts of radioactive liquid waste that needs to be properly managed. Very few organisations have the combination of knowledge and access to facilities to manage the waste produced to actually undertake this process – naturally creating a barrier to entry.

The fact that processing requires significant upfront capital (again, as noted in Chapter 2) creates another barrier to entry for potential entrants. A processing facility to serve a large market can cost greater than EUR 100 million. When looking at the potential return from ^{99}Mo, these high capital costs can serve as a significant barrier to entry.

There were some additional organisations that were interested in processing ^{99}Mo in the 1990s that had knowledge, the access to waste management facilities and access to existing processing facilities that could be used to produce ^{99}Mo. These organisations, however, reported that they faced additional barriers to entry that kept them out of the industry for a number of years.

Given the fact that the ^{99}Mo processing process is very capital intensive, the incumbent firms,[3] revenues are increased through expanding market share. As more units are produced and sold, there is a larger revenue base from which the fixed costs can be recovered – meaning that average fixed costs becomes smaller as more units are produced. This *reportedly* provided an incentive for the incumbent firms to undertake activities that would prevent entry, which would be classified as limit pricing in economic theory.

Under limit pricing, the incumbent firm would take actions that would make entry unprofitable for a potential new firm. Such actions as lowering prices, creating a situation of high switching costs or investing in capital that could lower production costs could make a new entrant decide to not enter the market. The primary strategy is for the incumbent to set low prices to generate high volumes of sales and a large experience base with their product, thus a new entrant would have to face the incumbent on the low price and on the costs to the customer of switching products (Hall, 2008).

In practice, it is difficult to actually determine whether limit pricing was undertaken, as the defining feature is that the actions undertaken would not have been done except to prevent entry. In addition, a firm undertaking limit pricing is not necessarily doing anything illegal. For example, building capacity to reduce prices and ensuring market expansion are perfectly legal ways to create limit pricing. What is relevant for this economic study is to reflect on what was seen to have occurred in the market and understand the impacts of these actions on the current supply chain economic situation.

The activities that occurred during the 1990s in the market provided many examples of apparent barriers to entry to the market, having effects that would be expected under a situation of limit pricing. Market entrants interviewed for this study reported significant barriers, especially related to contract price setting and "price wars" where aggressive pricing strategies were used with the effect of keeping

3. An incumbent firm is a firm that already exists in the market; in this case it is the ^{99}Mo processing firms that were already in the supply chain.

potential entrants out of the market. There were also capital investments that could be an example of sending a credible threat of the future ability to lower prices further.

One example was the use of exclusive contracts for the provision of bulk ^{99}Mo where customers were required to sign a long-term contract with one supplier if they wanted to have access to the product at the prices being offered by that supplier. The exclusive contracts exhibited the characteristics of setting prices that reduced the future profit potential for new entrants and created significant switching costs that a potential customer would have to absorb to go with a new entrant. What is relevant in the context of this economic study is that this strategy perpetuated the situation of few buyers for irradiation services – the monopsony power discussed in the previous section.

The pricing structure that was discussed in that section pointed to a situation where the market power, less than ideal contracts and an improper recognition of costs created a situation of prices that were unsustainably low at the reactor-processor transaction. This pricing structure and the revenue-sharing agreement that was established with the major processor allowed for possible price limiting behaviour. The reactor had no influence in bulk ^{99}Mo price setting and the processor was not faced with the actual costs of irradiation – paying the reactor based on revenue from units sold, not based on costs. This structure could thus eliminate the input costs of the irradiation services from the pricing decision of the processor, providing greater flexibility to lower prices. When a new processor tried to enter the market they observed ^{99}Mo prices dropping to a point where they could not compete and they had to walk away from potential clients.

Not only was the potential entrant faced with falling prices, they also had to contend with the situation of significant switching costs that the potential customer faced if they wanted to use their product. For the safety of patients there are regulatory safeguards that required health authority approval for specific sources of the bulk ^{99}Mo. As a result, if a customer wanted to change sources they would have to, in conjunction with the new entrant, seek approval from the health authorities to use the new source. This process is definitely manageable but does create additional expenses, effort and time delays related to using a new entrant's product.

As mentioned above, investment in capital that would have the potential to reduce future costs can be used as a form of limit pricing as it provides a credible threat that the incumbent could lower prices and affect the future profits of new entrants. In the 1990s there was significant investment undertaken on the MAPLES project that, along with the related processing facility, would have been able to produce enough ^{99}Mo to supply greater than 100% of the world market with equal redundant capacity. Again, this may not have been a limit pricing action as the strategy could entirely have been related to security of supply. However, it did have the effect of convincing potential new reactor and processing entrants that they would not be able to compete profitably and thus they did not enter the market. New entrants included a network of accelerators and some national laboratories in the United States.

This situation of market power has started to change, which will be discussed more in Chapter 5, but its effects on the current economic structure are important to understand as they still have an impact. The market power that existed and the related barriers to entry resulted in lower prices at the bulk ^{99}Mo stage than were necessary for new entrants and created a situation of limiting buyers of irradiation services. This maintained the oligopsony power that was discussed in the previous chapter, limiting what reactors could demand from processors and perpetuating the economic unsustainability of the upstream supply chain.

3.5 Generator pricing

The study has described how prices were unsustainably low at the irradiation stage of the supply chain and how the situation in the processing stage perpetuated these low prices. These low prices were also perpetuated through the pricing mechanism used for ^{99}Mo generators.

Generator manufacturers reportedly used loss-leader and low-margin selling models for ^{99}Mo generators. Interviewees indicated that the ^{99m}Tc generators were priced close to cost or even potentially below cost in order to encourage sales of the generator manufacturer's cold kits. The profits earned by the companies were made on the cold kits and not on the generators.

These cold kits were profitable to the generator manufacturer partly because they were patent protected. This patent protection allowed generator manufacturers to set a price for their cold kits that would provide them some return for the upfront research and development costs; according to interviewees, it also allowed them to obtain economic returns on the combined product of the ^{99}Mo and the cold kits, without having to increase the value of the ^{99}Mo. Although, as one interviewee pointed out, the cold kit is worthless without the ^{99}Mo, the market power created by the patent protection allowed the cold kit to be more valuable than the ^{99}Mo.

The undervaluation had a feedback effect on upstream prices. Since the generator manufacturers captured the economic value of the ^{99}Mo through their combined sales with cold kits, the profits they made did not flow back up through ^{99}Mo supply chain. Generator manufacturers were able to indicate that they were limited in their ability to pay increased prices for their bulk ^{99}Mo since they were not charging economic prices for the ^{99}Mo part of the product. This ability was further limited as the patent protection for various cold kits expired and generic cold kits entered the market, resulting in erosion of the generator manufacturers' overall profit margins. These impacts again perpetuated the low prices that reactor operators were seeing for their irradiation services.

3.6 Reimbursement rates

The final component of the supply chain is the preparation and provision of the patient dose from the radiopharmacy or hospital nuclear medicine clinic to the hospital for the patient procedure, which is then reimbursed by either the patient or a government or private health insurance. The historical market and pricing structure have also had significant impacts on this component of the supply chain; upstream actions impacted the pricing at this component, which then has had a feedback loop to maintaining this unsustainable pricing system upstream, as will be described below.

^{99}Mo prices were artificially low from the reactor and pricing strategies at the processor and generator manufacturer components maintained the downward pressure on prices. This had the effect of reimbursement rates for ^{99m}Tc medical procedures being set low as the isotope input costs were low and sometimes decreasing. This effect is continuing today with decreasing reimbursement rates for ^{99m}Tc nuclear medicine procedures (in the United States for example). Decreases have been seen while at the same time reimbursement rates for alternative imaging procedures using PET scans have actually increased in some cases (Positron, 2009).

These decreases in reimbursement rates are based on insurance organisations (private and public) attempting to reduce their expenses. There are a number of factors that play a role in reducing reimbursement rates, such as pressures on health care system funding or policy initiatives to reduce physician self-referral. The low price of ^{99m}Tc compared to other imaging isotopes is one contributing factor for these organisations to look at lowering reimbursement rates for SPECT procedures.

This has had the feedback effect of again maintaining low prices in the upstream supply chain. As reimbursement rates fall, some hospitals reportedly negotiate lower rates for the ^{99m}Tc (especially in situations where hospital co-operatives are able to exhibit purchasing market power). Interviewees reported that the level of reimbursement rates has been a limiting factor in the ability of the supply chain further upstream to increase prices. However, a contrary viewpoint also came out in the interviews that medical nuclear imaging is essential and the medical field would not be able to cope without ^{99m}Tc, therefore price increases, depending on the level of increase, could be absorbed by the medical community if implemented. Raising reimbursement rates to deal with rising ^{99m}Tc costs is not straightforward, with such changes often requiring a number of years to obtain approval.

3.7 Social contract

The question that obviously arises at this point is: *If the supply chain pricing structure was such that the irradiation services were unable to be offered on an economically sustainable basis, why did reactors continue to irradiate targets?*

The answer to this question is related to the social contract that governments had established with the medical imaging community. A social contract is often considered to be an agreement between a government and its citizens, whereby the citizens pay taxes or give up some rights in exchange for the provision of basic services by the government (e.g. security, rule of law). More generally, a social contract could be considered an informal agreement that holds people together in a common purpose. Social contracts can be either formally laid out, such as in constitutions or organisational rules or can be informally "agreed upon" through the actions taken by all parties, where the repeated actions of the parties establish a role for the parties that both accept and reinforce through continued action. In terms of permanence, a social contract is meant to be for the benefit of all parties and is only really considered legitimate while it continues to meet the general interest of those parties; where it no longer does so it can be changed.

The historical production of irradiated targets to produce ^{99}Mo for use in nuclear medicine diagnostic techniques pointed to a social contract (either explicit or implicit) whereby governments would subsidise its production through the development of research reactors and related infrastructure. Further, as demonstrated through the contracts established during the commercialisation of processors, governments were willing to provide favourable terms to processors based on this social contract.

In the early years, this social contract was logical given the required research and development that was needed to start and develop the nuclear medicine industry. In addition, nuclear development was often the legal domain of the government with limits to private involvement. In fact, without government involvement in the early years of the industry, there may not be the production of ^{99m}Tc today.

As a result, reactor operators continued to produce ^{99}Mo even with the unfavourable economic situation because of the social contract that they would do so and the fact that they had long-term contracts with processors. The social contract implied as well that reactor operators would be responsible for the related nuclear waste from the fuel used and in some cases from the processing of the ^{99}Mo. The advantage to the citizen in this contract was the access to an important medical imaging technique.

Although reactor operators were aware that government financial support for the reactor operations was increasingly used for ^{99}Mo production, this change may not have been transparent to governments. In some cases, the magnitude of the change did not become evident until there were requests to refurbish a reactor or construct a new reactor. This subsidisation was also supporting the production of ^{99}Mo that was exported to other countries. As a result, the citizen was being taxed to not only subsidise their own health care system but the health care system of other countries.

There was also a social contract between the sponsoring government and the research reactor, supporting the uneconomical production of ^{99}Mo. Under this contract, the government provided overall funding to the reactor for its operations to support scientific research projects and educational outcomes. If the reactor operators earned any revenue on the side, they were allowed to keep that revenue without any direct change in government support. As a result, a reactor operator mainly saw this revenue as additional funding and operational or capital cost recovery was not necessary. This social contract allowed for reactor operators to offer irradiation services at very low costs without needing to cover full costs. As the government became aware that these additional sources of revenue were, in some cases, becoming the principal focus of the reactor and that the costs were significant, they started to question this arrangement. In some cases, though, this social contract is still very active and setting the conditions around irradiation services.

As a result of increased awareness and mounting costs, some states started to question their social contract with the medical community and reactor operators, asking whether they wanted to continue with that model. There was the question of whether these social contracts were still in the general interest of its citizens. This process is quite similar to the questions raised around the changing social contract that led to restructuring efforts in the electricity supply industry.

However, the involvement of governments through these historical social contracts has had an impact on the current economic system. Although some governments want to rewrite the social contract (more on this in the next chapter) some market players expect that governments will come forward to invest in the required capital for continued and reliable supply of ^{99}Mo. This has resulted in reluctance on the part of the private industry to invest in capital for the upstream component of the supply chain.

3.8 Overall impacts on the current economic system

The overall impact of the historical market development on the current situation is that there is currently not enough reliable reactor capacity and there are constraints on processing capacity. This has been caused by a market structure that developed around an unsustainable economic model that did not remunerate reactor operators and processors sufficiently well to provide incentives to invest in new infrastructure. Government interest in funding research reactors in the 1980s and 1990s for other purposes was on a decline, further reducing the potential for new infrastructure investment.

During the same time period, a few research reactors that were producing ^{99}Mo went off line while there was growth in the ^{99m}Tc market. In the 1990s the demand for ^{99}Mo was around 6 000 six-day curies per week, which grew to approximately 12 000 six-day curies per week in 2007 (AIPES, 2008 and Vanderhofstadt, 2009). There were obvious reasons for this growth in the use of ^{99}Mo and ^{99m}Tc, including better image quality, lower radiation doses and faster patient throughput compared to other imaging techniques. There was however, the added benefit that ^{99m}Tc was extremely affordable given the pricing structure that had been developed.

There was some interest in developing new infrastructure to ensure reliable supply in the face of growing demand and the shutdown of reactors. This interest was based on a continuation of the social contract. These projects were put on hold however with the advent of the MAPLES project and its expected significant production at low cost. However, in 2008 the Government of Canada announced that it would no longer support the development of the MAPLES project, accepting the decision of Atomic Energy of Canada Limited (AECL) to terminate the project based on a number of factors, including technical malfunctions that "could not be resolved", regulatory challenges, commercial disputes and reviews by the Government's Auditor General that revealed concerns about the costs, delays and technical issues (Government of Canada, 2008). This termination left the market without the required infrastructure and the economic structure did not provide the incentive to develop additional infrastructure for ^{99}Mo production.

The historical development of the industry has had a significant impact on the current economic structure. The combined effects of: a lack of understanding of all the relevant costs related to ^{99}Mo irradiation and production, especially with growth in the industry; the favourable commercialisation of the processing sector, and the impacts that had on market power, the pricing structure and reserve capacity; the pricing model of generator sales and reimbursement rates; and the existence of a social contract that is changing, have resulted in a supply chain that is not economically sustainable. As one interviewee put it, the industry is responsible for it not making any money and has jeopardised its own business survival.

This lack of economic sustainability and the related lack of new investment have resulted in a system that has had reliability concerns over the last decade. The shortage seen in 2009 and 2010 is a **symptom** of this economic problem. Once the short-term supply becomes stable again, it is important to stress that although the symptom has been addressed, the underlying problem – the unsustainable economic structure – has not.

Chapter 4

CURRENT ECONOMIC SITUATION OF THE SUPPLY CHAIN

4.1 Introduction and methodology[1]

The previous chapters have provided a comprehensive look at the historical development of the ^{99}Mo supply chain, pricing structure and market, as well as how this development has affected the current economic situation. Repeatedly in these chapters there has been the assertion that these effects have resulted in a situation where the incentives are not sufficient to justify the production of ^{99}Mo, nor to develop new ^{99}Mo infrastructure, on economic criteria alone. This chapter will move beyond the discussion and clearly explain the current pricing structure and demonstrate that it is not sufficient.

The information presented in this chapter is developed from the data received during interviews with market participants at all stages of the supply chain. In order to respect commercial confidentiality, all information has been aggregated together and figures are presented as the median of the various data points.[2] Given that there are few players in the market, ranges will not be provided as they may reveal information that would not respect the confidential nature of the interviews; however, below there is a discussion on the data sets and the range of values provided.

In order to be able to compare the cost and pricing structure throughout the full supply chain, prices were normalised as EUR and USD per six-day curie EOP. The full normalisation conversion methodology is presented in Annex 2, including all the assumptions made, and is discussed briefly here.

Given the short half-life of ^{99}Mo and ^{99m}Tc, the assumed time required at each stage of the supply chain can have an impact on the normalisation of quantities and the final economic results as the decay of the product can significantly change final values. The supply chain process assumed for the calculation of the economic numbers is in line with what was described in Chapter 2. The time to finish the processing process was assumed to take 24 hours from the time that the irradiated targets left the reactor, with a 20% loss of product during the extraction and purification process, which is consistent with reported losses in the industry. The time to transport the bulk ^{99}Mo to the generator manufacturer, fabricate the generators and prepare the generators for transportation (thus, from the end of processing to when the generator leaves the manufacturing facility) is assumed to be 48 hours (two days from end of processing), with a normalisation from the date of calibration to six-day curies EOP.

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1. Section 4.1 presents an overview of the methodology and caveats around the current economic situation values, with a detailed methodology presented in Annex 2.

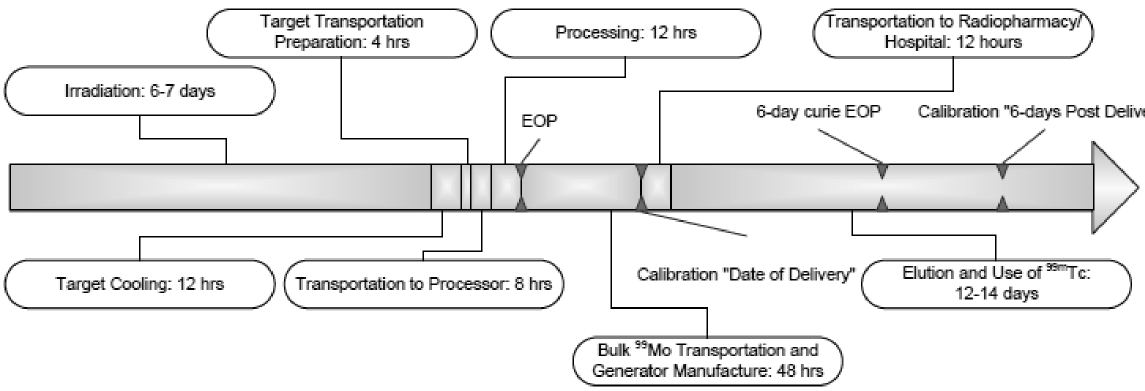
2. The median was chosen over using the mean since it was determined to be more reflective of the situation. With few data points (since there are few producers, processors and generator manufacturers) an outlier data point could significantly alter the mean, whereas the median is more representative of the central tendency of the sample set. In reality, the choice of the mean does not significantly alter the results in this study.

The normalisation for the radiopharmacy stage is much more complex as it requires a conversion from curies of ^{99m}Tc in the final delivered dose to a six-day curie EOP of ^{99}Mo. To undertake this conversion requires assumptions on the time of the first elution of the generator, the number of elutions per day from a generator and the time of those elutions, the amount of product not used (wasted) and the amount of ^{99m}Tc used in the final patient procedure. To attempt to accurately capture the various possibilities, median numbers were used for two "extreme" scenarios, with an assumption of elutions occurring three hours before the patient procedure:

- ^{99m}Tc eluted once per day from a generator calibrated noon Friday, first elution 6 a.m. Monday.
- ^{99m}Tc eluted three times per day from a generator calibrated noon Sunday, first elution 2 a.m. Monday.

From these scenarios, the amount of ^{99m}Tc was then converted to ^{99}Mo calibrated (i.e. the amount of ^{99}Mo reported to be in the generator) and then to ^{99}Mo six-day curie EOP. This process is explained in more detail in Annex 2. A visual representation of the times assumed for the normalisation process is provided in Figure 4.1.

Figure 4.1: Timeline assumed for normalisation process



It is important to be clear on what economic costs were included in the calculations. For the reactor and processing stages, the reported operating costs of the facilities divided by the amount of ^{99}Mo six-day curies produced were used to determine costs, while reported revenues divided by the amount of ^{99}Mo six-day curies produced were used to determine selling prices. It is important to note that no capital costs or refurbishment costs were included in the calculations as current pricing does not include these costs (this will be rectified in the next chapter which discusses economically sustainable pricing).

Generator unit prices were determined by the reported price of generators divided by calibrated quantity and normalised to six-day curies EOP. Costs for the fabrication and transportation of generators were not provided by industry participants and as a result no positive assertions were possible on the economic sustainability of the generator component of the supply chain.

Radiopharmacy selling prices were determined from either reported values or from calculations of the cost of generators divided by the potential ^{99m}Tc eluted, both normalised to six-day curies EOP.

It must be noted that the assumptions used in the methodology can have a very important effect on the prices calculated at every stage. For example, if there is an additional 12 hours added on to the assumed time of the processing stage, there will be an additional loss of about 12% of product, affecting the end value. Another example at the radiopharmacy stage: the amount of ^{99m}Tc obtained from a generator eluted three times a day with the first elution one day post calibration is three times that obtained from a generator eluted once a day with the first elution 66 hours post calibration (e.g. calibration at noon on Friday with first elution at 6 a.m. Monday).

A note on the numbers and data

Although the normalisation to six-day curies EOP and the determination of prices are complicated calculations and the assumptions used can greatly affect the final results, it is necessary to do these calculations to be able to compare the economics through the full supply chain. As a result of the potential impact of the assumptions on the final economics, the numbers presented in this chapter **should only be considered indicative of the current situation and not representative of any one individual supplier or region**.

It should be noted that the degree of confidence in the values provided for costs and prices is larger for the reactor and processing stages of the supply chain, with lower confidence in the downstream components. At the generator and radiopharmacy stage of the supply chain not all regions are currently represented by the data given a lack of available data. This paucity of information could have an impact on the final absolute values presented as the economic situation given that each country and region has different pricing regulations and insurance reimbursement rates related to radiopharmaceuticals. Additional information is expected but was not available at the time of publication; however, even with the current smaller data set, it is still considered, after discussions with supply chain participants, that the results discussed in this paper are relevant as indicative of the current economic situation and the conclusions derived are still valid.

In addition, the available data exhibits a much broader range of values for the downstream components. Using standard deviation as a measure of the degree of variability in the data, the data points for the current (pre-shortage) economic situation demonstrate greater confidence in the upstream components of the supply chain. The standard deviations of the data at the various points of the supply chain are provided in Table 4.1.

Table 4.1: Mean, median and standard deviation of reported costs and prices (EUR per six-day curie EOP)

	Mean	Median	Standard deviation
Reactor cost	85	65	43
Reactor selling price	40	45	18
Processor cost	170	150	157
Processor selling price	295	315	100
Generator selling price	405	375	220
Radiopharmacy selling price	2 390	1 810	2 101

One of the reasons for the large range at the radiopharmacy stage is the differences between values calculated for different elution patterns, with different patterns resulting in more than a tripling of ^{99m}Tc quantities eluted from a generator and a corresponding effect on calculated prices for ^{99}Mo (six day EOP).

Given the range of values for the data points, it is clear that **the values presented are only approximate and do not purport to represent the situation in every region or jurisdiction** as the values used in the study were derived from information provided by market players and aggregated together. The values are meant to provide an indication of cost and pricing levels.

It is important to point out that these uncertainties **do not affect the final conclusions** of this study. Even if the downstream components had a different value (reflecting the range of the data set), the magnitude of the impact would be unchanged. Importantly, final conclusions that will be discussed later in the study are robust.

4.2 Description of current situation

Recognising the caveats and the assumptions discussed above, Table 4.2 provides the selling prices for a six-day curie EOP at each of the stages in the supply chain before the supply shortage period of 2009-2010. The price increases at each stage of the supply chain do not necessarily indicate significant profits at the following stage. The increases are indicative of the other input costs at that level, such as labour and capital investments, as well as value-added in terms of making the ^{99}Mo usable for the patient procedure and delivering the product to the next supply stage.

It is reasonable to assume that there is a return on investment in those downstream levels, since the middle of the supply chain includes commercial players which require some return for shareholders. However, supply chain participants indicated that they were not making significant profits, if at all. An article in the New York Times supported this view, quoting Dr. Dale E. Klein, a member of the United States Nuclear Regulatory Commission, that a big pharmaceutical company "can make more on Viagra in two days that on tech-99m in a year". As noted above, this assertion could not be verified at all stages of the supply chain with the information provided.

At the reactor stage, however, sufficient information was provided to indicate that the marginal revenue received by reactors from production of each unit of ^{99}Mo was lower than the marginal costs. It should be reiterated that the current pricing does not include any significant value for capital maintenance or replacement. As a result, the costs presented here are less than what is required to be economically sustainable. From the information provided, the median reactor is facing a loss of EUR 26 per six-day curie EOP produced[3] (USD 36).

The prices presented in Table 4.2 are indicative of those seen before the supply shortage period of 2009-2010. During the shortage period, many market participants observed price increases, some of which were quite significant (upwards of 200% increases). These prices are not presented in this report as their longevity is not guaranteed and could be misleading as to the long-term economic sustainability of the supply chain.

3. This value is the median of the loss values from the reactor data, which is different from the EUR 20 that one would conclude if taking the difference between the median cost and price as presented in Table 4.1.

Table 4.2: Selling price of six-day curie EOP pre-shortage*

	Selling price EUR/six-day curie EOP	Selling price USD/six-day curie EOP**
Reactor	45	60
Processor	315	445
Generator	375	520
Radiopharmacy	1 810	2 525

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value seen in the market.

** An exchange rate of EUR 1 = USD 1.395, which is the average exchange rate for 2009 taken from www.ecb.int (European Central Bank). Exchange rates for other currencies are discussed in Annex 2.

Much of the price increases can be directly attributable to the shortage. With inconsistent supply, additional expenses were incurred across the supply chain by having staff work longer, irregular hours (when product was available) and by obtaining product from new suppliers with longer shipping distances, for example. These additional costs were passed on to customers where possible. Of course, some price increases are a result of market forces where prices rise when supply is below demand. These impacts would not be expected to remain once the short-term supply situation has returned to normal.

However, in some cases the recent price increases are more fundamentally based and are not directly related to the shortage. It would be expected that the impact of this type of price increase would remain even once short-run supply stabilises.

In some cases, the price increases during the current shortage at the generator and processor stages of the supply chain are an attempt to correct the economic pressures that have been facing the industry. Those supply chain participants that have had the ability to supply product during the shortage have been able to use that market position to increase their prices, providing the opportunity to make the price increases that they have wanted to do for a while.

Generator manufacturers were in the process of increasing prices to account for capital investments made and to recognise the value of the ^{99}Mo and the process of getting it to customers. In addition, there was a relaxing of market power at the processing stage in the past few years that allowed for addition players to come in the market, removing the limit pricing impacts. These changes will be discussed in more detail in Chapter 5.

However, these price increases have not yet been the result of increased prices from the reactor level. Although it has been reported that some reactors are in the process of increasing prices and are currently negotiating with their customers as to the degree of price increases (in the range of 20 to 200% increases), it is expected that these price increases would take effect over a period of a few years. Some reactors have indicated that they are still unable to increase prices at this time given the duration of contracts that have been established, but that they expect to negotiate increases when contracts come up for renewal. Also, in the market structure where the reactor and the processor are vertically integrated with some form of revenue-cost sharing agreement (c.f. Chapter 2) the price increases will be noted at the processor level and not necessarily at the reactor level. During interviews, it was consistently reported that the price increases being negotiated are not sufficient for the reactor-based production to become economically sustainable.

The last stage in the supply chain is at the hospital, where the ^{99m}Tc is used in patient procedures that are then reimbursed through health insurance plans. Table 4.3 provides the value of the ^{99}Mo/^{99m}Tc from each level of the supply chain at the final stage. The values do not include any other value that the supply chain stage may receive, such as through the sales of cold kits, but are only based on the supply of the ^{99}Mo/^{99m}Tc. These values were calculated based on the prices presented above and normalised to ^{99}Mo six-day curies EOP. As a result, it is important to remind the reader that these are indicative of the current situation as there could be a large range depending on the medical procedure (reimbursement rates and hospital costs can vary substantial between procedures).[4]

Table 4.3: Net revenue of each stage based on selling prices at the hospital level – pre-shortage*

	Revenue of ^{99}Mo/^{99m}Tc within the radiopharmaceutical price		Share of revenue of ^{99}Mo/^{99m}Tc in		
	EUR/dose	USD/dose	^{99m}Tc dose %	Radiopharmaceutical (^{99m}Tc and cold kit)[a] %	Reimbursement rate[b] %
Reactor	0.26	0.37	2.43	0.67	0.11
Processor	1.64	2.29	15.10	4.19	0.67
Generator	0.34	0.47	3.10	0.86	0.14
Radiopharmacy	8.62	12.02	79.37	22.03	3.51

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

a. The total does not equal 100% as the final radiopharmaceutical price also includes costs related to the overhead and value added at the radiopharmaceutical level.

b. The total does not equal 100% as the reimbursement rate also pays the hospital for its facilities, the doctors and nuclear clinicians, etc. used during the nuclear medicine diagnostic procedures.

The Table 4.3 first provides the net value of each stage of the supply chain as a proportion of the final ^{99m}Tc dose provided to the hospital for the patient procedure. For example, based on a median value of about EUR 11 (USD 15) for the ^{99m}Tc dose, the reactor gets about EUR 0.25, the processor about EUR 1.65, the generator about EUR 0.35, and the radiopharmacy about EUR 8.60 (about USD 0.35, 2.30, 0.50 and 12, respectively). The table then presents what percentage these net values represent of the final ^{99m}Tc dose price, the price of the total radiopharmaceutical (i.e. the price of the cold kit and ^{99m}Tc in the dose provided for the patient, calculated at about EUR 39/USD 55), and of the final reimbursement costs (median value of about EUR 245/USD 340).

The Table 4.3 indicates that the irradiation price from the reactor is less than one-fifth of 1% of the total reimbursement rate, representing only EUR 0.26 (USD 0.37). Again, this table should not be interpreted as implying that significant profits are being made at any of the downstream stages or by the hospital itself. There is no reason in principle that the reactor should get any more than 0.11% of the final reimbursement rate, provided that production was economically sustainable, but this is not the case. This table indicates the economics of the supply chain players and their respective shares in the final product prices; it is not derived to justify the proposal that the solution is simply to redistribute the value among the supply chain participants based on the pre-shortage prices.

4. Annex 2 provides more information on the derivation of the values for Table 4.3.

As noted earlier, all reactors are losing money on the production of ^{99}Mo. For these calculations, the only cost of production that was included was the portion of total operating costs that could be attributed to ^{99}Mo production. However, there are a number of additional costs that were not, but should be, included. The inclusion of these costs, such as capital maintenance and replacement capital would have increased the calculated losses in the current pricing structure for reactor operators.

On top of the exclusion of these costs, another issue that reduces revenues for the research reactor operators is that the nuclear industry tends not to be an industry with falling costs; costs tend to rise over time given increases in necessary regulatory requirements to ensure safety and security of nuclear reactor facilities. These regulations often require additional equipment or processes and the costs associated with fulfilling these requirements. As a result, over time it would be expected that the value of the losses would increase if the reactors are unable to increase prices. This issue is present in the full supply chain as improved safety regulations require additional expenses at each stage.

It is clear from these figures that there is not sufficient financial incentive for the development of new capital infrastructure for the development of ^{99}Mo or even for the maintenance of capital to ensure continued operation. This has resulted in a ^{99}Mo supply chain that relies on older reactors and new reactors are struggling to finance ^{99}Mo production capital.

4.3 Conversion to LEU

Another issue that needs to be examined in relation to the current economic situation of the supply chain is the necessary conversion to using LEU targets to produce ^{99}Mo. This study is predominately focused on costs for production using HEU targets as the major world players use these targets and their economics are based on that use. As a result, there is currently very little information available on the economic impacts of using LEU targets to produce a major quantity for the world market, either from current reactors and processors or for new reactors and processors.

The economic impacts are uncertain given that the technological impacts are currently uncertain. The main technical issue is the obvious fact that LEU targets contain less ^{235}U (less than 20%) compared to the HEU targets currently being used (from 45% to 98%). Since ^{99}Mo is a fission product of the ^{235}U in the targets irradiated in the reactor there is an impact on the yield of product from a target with less ^{235}U. Although there is uncertainty as to the actual decrease in yield, it is reasonable to state that there will need to be a factor increase in irradiation of targets of two to four to account for lower density of ^{235}U in the targets or that the density of the targets will have to significantly increase in order that there is more total uranium to account for the lower ^{235}U content.

The economic impacts are explicitly tied to yield, waste management and capital requirements. The potential lower yield per target can be overcome, at least partially, by increasing the density of the targets thereby "stuffing" more LEU in the target than HEU in the HEU targets. The industry is currently working to increase the density of the targets, including determining any possible changes required to the processing facility. The barrier to be overcome is that the use of LEU targets has been demonstrated for smaller scale production (i.e. at the OPAL, RA-3, and BATAN (Indonesia) reactors) but not yet for large scale production. Some industry participants have indicated this as a significant challenge, indicating that scaling up production is not a straightforward process and may require a reconfiguration of the current process; however, this view is not universally shared, with other participants being more positive on the possibility to scale up production.

If target uranium density cannot be increased to completely compensate for the lower ^{235}U content, there will be a need to increase the number of LEU targets irradiated to produce the same amount of ^{99}Mo. This increase would translate to an increase in reactor costs per six-day curie produced. It also could mean that there is a need for additional production capacity possibly requiring up to a factor four increase in capacity and related waste management facilities to continue producing the same quantity of ^{99}Mo globally.

In either case, the extraction processing may produce more waste volumes as more uranium will have to be processed to extract the ^{99}Mo. This could increase costs as the supply chain pays for the potential increased waste management process and infrastructure. Until final disposal strategies are implemented, it is difficult to quantify these potential cost increases.

However, reduced physical protection costs as a result of dealing with LEU instead of HEU may help to offset any potential cost increases of using LEU targets.

Governments have agreed that the conversion to using LEU targets should happen for security and non-proliferation reasons. In fact one major producer (NTP) expects to have converted their reactor and processing facilities to use LEU targets in 2010 (from targets of approximately 45% ^{235}U). This conversion was possible because sufficient hot cells are available to allow the conversion process without stopping production. The NTP experience should reveal interesting information on actual impacts on yields and costs from conversion of a major producer. There are also two reactors (the OPAL reactor in Australia and the RA-3 reactor in Argentina) that use LEU targets, predominately producing for their local markets.

However, at this time there is not yet an established body of knowledge as to the comparative yield, waste management costs, development costs, capital requirements and the related economic impacts. These uncertainties do not reduce the relevancy of the figures and the discussion presented in this study. The conclusion that the current pricing structure provides insufficient financial incentives can be seen easily to extend to LEU as the costs of ^{99}Mo production are generally expected to increase as the industry moves forward with LEU conversion, although the magnitude of any increase will depend upon the specifics of a particular situation.

4.4 Changing social contract

One of the main reasons why the economic sustainability of the reactor is an important factor to examine is because of the changing social contract regarding the provision of ^{99}Mo. As noted in the previous chapter, there was an historical social contract that governments would build research reactors and financially support their operation. This allowed for the continuation of an uneconomical ^{99}Mo supply chain, with the government subsidising the production and dealing with the waste management issues.

However, there are indications that this social contract has started to change. Governments across the world have indicated that they are no longer interested in subsidising the production of ^{99}Mo at the reactor level at historical levels (or at all). For example, the Government of Canada (who has traditionally provided financial support for the production of ^{99}Mo from the NRU reactor) has stated that it is not its intention to have the NRU produce isotopes beyond 2016, rather they are supporting efforts for "non-federal supply options" for the post-2016 period. In fact, the government has indicated that they are looking to:

> "transform the way Canada produces medical isotopes, and in particular Tc-99m, so that Canadian production is on a sound commercial footing without government support; is scaled to the needs of Canadians; it is sustainable in terms of

environmental impacts, health, safety and security; and Canada remains a global technological leader." (Government of Canada, 2010).

All other countries that are major global producers of ^{99}Mo have also provided some indication that they are no longer interested in maintaining the previous process, although in some cases it has been less formalised. For example, all the European reactors have indicated that their governments have provided direction to increase prices for irradiation services to reduce the amount that they are subsidising and increase the revenue from isotope production. In addition, the production of ^{99}Mo in South Africa must be done on a commercial basis; since the early 1990s a "very strong emphasis was placed on commercialisation… with a view to drastically reducing government funding and ultimately, the achievement of financial independence" (NTP, 2004).

This changing social contract is not only relevant for the current research reactors but also when looking at the development of possible new projects. There are currently a number of multipurpose research reactor projects being discussed in Europe to replace their ageing reactors, as well as efforts to encourage the development of production options in the United States. In most of these projects there has been an indication that ^{99}Mo production will have to be undertaken on an economically sustainable basis, including related to paying for an attributable portion of the capital investment.

In Europe, the Jules Horowitz Reactor (JHR) project is under construction at Cadarache, France and is expected to be operation by 2014; the PALLAS project is under discussion in the Netherlands to replace the HFR reactor in Petten and is currently planned to be operational by the second half of the decade; and the MYRRHA project is under discussion in Belgium to replace the BR-2 reactor and is currently planned to be operational by 2020.

In the case of the JHR project, the government dictated that 50% of the capital funding for the project must come from potential users of the reactor. In 2007, an international consortium of reactor vendors, utilities and public stakeholders was developed (Pere, *et al.*, 2010). Members of the consortium pay for a portion of the capital costs and in return receive Guaranteed Access Rights in proportion of the financial commitment. The user then pays an operation cost for using their access rights. The producers of medical radioisotopes are one of the potential users that are being approached to participate in the consortium and the French atomic energy agency, the CEA, has indicated that a partnership is necessary in order to proceed with developing capacity for production (Iracane, 2009). This funding model indicates that the social contract of full government funding for ^{99}Mo production capacity and operation has changed.

For the PALLAS project, there is a similar indication of the changing social contract. Public funding is expected to be used for the precompetitive research and science development carried out in the reactor but private funding will be required for the investment needed for the commercial production of isotopes. This requirement for private funding is in line with the European Union policy for public money spending for commercial production and reflects a formal change in the social contract (Van der Schaaf, *et al.*, 2010).

In the United States, the government is working to develop a "reliable and diversified ^{99}Mo commercial production capability in the United States. that does not use HEU". As part of these efforts, the government is supporting the private sector to accelerate the development of reliable commercial ^{99}Mo production capacity, without the use of HEU, through cost-sharing arrangements where the private company must provide no less than 50% of the total project funding (Staples, 2010). Again, this reiterates the changing social contract as the focus is on developing ^{99}Mo production on a commercial basis, not supported by continuous government funding.

This change in the social contract has come about for a number of reasons. One of the principal reasons cited by supply chain participants is the increased awareness by governments of the amount that they were subsidising ^{99}Mo production. As the reactor operators approached governments for renewing infrastructure or as governments were struggling to deal with the shortages that the supply chain has faced in recent years, this awareness was developed. As they became more aware of the level of subsidisation, they questioned why they, or rather their taxpayers, were subsidising global ^{99}Mo production.

Another key reason for this reflection on the social contract is that, in many cases, ^{99}Mo has become a significant consideration in the decision making on reactor operations. Instead of being a by-product that did not require much attention or did not account for much of the reactor operations, ^{99}Mo production now accounts for a respectable portion of the reactor operations. This growing proportion of reactor use for ^{99}Mo production brings with it questions of the government's role in a commercial activity, not only from a philosophical perspective but also a regulatory one, as is being faced with the PALLAS project.

An additional concern is that ^{99}Mo produced currently with government funding is predominately exported out of the country. This means that governments are supporting the health care system of other countries. For some countries, they are unable to afford this subsidisation given other priorities, especially during the current financial crisis. There is also a question as to why they should be subsidising a product that has a commercial value in a market that is now very well established. There have been some indications that countries may be willing to subsidise production for their own citizens, but no longer for export.

A related issue is that ^{99}Mo production results in radioactive waste that has to be managed. As its production is a larger proportion of the reactor operations, governments are asking why they should be responsible for managing this waste and the overall waste from the reactors' operations (e.g. fuel waste) for a product that is predominately exported to other countries.

The issues discussed above were clearly expressed by the Government of Canada in their recent response to an expert advisory body on ^{99}Mo production:

> "Canada's NRU reactor has satisfied a significant portion of world demand for ^{99}Mo; by producing at this scale, Canadians have been left to shoulder a disproportionate amount of the nuclear waste burden associated with reactor-based isotope production. This includes the significant costs associated with long-term management of the waste. The Government favours a new paradigm in which Canadians benefit from Canadian-based isotope production, supplemented if necessary from the world market, and supply is sustainable because of reduced waste and improved economics." (Government of Canada, 2010).

This reflection on the social contract and any move away from the traditional government role in subsidising the irradiation services and in some cases the extraction and purification of ^{99}Mo will have a significant impact on the economics of the supply chain. As noted in Section 4.2, the current economic situation results in a loss for reactors. In addition, previous chapters have indicated that some processors are not always financially viable on a year to year basis. The social contract that existed until recently allowed for the continued production of ^{99}Mo even though a fully commercial operation would likely have shut down production since marginal costs were not being covered, because governments were subsidising production. As long as the social contract did not change (and it was not expected to change), there was no need for reactor operators to cover reactor fixed costs or repair and replacement costs associated with ^{99}Mo production. With a changed social contract, the economics have to become sustainable on a full-cost basis or the availability of a long-term reliable supply of ^{99}Mo will be uncertain.

4.5 Value of reserve capacity

With the changing social contract, another factor of a reliable ^{99}Mo supply chain that could be affected is the provision of reserve capacity. As noted in Chapter 2, reserve capacity is a back-up capacity that can be used in two cases: 1) to account for operational realities of research reactors; and 2) in the event of unscheduled outages. Traditionally this meant that when one reactor was not operating, another could fill the void and irradiate targets for ^{99}Mo production.

Reflecting back on Tables 4 and 5, the costs and revenue presented did not mention any costs or revenues for reserve capacity. The reason for this is that the current economic structure does not provide any financial recognition of the value of the reserve capacity. The provision of reserve capacity has traditionally been part of the package provided by governments through their social contract – they paid for the capital costs for the capacity to exist and production was done when required. Capacity that was not used was not recognised for its valuable economic role in providing for security of supply. The processing stage faced a similar situation of receiving no economic incentive to maintain reserve capacity.

As noted in Chapter 3, the existence of this overcapacity and the fact that there was no economic remuneration unless it was producing ^{99}Mo (however small) resulted in the market price for irradiation services being driven downwards, especially given the situation of reported processor buying market power that existed. Current economic costs per curie produced are higher, and revenues lower, than if reserve capacity was financially rewarded.

This issue has been studied quite extensively for electricity markets and will be discussed further in Chapter 5. At this point, it is sufficient to state that as social contracts change there will need to be recognition in the market of the value of, and remuneration for, supplying reserve capacity. If this recognition does not arise, the existence of reserve capacity may diminish further, the economic sustainability of the ^{99}Mo supply chain will be threatened and the supply will continue to be unreliable.

4.6 Potential suboptimal use of ^{99m}Tc

Suboptimal use of ^{99}Mo may have been historically occurring further down the supply chain at the radiopharmacy and patient stages, given a lack of proper pricing signals. In terms of radiopharmacies, there have been some preparation and delivery practices that may have been suboptimal because of the historical economic structure. For example, hospitals may receive a generator and not elute in a manner that maximises the use of the ^{99m}Tc produced. In some cases, patient doses were prepared a number of hours in advance, requiring additional ^{99m}Tc to be eluted to account for the decay of the product, instead of eluting the ^{99m}Tc closer to the time of the actual procedure.

In regards to patient procedures, there has been much attention focused on the rising use of nuclear medicine imaging, of which ^{99m}Tc accounts for over 80% of all tests. There have been discussions as to whether this growth is based on the usefulness of the studies or whether tests are being overused. (Kamp, 2009) This issue has become especially relevant related to imaging done through self-referrals and is being questioned at the governmental level (American College of Radiology, 2010).

The current economic structure has not established the proper pricing signals in the downstream supply chain so there is the potential that these practices result in the suboptimal use (e.g. overuse) of the available ^{99}Mo/^{99m}Tc. As with the potential suboptimal use upstream, these practices may be appropriate and optimal but it is difficult to determine without accurate price signals.

Radiopharmacies, hospitals and physicians have been changing these historic practices during the current shortage period to cope with the reduced supply. For example, Covidien has created its "^{99m}Tc Conservation Program" that encourages more thoughtful unit dose ordering practices by its customers to maximise the availability of ^{99m}Tc. According to Covidien, this program has freed up enough ^{99m}Tc to serve about 10% more patients each day (Haynes, 2009). In addition, some hospitals have reduced their ^{99m}Tc orders during the shortage and have instituted practices to use the available supply more efficiently and do not expect to return to ordering 100% of their previous quantities even when more supply becomes available (Urbain, 2010). As well, there are a number of advances in studies and software that indicate the possibility of reducing the required dose of ^{99m}Tc for current practices without sacrificing the quality of the diagnostic test (Miller, 2010; Dalton, 2009; and Ultraspect, 2009).

These changes or potential for changes from traditional practices indicated that there are significant demand-side management options that could be exercised that may not have been considered before. Although these are being instigated as a result of the shortage and not necessarily as a result of changing prices, it does demonstrate that there may have been some suboptimal practices that have been occurring in the past. As noted earlier, suboptimal practices result in the required overproduction of ^{99}Mo, with the related waste and safety concerns. With accurate pricing, the supply chain players could make a more appropriate assessment on the best way to supply ^{99}Mo/^{99m}Tc.

4.7 Additional capacity, but not a panacea

Over the past year there has been much discussion and some action related to possible new projects that have or could come on line to support ^{99}Mo production. For example, in February 2010 Covidien and POLATOM announced that they were irradiating HEU targets at the MARIA reactor (Poland) for processing at Covidien's processing facility and in May 2010, IRE announced that the LVR-15 reactor (Czech Republic) had started producing ^{99}Mo (from HEU targets) for global distribution. There have been other projects that have been discussed and that are actively taking steps to produce ^{99}Mo, such as through irradiation at the FRM-II reactor (Germany) or the efforts in the United States to accelerate non-HEU production. In addition, the Russian Federation announced in May 2010 their intention to expand their domestic supply chain to be able to supply 20% of world ^{99}Mo demand by 2012.

The use of the MARIA and LVR-15 reactors and the possible future use of other reactors are encouraging for addressing the short- to medium-term supply shortages. Although all the projects being discussed will not come online in the short term, the contribution of those that do will help – but not solve – the current shortage situation.

It is important to note that these possible new projects could have a negative effect on the current supply chain economics. Depending on the remuneration provided to reactor operators and the related social contract with the host government these projects could potentially be detrimental to the long-term economic sustainability of ^{99}Mo provision. If any new projects follow the historical remuneration model, paying only for the direct costs of irradiation with no or partial payment for the reactor investment costs directly related to ^{99}Mo production, it will be the responsibility of the host government to cover those costs not included. As a result, the continued production of ^{99}Mo will depend on maintaining the previous social contract with the host government.

More problematic is the effect that this pricing structure could have in the broader market, where the current economically unsustainable situation could be perpetuated. Those existing reactors that are required to produce ^{99}Mo commercially would continue to find it difficult to increase their prices for irradiation services as long as existing production overcapacity is actively marketed. This would threaten the long-term reliability of the supply chain as these commercial operations would not be economically sustainable. This potential impact assumes that those reactors that are currently down return to service as expected.

Overall, while these projects will help in the short term, they could impact the long term by postponing the pending supply shortage as they themselves (with the exception of the FRM-II project) are not new reactors. If the pricing structure perpetuates the current economic situation with insufficient financial incentives for new ^{99}Mo production infrastructure without government assistance, the issue will not be solved in the long term.

That being said, these projects are important for helping to alleviate the short- to medium-term shortages. If they implement pricing that encourages the economic sustainability of the industry, they will not only be crucial in setting the industry on the right price path to ensuring long-term reliable ^{99}Mo supply but will also provide additional flexibility in the supply chain to give time for market changes to occur and new infrastructure to be developed.

4.8 Conclusion

Although it is very difficult to provide economic values in the ^{99}Mo supply chain with certainty given the number of assumptions that have to be taken to provide a coherent pricing structure, the numbers presented here provide an indication of the current situation. It was found that reactor operators and some processing facilities are not making any profit from the production of ^{99}Mo and in some cases are losing money (in almost all cases for reactors). This is problematic given the changing social contract, where governments are no longer interested or able to subsidise ^{99}Mo production and its related waste management, especially for the cases where ^{99}Mo is exported.

The current economic structure does not provide any remuneration for the existence of reserve capacity in the market. This means that current prices face downward pressure since reactor operators have an incentive to produce additional ^{99}Mo rather than keeping the space in their reactors idle. Again, this is problematic given the changing social contract, where historically overcapacity was supported financially through government funding of reactors.

The necessary conversion to LEU targets is not supported through the current economic structure since the current pricing model does not economically support the investment of new capacity (or refurbishing current capacity). The pricing model will need to be adjusted to support this change unless governments decide to fund the conversions.

Overall, the current economic situation points to the need for changes in the current pricing model, especially so if the changes to the social contract with governments remain on their current trajectory. The required change is discussed in the next chapter.

Chapter 5

REQUIRED CHANGES FOR ECONOMIC SUSTAINABILITY

5.1 Introduction

This chapter lays out the areas of the market that need to be changed in order to ensure economic sustainability for the ^{99}Mo supply chain. It provides an assessment of failure in the supply market based on the information provided in the previous chapters and then proceeds to describe various sustainable pricing scenarios. The chapter also introduces other areas for required market changes – recognising local production for global consumption, remuneration for reserve capacity and the need for a clear indication of the definition of the social contract.

5.2 Market failure

Before discussing what is required to change in the market for it to be economically sustainable, it is important to discuss if a market failure is occurring. If there is a failure, it is important to identify what type of failure exists in order to be able to determine the proper action that is required to address the failure.

The text box on the next two pages provides a discussion on the theory of market failure and its general causes. The essence of market failure is that there is an inherent value of a product that is not being realised in the prices observed in the market. The failure to reconcile these two values is as a result of some form of barrier in market operations, including transactions costs from imperfect or asymmetric information, institutional failure, historical circumstances and/or market power.

From this theory and the information presented in the previous chapters, it is clear that there is a market failure in the ^{99}Mo supply chain. This market failure is evident in that there is a breakdown of the pricing mechanism such that the resources are not allocated efficiently within the market.

It is important to properly identify the major reasons for the market failure. First, we need to be clear that the supply of ^{99}Mo or the supply of the capacity to produce ^{99}Mo is not in itself a public good and thus there is no market failure in this regards. It is possible to exclude any one party from the provision of ^{99}Mo or from access to capacity that produces ^{99}Mo. Since there is a way to restrict access to those customers that are not willing to pay for reliable supply, the supply of ^{99}Mo and its reliability supported by reserve capacity is not a public good.

This should not be taken to mean that reliable ^{99m}Tc supply is not in the public interest (the good for the public). When a good provides significant positive externalities, it is in the public interest to provide that good. A *reliable* supply of ^{99m}Tc creates a significant positive externality through patient access to timely medical diagnostic imaging that enables precise and accurate, early detection and management of diseases in a non-invasive manner.

There could be a market failure in the ^{99}Mo supply chain if the benefits related to the health of citizens and possibly lower disease treatment costs are not accounted for in the pricing structure. It has been noted by some industry participants that this provides a justification for government funding of research reactors to provide sufficient ^{99}Mo capacity and production. There are, however, two reasons why this justification is weak.

Box 1: Market failure

Economic theory recognises the value of the market as an allocation method. However, the theory is also very clear that markets can only operate satisfactory within a framework of legal, political and moral restrictions (Medema, 2004). In addition, economists are aware that there are cases where the market can fail to provide the optimal outcome for society. These are instances that economists call market failures. Throughout the years economists have defined market failures differently but in general all the different approaches were based on one assertion: the market left to itself did not allocate goods in the most economically efficient manner in certain cases.

In these cases, there exists another outcome where the market participants' overall gains from a different outcome outweighed the losses from changing. Where such an outcome exists, the current result is considered to be pareto inefficient. A situation is *pareto* efficient when any change to make any person better off is impossible without making someone else worse off. In a case where someone appears to be made worse off by moving to a *pareto* efficient outcome that party would have to be able to be reimbursed through the gains from the change.

Henry Sidgwick in his 1897 publication recognised that there was no reason why an aggregate of persons each seeking their private interests is certain to realise the greatest attainable happiness for the aggregate (Sidgwick, 1897). He identified a number of situations where individuals following their own interests would not result in the economically optimal outcome, including using common goods such as natural resources or situations where the benefactors of actions were not party to the decision making (such as future generations) (Medema, 2004).

Today, there are a number of identified situations where a market failure could occur. The first is where the good being provided is a public good. In economic terms, a public good is a good that provides value to individuals but that cannot be withheld from any individual if it is provided to some. An example of a public good is a lighthouse as all ships benefit from the service it provides and would be willing to pay for it, but once it is in place there is no way to exclude a ship from using it even if they did not pay – a free-rider. Goods that are public goods are often under provided in markets as it is difficult for market players to make a profit from them and therefore they will not provide them. It should be clear that a public good is not merely a good that is good for the public – it must be a situation where non-paying individuals cannot be excluded from using it.

Another case of market failure is when the market transaction creates an effect on a party that is not part of the decision making process. These effects are called externalities and can be either positive or negative. An instance of the former would be where an individual maintains a nice garden because they enjoy gardening but their neighbours benefit because they can look at and appreciate the garden as well; an example of the latter would be traffic congestion, where those individuals driving their cars can create noise and pollution that pedestrians have to suffer. Those goods that provide a positive externality are normally under provided in the market and those that have a negative externality are often over provided in the market. The existence of externalities is often a reason for government intervention in the market, attempting to internalise the externality (making the full impact part of the decision makers' considerations).

Market failure can also exist in the case of incomplete, imperfect or asymmetric information. Proper functioning markets require complete and accurate information so that market players can make the appropriate choices with all the available information. In cases where not all the information is available, or where one party in a market transaction has more information than another party, it is possible that trades that would have been mutually beneficial would not occur because one party may not know the full value of the trade.

Another case where a market failure can occur is through the existence of non-competitive markets, where there is market power by one party or group in the market over another party (normally buyer vs. seller). Where one party has market power they can block beneficial gains from trade from occurring by altering production decisions to influence prices, thus diverging from the market efficient outcome that would have occurred under normal competition. Under a monopoly situation (one seller of a product) this will result in prices that are higher and production that is lower than expected in a well functioning market.

In the cases of market failure there is a general consensus that government intervention has the potential to be able to correct the market failure *if* it can find the appropriate tool. Many economists turn to market-based solutions to address market failure, for example through creating a market for the valued, but unaccounted for, good and then allowing trading of market credits to ensure the most economical manner to achieve the required outcome. This is the theory behind tradable credits in fisheries, water rights and greenhouse gases.

For the ^{99}Mo supply chain, there are cases of market failure in terms of externalities, incomplete information and non-competitive markets. It must be noted, however, that some of these market failures came about as a result of government involvement in the market development.

The first is that government funding of research reactor capacity and utilisation for ^{99}Mo production, and in some cases ^{99}Mo processing capacity and operation, supports these positive externalities in other countries. As noted earlier, this is a subsidisation by one country's taxpayers of another country's health care system. Many governments have indicated that they are no longer willing to provide such subsidisation.

The second reason is that economic efficiency dictates that the solution should be directed as close to the problem as is feasible. In this case, the positive externalities are received at the level of the health care system and not upstream. Therefore, funding from governments to recognise these positive externalities (or private insurers where the testing saves future health care costs) should be at the health care system level, through reimbursement rates and not at the research reactor level. This recognition would have to be sufficient to remunerate the supply chain for the economically sustainable provision of supply, including the development and support of reserve capacity.

There is also a clear market failure through imperfect information. In many cases the full impact of ^{99}Mo provision was not transparent to or appreciated by governments who were financially supporting research reactors' ^{99}Mo production. The full costs of waste management, reactor operations, fuel consumption, etc. were not included in the price structure, thus providing a significant deficiency in the pricing mechanism. This information is now known and appreciated by governments and they have indicated that these costs should be accounted for in the pricing structure.

An additional market failure that has been clearly demonstrated in previous chapters is the existence of significant market power that interviewees indicated provided a barrier to developing a proper pricing mechanism for the efficient allocation of resources. This has had the impact of creating a market that does not allocate sufficient financial resources to develop capacity for continued investment in infrastructure. As will be discussed later in this chapter, this market power has been reduced over the past few years so now it is less of a concern.

Overall, it is clear that there is a market failure in the ^{99}Mo supply chain. This market failure has contributed to a supply chain that is economically unsustainable. This pricing structure has resulted in a lack of investment in current and new infrastructure to reliably supply ^{99}Mo.

5.3 Policy failure

In addition to market failures, the supply chain is also faced by a situation of policy failure. As noted in the text box on market failure, government policy initiatives to address concerns in the market place can sometimes result in outcomes that create their own problems – at times resulting in an overall situation that is worse rather than better. When this occurs, the policy interventions can lead to inefficient allocation of resources in the economy.

In the case of the ^{99}Mo supply chain, the original involvement of the government was logical given the research and development that was necessary in the fledgling market. However, as the previous chapters clearly demonstrated, the way that the industry was commercialised set it on the path toward unsustainable pricing and reinforced market power. This resulted in the perpetuation of an uneconomical pricing structure and potential inefficient use of ^{99}Mo.

The move by some governments away from the traditional social contract has created a situation where the uneconomical pricing structure is prohibitive to the continued operation of the market. When governments decide to no longer subsidise ^{99}Mo production, the reactor operator (and potentially some processors) will not be able to continue production based on economic criteria alone.

This is not to say that governments should be faulted for wanting to change the social contract. In fact, this action will allow for the proper functioning of the ^{99}Mo supply market. A situation of commercial-based pricing will encourage the efficient production and use of ^{99}Mo and ^{99m}Tc, as well as allow for price signals that will determine whether reactor based production of ^{99}Mo is the most economically efficient method of production. It will also allow for the determination of whether ^{99m}Tc technologies (SPECT) are the best technologies for nuclear diagnostic imaging.

5.4 Technology failure

There can be no denying the fact that the development of new ^{99}Mo production capacity was stalled for a decade or more given the expected development of the MAPLES project in Canada. This project was cancelled by the Government of Canada in 2008.

If this project had proceeded[1] there theoretically would not be a supply issue at the moment as the MAPLE project would have had production capacity in excess of 100% of world demand. However, there could still have been significant market issues based on market power with one supplier for the entire global market.

In terms of supply reliability, this situation could have created problems related to the possibility of a single point of failure. In addition, the centralisation of global supply would have resulted in increased safety and security risks as the product would have been transported around the globe. This transportation would also have resulted in significant decay of the product as the supply would not have been spread out geographically.

Also, it should be noted in terms of the economics that the MAPLES project was based on certain assumptions related to capital costs that were not realised during construction. At the time of cancelation, the project costs had more than doubled from original expectations and the Government of Canada, through the Atomic Energy of Canada Limited, had invested a significant portion of funding as well (WNN, 2008). This increase in capital costs had an effect on the overall economic sustainability of the project and was one of the reasons cited by Canada for the cancellation (Government of Canada, 2008).

1. Note that this paper is not presenting a view on the technology of the MAPLES project and its cancellation. This paper is only interested in the effect on the market.

5.5 Increases in prices

5.5.1 Introduction

According to economic theory, if there are accurate pricing signals, resources will be efficiently allocated. In the case of ^{99}Mo production, the pricing signals do not accurately reflect all the costs associated with its production. As a result, it cannot be said that resources are efficiently allocated in the supply chain since there is not sufficient infrastructure investment to sustain the industry.

Proper pricing for ^{99}Mo production must reflect the full costs of production, the benefits of the product and the transportation and logistics. To do so, the pricing structure must change to include remuneration to reactor operators to account for necessary repairs, maintenance, conversion to LEU targets and finally replacement of the infrastructure. Without continued government financial support through the social contract, the only way to make the industry economically sustainable is for it to operate on commercial terms.

There is the possibility that the creation of a proper pricing structure may result in price increases for ^{99}Mo from research reactors that would put too much of an economic strain on the companies further downstream. Some industry participants indicated that they would be priced out of the market if the downstream market has to pay for the full costs of infrastructure investment; while others indicated that the price of ^{99}Mo could rise significantly and not affect the end user demand for the medical imaging procedures based on ^{99m}Tc.

The numbers presented in the following tables do not support the assessment that ^{99}Mo will be priced out of the market given the small final effects of the price changes. However, price increases that would result in ^{99}Mo being priced out of the market may not be negative for society overall.[2] This event, were it to happen, would indicate that ^{99}Mo production via research reactors for the use of ^{99m}Tc in nuclear diagnostic imaging techniques was not economically efficient. For this to happen, there would need to be at least one of the following to occur: more economically efficient[3] diagnostic techniques replace those using ^{99m}Tc; more efficient alternative technologies for producing ^{99m}Tc are developed; and/or more efficient use of ^{99m}Tc or ^{99}Mo results in a reduction of demand.

Without proper pricing signals, it is difficult to determine the price elasticity of demand for ^{99}Mo. However, it has been reported that hospitals will continue to purchase ^{99m}Tc generators even with rising prices given the value of the testing to the medical field. Clearly, there is a price where alternative tests, even at lower quality, will become more widely used. However, that price is reportedly much higher than the prices that provide for economical sustainability in the supply chain.

Price elasticity of demand is the measurement of how sensitive demand is to changes in price. If a product has a high elasticity, it is very sensitive to changes in price and an increase in price will create a significant reduction in quantity demanded.

2. Of course, this will create economic issues for those in the industry but the point of this paper is not about supporting ^{99}Mo production for the sake of its production.

3. Note that economically efficient does not necessarily mean cheaper, it means cost for the value received. For example, a PET scan that is significantly more expensive that current SPECT scans could be considered more economically efficient if the quality of the scan was substantially better when compared to the price difference.

5.5.2 Methodology, assumptions and caveats

To be able to assess the pricing structure that would economically support and sustain the ^{99}Mo supply chain and the impact of that pricing structure on the end user, the study uses a levelised unit cost methodology. This methodology is widely used in other areas where there are significant investments of indivisible capital required, such as in determining pricing for electricity and water provision.

The levelised unit cost provides a reasonable assessment of long-run marginal costs related to meeting an increase in demand over an extended period of time and is calculated from the discounted values of required capital investments and operation and maintenance costs to meet that increase in demand. The discounted expenses are then divided by the discounted value of the incremental product developed. The levelised unit cost measurement provides the constant price required for the stream of costs to be fully covered by the revenue obtained from the product (Intelligent Energy Systems, 2004; Marsden Jacob Associates, 2004; NEA, 2010).

For the ^{99}Mo supply chain, the levelised unit cost of ^{99}Mo (LUCM) was developed using the replacement of supply capacity with a constant demand, rather than the normal practice of investment to meet incremental demand changes. The two approaches are identical in practice as capacity is needed to meet demand. The calculation of LUCM is based on the information received from industry participants during interviews. Costs and revenues of the reactor and processing facility were determined and discounted to a common year (based on 2009 currency) and normalised to ^{99}Mo six-day curies EOP[4] based on the formula below. This shows the total discounted value of the ^{99}Mo produced in year "t" and sold at the constant break-even price, which is equal to the total discounted costs:

$$\sum_t(^{99}Mo_t * P_{99Mo} * (1+r)^{-t}) = \sum_t((Investment_t + O\&M_t) * (1+r)^{-t}).$$

This equation becomes the formula for LUCM through isolating the constant price variable:

$$LUCM = P_{99Mo} = \sum_t((Investment_t + O\&M_t) * (1+r)^{-t}) / (\sum_t(^{99}Mo_t * (1+r)^{-t}))$$

where:

$^{99}Mo_t$:	The amount of ^{99}Mo produced in year "t" in six-day curies EOP;
P_{99Mo}:	The constant price of ^{99}Mo in six-day curies EOP;
$(1+r)^{-t}$:	The discount factor for year "t";
$Investment_t$:	Investment costs in year "t";
$O\&M_t$:	Operations and maintenance costs in year "t".

O&M costs include the attributable portion of any O&M related to "common" infrastructure of the multipurpose reactor, including a portion of staff salaries, fuel and repairs. Although there were no costs directly attributed to decommissioning of the research reactors, interviewees indicated that O&M costs included a set-aside for decommissioning.

There is no specific variable in the LUCM formula for waste costs. Interviewees indicated that short-term waste management costs were included in reported O&M costs but that final waste

4. See methodology in Annex 2 for the normalisation methodology.

management costs were not included as the final disposal or recycling plan was not established. Once the long-term costs of waste management are known, the portion that is attributable to ^{99}Mo production will need to be included.

This formula is based on one used for levelised unit electricity costs that has been used in previous editions of the IEA/NEA series on the cost of generating electricity, as well as in most other studies on the topic. The methodology and assumptions used in determining the LUCM values are discussed more in the Annex 2.

A number of capital investment scenarios were developed to compare different options available to the industry, based on the construction of a:

- Fully dedicated isotope reactor (FDIR).
- A multipurpose reactor where 20% of operations are for ^{99}Mo production (MP 20%).
- A multipurpose reactor where 50% of operations are for ^{99}Mo production (MP 50%).
- An existing multipurpose reactor (no capital costs) with 20 and 50% of operations for ^{99}Mo production.
- The above scenarios with processing facilities (Proc).

For all these options, sensitivity analysis was undertaken on discount rates and payback periods. Discount rates of five and 10% were applied to the reactor projects. This follows the practice used in the IEA/NEA 2010 report on electricity generating costs (NEA, 2010). For processing projects, discount rates of 10 and 15% were used. This higher value is meant to recognise that the operations of processors are more commercially orientated than reactors and therefore face an increased sensitivity to risk (a risk premium), higher financing costs and the need for a higher profit margin.

For the second factor, three different payback periods were used for the calculations for both the reactors and the processing facilities: 10 years, 20 years and 30 years. Although the actual capital would be expected to last for 50 years or more, reactor operators indicated that they would require a payback period that was much shorter to account for demand uncertainty risk. A payback period of 50 years was used in a previous study (National Research Council, 2009) but operators indicated that this was too long for investment decisions. The concern of operators is whether there will be a demand for ^{99}Mo 20 years out and thus their calculations for investment decisions are reportedly based on 10 to 15 year payback periods.

Sensitivity analysis was also undertaken on the amount of ^{99}Mo produced per week. The full results are not reported in this study for simplicity. However, suffice it to say that reduced amounts of ^{99}Mo produced will increase the LUCM (and vice-versa) since the capital costs do not vary significantly. As a result, the same costs will need to be covered by less production.

For the above options, reactor investment was normalised to production of 2 500 six-day curies per week EOP for a period of 37 weeks. For determining LUCM at the processing stage, the processing facility was normalised to be able to process the reactor output, with irradiation service costs from the normalised reactor with 5% discount rate being an input cost for the processor. The necessary capital and annual operating costs were determined to be (2009 Euros) approximately:

- FDIR – EUR 191 000 000 capital costs/EUR 19 325 000 operating costs.

- MP – EUR 435 000 000/EUR 26 000 000:
  - Allocated for 20% – EUR 87 000 000/EUR 5 157 000;
  - Allocated for 50% – EUR 217 000 000/EUR 12 893 000.
- Processing facility – EUR 140 000 000/EUR 23 200 000.

A separate scenario was not undertaken to determine the LUCM produced from a reactor that was converted to use LEU targets. This was because of uncertainty around the final outcomes given that there is not yet a body of knowledge concerning costs and impacts of conversion on production, waste and the related economics. However, a reasonable indication of the economic impact of LEU conversion where the density of the uranium in the targets cannot be increased significantly would be found by comparing the differences between the investment scenarios for the 20 and 50% ^{99}Mo-attributed multipurpose reactors and new processing facilities. This comparison recognises the increased production and processing capital requirements that may be required. New LEU-based reactors and processing facilities (Greenfield) would likely have similar capital costs to HEU production facilities, but may have increased operating costs per ^{99}Mo curie produced based on current target design. It is reasonable, however, to assume that the conclusions related to the need for economically sustainable pricing and the impacts on the end user for production from HEU would continue to hold for production from LEU.

It is not the role of the NEA to state what the price of ^{99}Mo should actually be within the supply chain. The numbers presented below are to provide an indication of the type of magnitude of price increases that would be necessary to sustain the development of new infrastructure, based on the assumptions discussed above. This also provides a tool to assess the impact of these price increases on the final end user. Each supply participant should do their own calculations to determine their pricing requirements, with all the information available to them.

As discussed in Chapter 4, the numbers presented in this chapter are based on information received from supply chain participants during a series of interviews and information collecting surveys. The values obtained by using this information in the methodology described in Annex 2 **should only be considered indicative of the pricing that would provide for economic sustainability and should not be construed as representing the situation exactly in any particular region or jurisdiction.**

The value of assessing and presenting such approximated values is that it provides an indication of the general magnitude of changes necessary in the pricing structure. It also allows for the assessment of the magnitude of the impact of these changes throughout the supply chain.

5.5.3 LUCM results for economically sustainable pricing

Recognising the assumptions made above (and those previously discussed in Chapter 4, Table 5.1 provides the LUCM results for the various reactor scenarios in EUR per six-day curie; Table 5.2 provides the results in USD per six-day curie. For the scenarios where there are no capital costs included (e.g. no refurbishment or replacement costs) the full associated operating costs are included.

Table 5.1: Economically sustainable pricing from reactor in EUR/six-day curie EOP*

	5% discount rate for reactor			10% discount rate for reactor		
	10 year payback	20 year payback	30 year payback	10 year payback	20 year payback	30 year payback
FDIR	515	400	360	645	525	495
MP 20%	195	140	125	255	200	185
MP 50%	485	355	315	640	500	465
MP 20% – no capital costs	55	55	55	55	55	55
MP 50% – no capital costs	140	140	140	140	140	140

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

Table 5.2: Economically sustainable pricing from reactor in USD/six-day curie EOP*

	5% discount rate for reactor			10% discount rate for reactor		
	10 year payback	20 year payback	30 year payback	10 year payback	20 year payback	30 year payback
FDIR	715	555	505	900	730	690
MP 20%	270	200	175	355	280	260
MP 50%	680	495	435	890	695	645
MP 20% – no capital costs	80	80	80	80	80	80
MP 50% – no capital costs	195	195	195	195	195	195

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

As would be expected a shorter payback period requires an increase in six-day curie prices for each investment scenario. As well, a higher discount rate would require an increase in six-day curie prices. This indicates that increased uncertainty in the future of the industry (either related to government funding, demand or regulatory uncertainties), which can either result in shorter required payback periods or a risk premium that increases the discount rate, would require an increase in six-day curie prices to support the necessary infrastructure funding.

The tables demonstrate that among the capital investment options the fully dedicated isotope reactor is the most expensive option. Although the capital costs themselves are cheaper for the dedicated reactor when compared to the full cost of the multipurpose reactor, the latter having the advantage of receiving funding from other operations (either from governments recognising the positive externalities and public good role of nuclear research or from industry for additional irradiation services).

These tables also reconfirm the assessment that the current pricing structure, as described in Chapter 4, is not sufficient to pay for capital or even operating costs of the reactor. The value for the current pre-shortage prices received by the reactor was presented as EUR 45, which is substantially less than all the values seen in Table 5.1 above.

Using the LUCM from the reactor level as an input cost for the processing facilities provides the LUCM at the processing level of the supply chain. Table 5.3 provides these results for the various scenarios in EUR per six-day curie; Table 5.4 provides the results in USD per six-day curie.

Table 5.3: Economically sustainable pricing from processor in EUR/six-day curie EOP*

	5% discount rate for reactor; 10% for processor			5% discount rate for reactor; 15% for processor		
	10 year payback	20 year payback	30 year payback	10 year payback	20 year payback	30 year payback
FDIR no Proc	765	650	615	950	650	615
MP 20% no Proc	445	390	375	630	390	375
MP 50% no Proc	735	605	565	920	605	565
FDIR + Proc[a]	1 050	855	800	1 325	950	900
MP 20% + Proc	730	600	560	1 005	680	665
MP 50% + Proc	1 020	810	750	1 295	905	850
MP 20% – no capital costs +Proc	590	515	490	680	610	595
MP 50% – no capital costs + Proc	675	595	575	765	690	680

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

a. "+Proc" indicates that a processing facility is also constructed and the relevant capital costs are passed through the supply chain.

Table 5.4: Economically sustainable pricing from processor in USD/six-day curie EOP*

	5% discount rate for reactor; 10% for processor			5% discount rate for reactor; 15% for processor		
	10 year payback	20 year payback	30 year payback	10 year payback	20 year payback	30 year payback
FDIR no Proc	1 065	905	855	1 320	905	855
MP 20% no Proc	620	545	525	875	545	525
MP 50% no Proc	1 025	845	785	1 285	845	785
FDIR + Proc[a]	1 465	1 190	1 110	1 845	1 325	1 255
MP 20% + Proc	1 020	835	740	1 400	945	925
MP 50% + Proc	1 425	1 130	1 045	1 805	1 265	1 185
MP 20% – no capital costs +Proc	825	715	685	950	850	830
MP 50% – no capital costs + Proc	940	830	805	1 070	965	945

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

a. "+Proc" indicates that a processing facility is also constructed and the relevant capital costs are passed through the supply chain.

Again, comparing the calculated economically sustainable pricing presented in these tables to the current economic situation as presented in the tables in Chapter 4, it is clear that the current funding situation does not provide sufficient incentives to encourage investment in new capacity development. The economically sustainable prices are significant increases from the pre-shortage pricing but are in line with the direction that the market is heading during the shortage period.

In order to assess whether these required prices changes are reasonable and achievable it is necessary to determine the impact on the full supply chain, especially the final impact on the medical procedure.

Ideally, LUCM values would have been developed for the downstream components of the supply chain as well. However, given the lack of cost data for generator and radiopharmaceutical production, LUCM calculations could not be undertaken beyond the processing stage. In order to assess the impact on the full supply chain, especially on the end user, the first step is to take the LUCM values presented in Tables 5.1-5.4 and apply the absolute price increases (not a percentage increase) to the calculated current supply chain pre-shortage prices (as described in Tables 4.2-4.3).

For simplicity, it was assumed that the entire absolute cost increase (again, not the percentage price increase) will be able to be passed through the supply chain. This assumption may be questioned as the degree of price pass through depends on the price-elasticity of demand at the various supply stages. However, the point of this exercise is to determine the impact of these price changes on the supply chain and finally on the end user (the patient and/or the health insurance system) and thus this assumption is satisfactory.

Tables 5.5 and 5.6 provide the required price increases derived from comparing the LUCM calculations to the pre-shortage pricing and apply the difference to the pre-shortage values. As a result, the tables show the approximate supply chain prices for each reactor/processing scenario, at each stage of the supply chain, that were calculated to provide economically sustainable pricing based on the various investment scenarios examined. These values are then applied to the end-user prices to determine the impact of significant price increases upstream on the end user.

Table 5.5: Supply chain prices for economic sustainability, in EUR/six-day curie EOP*[a]

	Required price increase	From reactor	From processor	From generator	From radiopharmacy
Current situation pre-shortage	n/a	45	315	375	1 810
FDIR no Proc	355	400	670	730	2 165
MP 20% no Proc	100	145	415	475	1 910
MP 50% no Proc	310	355	625	685	2 120
FDIR + Proc[b]	355 R; 185 P	400	855	915	2 350
MP 20% + Proc	100 R; 185 P	145	600	660	2 095
MP 50% + Proc	310 R; 185 P	355	810	870	2 305
MP 20% – no capital costs +Proc	10 R; 185 P	55	510	570	2 005
MP 50% – no capital costs + Proc	95 R; 185 P	140	595	650	2 090

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

a. For simplicity, only the LUCM values calculated using 5% discount rate for reactors and 10% for processors, 20-year payback are presented.

b. "+Proc" indicates that a processing facility is also constructed and the relevant capital costs are passed through the supply chain.

Using these values, Table 5.7 provides the impact of the various scenario price increases on the end user. The methodology discussed in Chapter 4 and in Annex 2 related to the conversion of ^{99}Mo to ^{99m}Tc was applied for developing this table as well. As a result, the reader must be aware that there are a number of assumptions behind these numbers that could, if changed, have an impact on the end results but not the final conclusions.

Table 5.6: Supply chain prices for economic sustainability, in USD/six-day curie EOP*[a]

	Required price increase	From reactor	From processor	From generator	From radiopharmacy
Current situation pre-shortage	n/a	60	445	520	2 525
FDIR no Proc	495	555	935	1 015	3 020
MP 20% no Proc	135	195	580	655	2 660
MP 50% no Proc	435	495	880	955	2 960
FDIR + proc	495 R; 255 P	555	1 195	1 270	3 275
MP 20% + proc	135 R; 255 P	200	835	910	3 615
MP 50% + proc	435 R; 255 P	495	1 135	1 210	3 215
MP 20% – no capital costs +proc	15 R; 255 P	75	715	790	2 795
MP 50% – no capital costs + proc	135 R; 255 P	195	835	910	2 915

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

a. For simplicity, only the LUCM values calculated using 5% discount rate for reactors and 10% for processors, 20 year payback are presented.

Table 5.7 demonstrates that the required price changes at the reactor and processing components of the supply chain have very little effect to the end user even under the assumption of full pass through. These price increases can be quite significant along the supply chain but the impact is quite small for the end user. To be economically sustainable, irradiation services require prices to increase from about EUR 45 per six-day ^{99}Mo curie to between approximately EUR 55 and 400 depending on the investment scenario, which is a maximum factor increase of about nine. In terms of the end user, the reactor was getting revenue of approximately EUR 0.26 per procedure under the original pricing structure. The price increases would increase revenues to a range from EUR 0.33 up to EUR 2.39, with the lowest value related to an existing multipurpose reactor with no capital cost requirements and the most expensive option being the fully dedicated isotope reactor.

Even at the most extreme price increases at the reactor level (capacity development of the fully dedicated isotope reactor) this would result in the value of irradiation being only 0.97% of the final reimbursement rate for the procedure. When compared to the original 0.11% this is a substantial increase but when compared to the overall reimbursement rate of the procedure it is not very significant.

In terms of the final impact of the price increases passed through the supply chain (including the required price increases at processing facilities), the impact of the increased radiopharmacy price on the final reimbursement rate is minimal, increasing from 4.42% of the reimbursement rate to a maximum of 5.69%. Again, the highest value is from the fully dedicated isotope reactor investment option.

As indicated earlier, the information available at the time of writing this study did not allow for an assessment of the impact of these price increases on the viability of the downstream supply chain. The demonstrated small impacts indicate that the downstream components should be able to absorb these price increases. However, this issue may require further study and possible assessment by hospitals and medical insurance plans especially in the context of continued downward pressure on reimbursement rates or where the health system provides fixed budgets to hospitals for radioisotope purchases.

Table 5.7: Impact of price increases at hospital level*

	Irradiation value within final radiopharmaceutical price EUR	Final radiopharmaceutical price of ^{99m}Tc per procedure EUR	Irradiation value within final radiopharmaceutical price USD	Final radiopharmacy price of ^{99m}Tc per procedure USD	Irradiation value as % of reimbursement rate	Radiopharmacy price of ^{99m}Tc as % of reimbursement rate
Current situation pre-shortage	0.26	10.86	0.37	15.14	0.11	4.42
FDIR	2.39	12.98	3.33	18.10	0.97	5.29
MP 20%	0.85	11.45	1.18	15.96	0.35	4.66
MP 50%	2.12	12.72	2.96	17.73	0.86	5.18
FDIR + proc	2.39	13.96	3.33	19.46	0.97	5.69
MP 20% + proc	0.85	12.43	1.18	17.32	0.35	5.06
MP 50% + proc	2.12	13.70	2.96	19.10	0.86	5.58
MP 20% – no capital costs + proc	0.33	11.91	0.47	16.61	0.14	4.85
MP 50% – no capital costs + proc	0.84	12.41	1.16	17.30	0.34	5.05

* As with all values presented in this report, these values are meant to be illustrative of the situation being described and should not be construed as being the absolute true value.

5.5.4 Conversion to LEU targets

As mentioned above, the effects of converting to LEU targets under a situation where the density of the uranium in the targets cannot be increased significantly can be simulated by looking at the difference in the calculated LUCM between the investment scenarios for the 20 and 50% ^{99}Mo-attributed multipurpose reactors and the related effect throughout the supply chain. As more experience is obtained on the impacts of conversion a more accurate examination could be undertaken.

At the reactor level of the supply chain, the difference between the 20 and 50% scenarios is a price increase of 150% for the irradiation services. Including the possible requirement of a new processing facility, the overall price increase for bulk ^{99}Mo is in the range of 29 to 40%, where the variation is based on different discount rates and payback periods. Applying these price increases through the supply chain, the impact on the prices at the radiopharmacy is an increase of about 9%. And as a percentage of the reimbursement rates, the value of the ^{99m}Tc goes from 5.06% to 5.58%, an increase of 10%.

Although the original price impact of the conversion appears to be quite significant, the end result on the patient procedure (with the revenue for the irradiation services going from 0.35% to 0.86% of the final reimbursement rates) is quite small. Again, this study does not provide an assessment on the ability of the end user to absorb this cost increase.

5.6 Recognition of global benefit from local production

Price increases are a key necessary change to ensure the economical continuance of the ^{99}Mo supply chain. Creating a pricing system that will cover the full costs of production should reimburse for the local impacts of production for the global market. Currently the domestic tax payer is subsidising ^{99}Mo production and the related waste management for the global market. The taxpayer may not even benefit from the subsidisation when the irradiated targets or bulk ^{99}Mo are exported and the generators are then imported back into the country.

If the pricing structure includes the full cost of production it will pay for these local effects. The negative externality imposed on the local population will be internalised as it would form part of the purchasing decision of downstream players through increased costs.

Another option, which will be discussed further in Chapter 6, is for countries to impose an export tax on the ^{99}Mo or ^{99m}Tc that is exported. This would permit the country to subsidise domestic use and accept the waste management responsibilities but would allow for compensation for the negative local effects attributed to the production for the global market.[5]

5.7 Recognition of value of reserve capacity[6]

As noted in Chapter 4, the current pricing structure does not recognise the value of having *and not using*, reserve capacity. The LUCM derived pricing structure presented in this chapter also does not recognise the value of reserve capacity.

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5. Where the raw material is exported this subsidisation would not benefit the end user at all. In this case, it may be more relevant to increase the subsidisation to the nuclear medicine procedure via reimbursement rates.

6. Chapter 2 provides an overview of the need for reserve capacity. For simplicity some of that information is repeated here and is used to take the discussion further.

In order for a reliable supply chain to exist, reserve capacity needs to exist. This capacity is needed for two reasons: 1) to account for the operational realities of research reactors as they do not operate 100% of the time; and 2) to serve as a back-up in the event of unscheduled or extended maintenance outages. For simplicity, this study will refer to reserve capacity addressing the first issue as WRC and that addressing the second as ORC.

In general, discussions have not made a distinction between the two motivations for reserve capacity. Of course, any reserve capacity could address both issues but the distinction is important when looking more in-depth at the need for reserve capacity and the ways to value and support it.

Historically, WRC was the principal reason for reserve capacity development as the reactors were generally reliable. There was a need to ensure continued supply of irradiation services and bulk ^{99}Mo to the supply chain and the operation requirements meant that additional irradiation capacity was required. However, as the reactors (and processing facilities) have aged, there has been an increase in the incidences of unexpected or extended repair shutdowns and the ORC has become of paramount importance in the short term.

At an OECD/NEA workshop on the supply of medical radioisotopes in January 2009 experts noted that a reliable supply chain required capacity of about 200 to 250% of global demand. Although not specified, it is logical that this figure includes both WRC and ORC purposes and was based on historical capacities.

One would expect that the WRC component of total reserve capacity would result in an annual supply capacity equal to the annual amount of product demanded, since, on an annual basis the total reactor and processer supply chain would meet demand. However, this would only be the case if there was effective co-ordination among reactor operators and processors such that processors source from multiple reactors in a fashion that allows for full usage of operating reactor capacities. In this case, annual reactor capacity should equal 100% but "peak" capacity would depend greatly on operating days and effective co-ordination.

For ORC there would need to be some annual excess capacity as one or more reactors may have to be shut down for an extended period. This excess capacity could be in the form of a reactor that does not operate as often as possible or as capacity within a reactor left idle (e.g. using only 60% of ^{99}Mo irradiation channels). Regardless of its form, the ORC must be available and operational, with all the required regulatory approvals in place for the operation, transportation and use of the ^{99}Mo/^{99m}Tc.

In electricity markets, there is much literature about the level of reserve capacity required. Often in these markets there is talk about the need for reserve capacity at a level defined by the n-1 criterion. This criterion basically says that there needs to be enough reserve capacity to compensate for the failure of the largest generating unit in the system (NEA, 2010).

In the ^{99}Mo supply chain, if there was a system of generally reliable reactors and processors the n-1 criterion at both the reactor and processing stages of the supply chain could be seen to be sufficient. However, with the current ageing fleet, there was a period in 2010 with the two major reactors unavailable, thus calling for an n-2 criterion if older, less reliable reactors remain the main suppliers of ^{99}Mo. In addition, there is currently sufficient processing capacity *globally* but the excess processing capacity (ORC) is not located where there is excess reactor capacity (ORC).[7]

7. The main processing reserve capacity exists in Canada where as the current reactor reserve capacity is centred in Europe (when the Canadian reactor is not operating). The processing capacity in Europe is

In the current supply chain, there is no economic value attached to ORC. The value of WRC is recognised in as much as the available capacity is used in a co-ordinated manner to ensure sufficient production at all the available reactors. Any capacity that is not used for WRC is either ORC or overcapacity. ORC has an inherent value, whereas overcapacity does not – it is surplus and should be eliminated.

The existence of WRC and ORC creates economic challenges for the supply chain. In the case of WRC, proper co-ordination of reactor schedules is necessary to ensure that the available capacity is well used respecting all appropriate competition regulations. For example, if a lack of co-ordination results in two regional reactors operating at the same time and then a period of no reactors operating, there will be a call for an increase in reactors when in reality it is a problem of co-ordination, not capacity. This could result in the construction of too much capacity which would drive prices below economically sustainable levels and would be a drain on available investment capital in the economy.

In the case of ORC, there has to be recognition of its value and a manner to financially support its capacity development, its availability and the action of *not* using the capacity when it is not necessary. If this value is not recognised and remunerated, there will be a tendency for reactor operators to use the capacity to gain revenue rather than leaving it idle (i.e. as empty channels when the reactor is operating). The consequence of this would be to drive down the prices of irradiation services and perpetuate the market power at the processor level (since they would be able to go elsewhere for irradiation services without another customer stepping in to take their place).

In electricity markets there are a number of ways that liberalised markets are working to ensure the existence of reserve capacity and, in some cases, to pay for that reserve capacity. Although there has not been a clear winner in electricity market design (IEA, 2007), there are a few principal methods that are being used.[8] It has been recognised that electricity markets must be designed, including through regulatory frameworks where necessary, to provide sufficient remuneration and incentives for investment, covering both variable and fixed costs. The way to properly design the market continues to be one of the most debated aspects of market design (IEA, 2005).

One market design is an energy-only market. With this market design, the wholesale electricity price provides remuneration for both variable and fixed costs. Generation plants recover invested capital during those periods where the market price is higher than its marginal costs. This occurs when the market price is set by more expensive generating facilities that are required to meet peak demand (IEA, 2005).

In some cases, extra capacity measures have been implemented to encourage additional investment in reserve capacity. One way this is done is through a payment to a generator to ensure available reserve capacity. This has been done through a central system operator, but in some cases has been subject to significant gaming by withholding capacity and driving up capacity payments. Another approach used is to base the capacity measure on volume rather than price, making it an obligation of retail companies to contract for an amount of generation capacity that includes contracted load plus a reserve (IEA, 2005).

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sufficient to meet European demand, but not sufficient to process all the targets that could be irradiated in European reactors and used to support global needs. This issue is discussed further in the forthcoming NEA HLG-MR Interim Report.

8. These methods will be discussed very briefly in this study, but if the readers are interested they are encouraged to read more, especially from the work that the IEA has done on this subject.

In some cases, auctions are held for operating reserve capacity, with significant sanctions if the bid capacity is not available when required. If the reserve capacity is called upon the producer also gets the value of the electricity in the market (Amundsen, 2007). Capacity options are used in other markets as well as viable ways to ensure back up capacity if required (Tan, 2002).

Although much current research on electricity market design is still focused on the functioning of capacity markets, there are available lessons for the ^{99}Mo market. There are differences though in the functioning of electricity and ^{99}Mo markets. One key difference is the variability of the quantity of product demanded. In electricity, the key motivation for reserve capacity is the ability to quickly meet changing demand, especially peaks at certain times of the day and between seasons. For ^{99}Mo supply, the demand is reasonably steady, historically growing year over year but not having cyclical peaks. In this case, the requirement for reserve capacity comes from changes in supply availability as reactors are momentarily or permanently removed from the supply chain – supply valleys instead of demand peaks.

A key feature of this difference in demand variability is that the ^{99}Mo market does not exhibit peak pricing. As a result, the "energy-only" market is not a viable way to provide the financial incentive for the needed ORC. Therefore, to ensure sufficient ORC there has to be some form of capacity market developed that is supported by regulatory requirements for reserve access and methods to ensure payment for that reserve capacity.

One final note is necessary when comparing ^{99}Mo market design to electricity market design. In electricity markets, there has been the establishment of system operators to manage the transmission system and often to ensure the balance of electricity load. This operator addresses a market failure in electricity markets; reliable electricity supply is a public good in that one user cannot be excluded from the benefits of a reliable system (IEA, 2005). In ^{99}Mo, as was discussed earlier in this chapter, one user can be excluded from a reliable system (one user can have contracts with multiple suppliers, where others can choose not to). In the absence of this market failure, there is less of a justification for a ^{99}Mo system operator. However, some form of co-ordination is useful and important.

Recognition of the value of reserve capacity does not necessarily have to be at the reactor level; it could also include demand management practices. Demand management, including demand shifting, can provide an additional source of "supply" and reduce the need to develop capacity. These demand management techniques may reduce the amount of WRC or ORC required. For example, if a client knows that a reactor maintenance outage is expected they can take actions to shift patients to the period before or after the outage. This possibility of "reserve capacity" also requires some value recognition.

5.8 Clear definition of social contract

As identified in previous chapters, the traditional social contract had governments funding capacity (including reserve capacity) and production of ^{99}Mo. More recently, this social contract has been changing, with many governments being less ready to subsidise the capacity or the production. This changing social contract is altering the economic requirements for the supply chain but the uncertainty around the actual social contract makes realising those necessary changes difficult. Another uncertainty is the differing social contract in different countries, where some countries seem more interested in continuing to subsidise ^{99}Mo production.

The key reason why governments need to clearly define their approach is the effect that an uncertain social contract has on the industry. Where the industry has the impression that governments will continue to subsidise the ^{99}Mo supply chain, they will be less accepting of a change in the price structure. For example, one interviewee indicated that industry participants were less willing to discuss capital funding during the shortage situation than before. The interviewee indicated that there was an expectation that the government would intervene to ensure adequate capacity. If industry financially supported capacity at this time of uncertainty, there is a risk that they would fund infrastructure development that the government may have been ready to do.

It is very difficult to change the social contract as expectations remain about the role of governments. In addition, there is often significant uncertainty around the extent of the political will to actually change the social contract that can result in delays in industry investments as they wait to see the final outcome. This has been seen in electricity restructuring processes where governments attempted to change the social contract (so that they were no longer responsible for the production and supply of electricity) and, in some cases, ended up either cancelling the restructuring process, stalling it or redefining it such that the social contract was maintained (Heller, 2003).

Given this difficulty, the central message is that if there is a change in the social contract this change must be very clearly stated with a strong signal and governments must remain committed to the change. The best way to credibly indicate a commitment is to undertake an irreversible strategy. In the case of ^{99}Mo, a clear public statement of the changed social contract is a first step. To support that step, as with electricity markets, the key will be that governments indicate their political commitment by *not* intervening in the market even when there is public pressure to do so as short-term issues such as rising prices or shortages arise (IEA, 2005). This clear signal is currently missing in the ^{99}Mo supply chain, except in a few countries such as Canada and South Africa, with the position of some other countries not being clear.

5.9 How things are already changing

Previous chapters in this study have indicated that the historical development of the market has had an impact on the current economic structure and has resulted in difficulties to changing that structure. The discussion covered issues of market power and barriers to entry, including exclusivity contracts, and how that market power reportedly encouraged and perpetuated low prices that were uneconomical in the absence of government funding.

During interviews, one responder indicated that five years ago there was a need to disrupt the market to be able to reset it and correct the historical problems. The current shortage has effectively served this purpose – clearly not intentionally undertaken to do so however. There have been alterations to the market structure that have allowed for the commencement of some of the required changes.

The market power at the processor stage of the supply chain is one of the changes that have slowly occurred. As noted in earlier chapters, in the early 1990s there were effectively only two processors, who were thus able to exert some market power on reactors. The current and previous shortages have removed some of the barriers that prevented other processors from entering the market, reducing the market power (although it has not been completely eliminated given existing contracts). The shortages have also convinced bulk ^{99}Mo clients that they should be multisourcing for reliability such that their supply is not subject to a single point of failure in the supply chain. For example, the board of directors of one Japanese firm have a directive to never single source bulk ^{99}Mo again. This is further evident by the diversity strategies being undertaken by the major North American and European generator manufacturers.

Another way market power has been reduced is the potential increase in demand for irradiation services at the major research reactors. With the revived interest in nuclear energy there is an increase in demand for irradiation services for material and fuel testing, for example. In the past, there was limited decision making necessary related to the balance of activities in a reactor since there was available space and less demand for irradiation services. The resurgence of interest in nuclear has resulted in conflicts for irradiation space and planning at some ^{99}Mo producing reactors, reducing the market power of processors wanting irradiation of targets for ^{99}Mo production.[9]

The effect of this reduction of market power has resulted in reactor operators and other processors being able to gradually increase prices of ^{99}Mo toward more commercially sustainable levels. The shortages have reportedly stopped the price wars (at least temporarily) and diversification strategies have allowed for prices to increase.

There has also been an increase in downstream prices, partly as a result of the low margin pricing models being replaced by more appropriate pricing of ^{99}Mo at the generator stage of the supply chain, an effect that had already started before the present shortages. These price increases have not necessarily resulted in increased remuneration to reactor operators but have increased awareness of the value of ^{99}Mo, with supply chain participants indicating that there is greater acceptance of rising prices.

Overall, supply chain participants indicated that there is greater acceptance on the part of other supply chain players to rising prices. However, there is concern among downstream players that the final levels of the required price changes will increase too much, and among the upstream that the increases will not be sufficient. There is also concern on whether the price increases that are starting to happen will be able to be maintained once the technical issues related to short-term supply reliability are resolved and short-term capacity increased.

5.10 Conclusion

This chapter identified that there were failures in the supply chain through market failures, policy failures and technology failures. In order to address some of the failures, it is necessary to increase prices within the supply chain. The calculations undertaken and presented in this chapter indicate that significant price increases are required at the reactor stage of the supply chain to support the required infrastructure investments and these will create significant increases in the upstream supply chain (assuming a price flow-through of the absolute value). However, these significant increases, including those simulated to estimate LEU conversion, do not result in a large impact for the end user, as observed via costs of the final procedure.

In addition to rising prices, there needs to be recognition in the market of the local impacts of ^{99}Mo production for the global market and of the value of reserve capacity. The confusion around the changing social contract needs to be eliminated in order to create the proper environment for investment.

Changes have started to occur in the market as a result of disruptions in the supply chain. These changes include the gradual increase in prices for upstream supply chain players. However, in order to ensure that these changes are sufficient and continuous there are actions that still needs to be taken. These are the subject of the next chapter.

9. This effect was not unanimously reported. Some reactor operators indicated that there was not a sufficient increase in demand to create conflicts and IAEA has reported that 50% of all research reactors are currently underused (although not all of them are technically able to produce ^{99}Mo).

Chapter 6

RECOMMENDATIONS AND OPTIONS

6.1 Introduction

The study has pointed out that the market is not operating efficiently for a number of reasons but that there are some changes that have been happening. It is clear that the key economic figures point to a supply chain that is not economically sustainable, especially in the upstream components. With changing circumstances, such as continued increase in growth in demand for ^{99}Mo, the need for additional capacity and governments questioning the traditional social contract, there are changes that are required to ensure an economically sustainable supply chain. This chapter discusses the possible options for changes and a visual representation (Figure 6.1) is presented at the end. These are not intended to be either comprehensive or definitive but are put forward as options.

6.2 Options for overall capacity

6.2.1 Defining the social contract

The first thing that needs to be done is for governments to assess and confirm their role in respect of the industry, especially on whether or not they are willing to continue to subsidise ^{99}Mo production in the upstream components (reactors and in some cases the processors). This is predominately a policy decision rather than an economic one. As a result, this study is not recommending what a government should define as its social contract but only that the government should define the social contract and should harmonise the approach with other producing nations.

It must be recognised that the decisions made by governments related to financial support for research reactors are multifaceted. The effects on the health community are only one important part. Governments may consider supporting research reactor infrastructure development and operations even if these reactors are producing ^{99}Mo at a loss given other social utility functions of the reactor. For example, research reactors provide benefits for education, research and maintaining a nation's technology and knowledge base in nuclear activities.

The production of ^{99}Mo at the reactor provides a useful valuation and communication tool for decision makers in this regard. It is hard to determine the exact value of these other social utility activities and then to clearly communicate these values to the public to justify financial support from government; it is much easier for decision makers to communicate the value of ^{99}Mo production in a new research reactor project and its benefits for the health community.

The options for defining the social contract are based on the expected role of the government and the degree of subsidisation that they are interested in providing to the industry. The three options for definition of the social contract are based on the traditional model, a modified traditional model and a commercial model.

Under the **traditional model**, the government would build the required reactors and would irradiate targets for the processing component of the supply chain. Under this model, the reactor operator would continue to charge only for direct marginal costs. The reactor operator could also charge for some capital costs that are directly related to the ^{99}Mo production, such as any rig installations that are required. The government must be aware that this social contract would not lead to the economical sustainable operation of the reactor and would require continued dedicated funding, including replacement costs when necessary. If a government decides to proceed with this type of social contract they must be willing to provide for long-term funding for the reactor.

Under the **modified traditional model**, the government would again build the reactor and irradiate the targets for the processing stage of the supply chain and not charge for any significant capital replacement costs. The difference with the traditional model is that the pricing to processors would also include remuneration for costs related to maintenance, upgrades, share of total reactor operating costs/overheads and waste. Under this model, the government would be required to fund the infrastructure development but the reactor should be able to *operate* on a commercial basis.

The modified traditional model allows the government to maintain full economic control over the reactor itself, supporting the notion that the development of a research reactor is the responsibility of the government because the principal purpose is research and research is a public good. The fact that the reactor should be able to produce ^{99}Mo on a semi-commercial basis (operationally commercial) would mean that the government would not have to provide long-term funding for ^{99}Mo production. However, the government would have to continue to provide long-term funding for the rest of the reactor operations and would have to be committed to fund any new infrastructure that may be required.

Under the third option for the definition of the social contract, the **commercial model**, the portion of the reactor facility that is attributed to ^{99}Mo production would be funded on a completely commercial basis. This would require that all costs discussed in this study, including the attributed portion of the capital costs (or replacement costs) of the reactor, would have to be covered by prices of irradiation services for ^{99}Mo production. The pricing model options are discussed below in the section on increasing prices. This model would allow governments to not subsidise ^{99}Mo production at all *at this stage in the supply chain*.

The advantage of the commercial model is that the government does not have to commit significant resources to capital development or continued operation of the reactor for ^{99}Mo production. This removes the concern about subsidising production through taxes and dealing with the negative effects of waste for a product that may be exported for use by the health care system of another country. However, the government would still have to fund the other non-commercial uses of the reactor.

This model does not necessarily imply that the reactor operator will lose control of the research component of the reactor because it could define the role of ^{99}Mo production within the priorities of the reactor. In addition, this model does not mean that governments need to withdraw from the industry as a government enterprise could be responsible for ^{99}Mo production, but on a commercial basis. Of course, this social contract model would also allow for commercial entities to exist in the market along with government enterprises where regulations permit.

The commercial model does not result in the government abdicating any responsibilities it has to providing health care to its citizens. Governments may decide to continue to pay for the use of ^{99m}Tc through increasing health insurance reimbursement rates, which are currently falling in many jurisdictions. This is a more appropriate place to subsidise the supply chain as it ensures the continued supply of ^{99m}Tc without specifying how it is produced, thus avoiding governments needing to pick technology winners. This would enable alternative technologies, if they are economical and efficient, to enter the market freely while recognising the positive externalities of nuclear medicine testing.

One key issue related to defining the social contract is that producing nations should make every effort to harmonise their approaches. This harmonisation would avoid creating distortions in the market place or between regional markets. Without harmonisation, those countries that have already decided and committed to commercial ^{99}Mo production could effectively be forced to quit the supply chain. The need for harmonisation is well discussed in other markets, including electricity, with a general agreement that it is necessary to avoid distorting markets in other jurisdictions (IEA, 2005).

The challenge is how to develop a harmonised framework that will allow transition to full-cost remuneration in a period when there are both old and new reactors, some with HEU and some with LEU targets and where there will be a number of operators of older reactors that have the incentive to maximise revenue before closure of these reactors. One option to address harmonisation under these conditions would be to develop a panel of experts from producing countries (or an international body) to review the market and provide a view on whether producers are applying the agreed upon social contract (e.g. full-cost pricing) or have clear plans to do so.

Once the definition of the social contract has been defined, it is essential that governments send a clear and strong signal as to whether or not they are willing to subsidise ^{99}Mo production. This clear signal is necessary so that the industry can know how to respond and move forward to fulfilling their role in ensuring reliable supply. The governments should demonstrate their social contract through a committed action: either removing subsidies, defining a removal of financial support over a transition period, or committing funding to the ongoing operation and capital development of reactors for ^{99}Mo production.

6.2.2 Remuneration under continued government support

If the social contract is defined such that governments continue to subsidise ^{99}Mo production, they need to be willing and able to increase ongoing remuneration to reactor operators specifically for ^{99}Mo production. This remuneration would have to account for the full costs of ^{99}Mo production and related capital investments minus any revenue that the reactor should be able to earn. In the current supply chain, additional LEU-based supply capacity and any related processing capacity is needed to account for ageing reactors and international commitments. As a result, governments will be required to provide funds for this capital.

The options for government funding are based on unilateral or international funding arrangements. The latter could be subdivided into directly funding a specific project through multilateral efforts or creating an internationally managed "fund". All of these arrangements would need to support ^{99}Mo production either through the traditional model or the modified traditional model as discussed above.

The **unilateral funding arrangement** would require one government to subsidise ^{99}Mo production through their own research reactor facilities, continuing to supply the global supply chain. In order to address the concern that one government is subsidising the health care system of another country while bearing the risks and costs of waste management, the government could impose an export tax on ^{99}Mo anywhere in the supply chain that it is exported. This export tax could then be set aside to partially offset the costs to the government.

The **direct international funding arrangement** would consist of mutually interested governments agreeing to support a specific project. Again, this arrangement could impose an export tax on product sold to non-funding countries to avoid the situation of subsidising another country's consumption.

In both of these options, there is the potential for free-riders to benefit from government subsidisation; non-participating countries could still benefit from the increase in capacity on the global market. Even where export taxes are imposed, an external country would benefit from the freed-up supply in the global market and thus may be able to have access to the supply without paying for any portion of capacity.

The third option for government funding would be the creation of an **internationally managed ^{99}Mo production fund**. Under this option, consuming nations would have to financially support the fund by paying a fee proportional to their consumption. The fund would then support the development of international projects to produce ^{99}Mo. The fund's governing body would decide which projects deserved funding based on the criteria being developed by the NEA to evaluate different project options (c.f. HLG-MR Interim Report). Ideally, the fund would have enough resources to support projects in various regions to ensure equal access.

This third option avoids the free-rider problem as the support to the fund is based on consumption, not production. Thus any nation that consumes would have to support the fund. The problem of this option will be its enforceability; how to ensure that consuming nations provide the funding required for the fund? In addition, it is recognised that the implementation of any international funding mechanism would be extremely difficult.

This third option, instead of being organised globally, could also be organised around regional network lines. Governments involved in a region could support a regional ^{99}Mo investment fund based on consumption proportions and impose a region export tax to avoid free-riding between regions or non-participating countries. This option would still be susceptible to free-riding through the ability to use freed-up supply, if an excess exists.

All of the above options could also be used to support processing capacity if it was deemed to be a limiting factor in a region (as it currently is).

6.2.3 Increasing prices under commercial-based social contract

If the social contract is redefined so that ^{99}Mo production should be operated and developed under a commercial model, then the pricing structure will need to be altered to provide for more appropriate market prices. This will mean an increase in prices and the maintenance of these higher prices once the current short-term shortage situation is resolved.

This report clearly demonstrates that the current pricing structure is insufficient if the supply chain has to operate in an economically sustainable manner. Previous chapters indicate the benefits of proper price signals both for providing incentives for new infrastructure and for encouraging the optimal use of ^{99}Mo. Such a move towards commercial-based pricing would have to be reflected in industry contracts over time, providing for a better operating market. Affirming the principles discussed in this report in industry contracts is necessary for the survival of a supply chain based on the commercial model and for the long-term supply reliability of ^{99}Mo.

As described in the previous chapter, the pricing structure that will need to be demanded by reactors will account for the full costs of operation that are related to ^{99}Mo production, including a share of common costs, and a reasonable share of the capital costs of the production facility or replacement costs. The pricing structure should not cross-subsidise research projects. In order to determine the appropriate price levels, the reactor operators could use an approach similar to the LUCM model used in Chapter 5 of this report. In order to ensure a smooth functioning of the market, it may be realistic to look at a transitional period to arrive a full-cost pricing.

Various options exist on how to deliver the revised pricing, including: levelised cost pricing; levelised cost pricing with a fixed component; and access fee and service fee. These methods differ in delivery but should be equal in terms of levels of the present value of remuneration to the reactor.

For **levelised cost pricing**, the price would be based on actual irradiation services or ^{99}Mo produced, as a price per unit. The reactor operator would be required to estimate the expected production from the infrastructure and the expected cost structure (including capital costs and refurbishments) and determine what selling price per unit would make the project economically sustainable. This pricing structure would provide no guarantee of minimum funding as remuneration would be based entirely on product produced and sold. However, when the reactor is producing the price received would include all costs including any financing costs for the attributable portion of the infrastructure. In this pricing model, annual revenue for the reactor would be calculated by the following formula:

$$Annual\ revenue = \sum_t LUCM*^{99}Mo_t$$

where:

$^{99}Mo_t$: The amount of ^{99}Mo produced in year "t" in six-day curies EOP;
LUCM: The constant price of ^{99}Mo in six-day curies EOP.

The **levelised cost pricing with a fixed component** pricing structure is very similar to what is done in many industries today, including other utility based products such as electricity and water provision. For this pricing structure, the reactor operator would again determine the LUCM of production but would be remunerated through a fixed component for service provision and then a variable cost for production. The fixed component could be thought of as a subscription – if the customer wants access to the product there is a minimal amount they must pay each month or year that would cover the fixed portion of costs. From there, the customer would be charged a variable amount that would cover only the variable costs of production. This delivery model would provide the reactor operator with a guaranteed minimum price covering fixed costs. The total real remuneration to the reactor operator should be the same as with the above model under similar production conditions, but with reduced risk. In this pricing model, annual revenue for the reactor would be provided by the following formula:

$$Annual\ revenue = \sum_t (A + C*^{99}Mo_t)$$

where:

A: The fixed charge to the customer;
C: The unit variable price of ^{99}Mo in six-day curies EOP, and $C<LUCM$;
$^{99}Mo_t$: The amount of ^{99}Mo produced in year "t" in six-day curies EOP.

The third pricing structure should also provide the same real remuneration as the two above, but is delivered with more upfront funding. The **access fee and service fee** pricing structure would require customers of irradiation services to provide upfront funding to the portion of the capital investment that is related to ^{99}Mo production to support the development of the project. This funding would guarantee the customer access to the services provided by the infrastructure, with some guaranteed minimum amount of irradiation service. When the customer requests production of ^{99}Mo in the reactor, they would then pay a service fee based on the full variable costs of production. Depending on the portion of the access fee, the customer would have a say in the operation of the reactor and minimum/maximum levels of production could be specified in the contract, recognising the requirements of the other access fee subscribers. For economic efficiency, these access rights should be as any other property right and should be transferable. This third model is similar to the model being used by the Jules Horowitz Reactor project. In this pricing model, annual revenue for the reactor would be provided by the following formula:

$$\textit{Annual revenue} = I_t^0 + \sum_t C{*}^{99}Mo_t$$

where:

I_t^0:	The share of capital investment in year 0 paid in year t (or avoided amortisation payments);
C:	The unit variable price of ^{99}Mo in six-day curies EOP, and $C<LUCM$;
$^{99}Mo_t$:	The amount of ^{99}Mo produced in year "t" in six-day curies EOP.

During interviews for the economic study, some supply chain participants indicated that the industry would not survive if ^{99}Mo production at reactors was done on a commercial basis. The concern raised was that the price increases would create too much of a required increase downstream that the players would be priced out of the market. Other interviewees indicated that the downstream, including the end user, must be willing to pay for irradiation services and processing and be prepared to fund reserve capacity (see section below on reserve capacity) or else the supply won't be available.

The economic analysis presented in this paper does not seem to support the assessment that ^{99}Mo would be priced out of the market. Significant price increases at the reactor level and even at the processor level that are passed through to the end user are not expected to have a significant absolute or proportional impact on the end user. In addition, it is clear that commercial pricing is necessary for the continued supply of reactor-based ^{99}Mo in the medium to longer term if there is not ongoing financial support from governments.

The final declaration on the impact of a price increase on the downstream market would be made after a move to produce ^{99}Mo on a commercial basis, testing the economic assessment presented in this study. It is expected that the benefit of ^{99m}Tc based nuclear imaging testing would allow for an absorption of cost increases downstream and a move to encourage medical insurers to increase reimbursement rates for these types of procedures. Another possible outcome would be the increased development and use of alternative imaging techniques, increased demand-side management to use the product more efficiently, and increased development and use of alternative means of producing ^{99m}Tc, all where economically viable. A proper pricing structure would allow for the accurate assessment of the value of ^{99}Mo and its production by research reactors. The proper pricing structure would also allow for an accurate assessment of the required level of reimbursement rates.

One additional option for increasing prices for irradiation services and processing that had been raised in previous discussion was regulating prices. Under this option governments would set prices for the irradiation services and bulk ^{99}Mo to be paid in the global market at a rate that would pay for the full costs, including replacement costs and reserve capacity. However, if pricing was to be set on a commercial basis at a price that would be economically sustainable based on a clearly defined social contract, pricing regulation would not be necessary.

In addition, the regulation of prices across international borders presents its own difficulties that would likely be prohibitive to undertaking such regulation. International agreement is difficult to achieve where there are various considerations affecting different jurisdictions. For the production of ^{99}Mo there are a number of policy, technical and medical factors that are considered by governments. These would affect a government's position as to the level at which prices should be regulated. As well, prices can change dramatically from location to location (given decay rates, transportation costs, insurance reimbursement, etc.) and between suppliers (given different production techniques and practices). The different market structures (c.f. Chapter 2) create an additional difficulty as each structure provides the possibility of a different assessment of costs at different levels of the supply chain. As a result, it would be difficult to determine an accurate price that would be acceptable to all governments and their stakeholders. A more appropriate policy would be to define the social contract and set the appropriate pricing structure (not prices).

6.3 Options for reserve capacity

6.3.1 Introduction

As indicated in previous chapters, there is a requirement to have reserve capacity to account for WRC and ORC needs. Without this reserve capacity, the supply chain would not be reliable, creating ongoing uncertainties in the supply chain that would greatly affect the ability to deliver quality health care.

A key feature of reserve capacity is that the capacity must be available when required, with the full supply chain ready and able to respond. This means that the regulatory approvals for the development and transportation of the ^{99}Mo must be in place, as well as the approvals from the necessary health authorities to use the delivered ^{99}Mo/^{99m}Tc. Without these in place, the reserve capacity would not be useful. An additional key feature is that the reserve capacity must not be used or made available for use (e.g. offering its services) if it is not required. Otherwise the effect would be to create a situation where prices will be depressed below economically sustainable levels.

It seems that the best technical option for the provision of reserve capacity is for research reactors and processors to not use their maximum ^{99}Mo irradiation and processing capacity, rather producing a portion and maintaining a portion of the capacity free (e.g. leaving channels empty or a series of hot cells available) that could be used when it is required. This would provide compensation to the reactor and processor for the amount produced (including attributable capacity).

Spreading the reserve capacity over the supply network would provide depth and fairness in reserve. All producers would be producing regularly but operating at less than 100% of capacity. This method would allow the capacity to be ready and available with the regulatory approvals in place since production would already be occurring. Supply routes would be established and used and the reserve capacity would be able to be ramped up or down when required in a reasonably short time-frame to account for ORC needs.

In principle, supply chain participants that provide reserve capacity should be remunerated for holding reserve capacity unused, as well as when they are called upon to use the capacity. It would be expected that the level of remuneration for the reserve capacity would be less than the actual amount received for production since the provider would not be required to cover the variable costs of production. However, there would have to be sufficient remuneration to cover the attributable portion of capital costs and overhead costs of the facility. Otherwise, it would not be in the interest of the supplier to provide reserve capacity and they may decide to offer their full ^{99}Mo irradiation capacity, driving down market prices due to over availability.

In all cases, the provision of reserve capacity and the appropriate use of the capacity must be enforceable. If a supply chain participant promises to be able to produce when needed, they must *be able* to produce when asked; if they promise to not produce when not needed, they *must not* produce when not asked. Capacity set aside as reserve should not be able to be used if not needed, even if asked by a downstream industry player, to avoid the creation of a surplus in the market.

In terms of enforceability, there should be some mechanism to encourage the fulfilment of reserve capacity commitments. To ensure that the reserve capacity can be accessed on short notice to account for ORC requirements the agreement for the reserve capacity (whether contractual or through governments) should have penalty clauses that would be exercised if commitments are not met. Such clauses could be forfeiting rights to reserve capacity payments and/or required reimbursement for payments received. In the case of WRC requirements, similar action would have to be taken where a WRC supplier produces during times that do not respect the WRC agreement.

6.3.2 Co-ordination and communication

In order to ensure the proper management of reserve capacity and avoid the potential for price depression as a result of reserve capacity entering the market when not required, co-ordination of research reactor schedules and capacity used is essential. This co-ordination would also support efforts of the supply chain and the international community to provide a consistent supply of ^{99}Mo to the world market.

In addition, a key role of effective co-ordination is the reduction of transaction costs, supporting a better functioning supply chain. The co-ordination will support the use of available capacity without depressing prices. Without co-ordination, each reactor operator is determining their production schedule without the knowledge of the other capacity expected to be used. Co-ordination will help to eliminate this uncertainty and ensure that the appropriate production decisions are taken.

Currently, this co-ordination function is being undertaken by the Association of Imaging Producers and Equipment Suppliers (AIPES) and the voluntary participation of reactor and processor operators. These efforts have been successful in reducing the impact of the current shortage situation by co-ordinating operating schedules as much as possible to maximise production from the available reactors. This co-ordination function has not yet been tested in a situation where there is excess capacity in the market, where the role would be to ensure a limitation of production to meet but not exceed levels of demand. This action may be difficult as it is easier to co-ordinate to maximise capacity from limited sources than to hold back using capacity during times of excess to ensure sufficient reserve capacity.

As new reactors and processors enter the market they will have to voluntarily join these co-ordination efforts to avoid the situation of market power developing because of the excess capacity, which would result in depressed prices. Where new entrants are not willing to join the co-ordination efforts there will have to be supply chain pressure exerted to encourage their participation; currently there are no regulations requiring participation in co-ordination efforts. This pressure could take the form of downstream players not being willing to purchase from upstream supply chain participants that do no co-ordinate.

If this voluntary co-ordination does not work in a situation of reserve capacity, governments may have to consider requiring those supply chain participants that operate in their jurisdiction to participate in co-ordination efforts. For example, if a reactor operator does not co-operate in international co-ordination efforts, the government could enforce co-ordination through requirements in operating licenses; if a reactor in another country does not co-ordinate, governments could enforce "non-purchasing" by those processors and generators that operate within their jurisdiction. The value of such international co-ordination has been recognised as useful in other markets that require reserve capacity for the public benefit, such as in electricity, and the possible role of government to ensuring co-operation (IEA, 2005).

Such co-ordination is not without its challenges however. There will be a requirement for decisions to be made on the expected level of demand and the required level of reserve capacity. How the demand is met should be an iterative process (as is done now) that ensures that it is met while avoiding the situation of a surplus being produced. Commercial contracts between reactors, processors and other market participants would have to be respected, as well as any applicable competition regulation.

This co-ordination is important in efforts to address the management of the WRC, as the production schedules of reactors would be co-ordinated to ensure a consistent supply of ^{99}Mo. The co-ordination would also help with ORC such that it would be available when required. Of course, this co-ordination role should by no means be used to restrict available production to levels below expected demand in order to increase prices beyond what is commercially required. If it was suspected that co-ordination efforts were being used as such, consideration could be given to the creation of a watchdog agency that would examine whether demand was being met or, in the extreme case, an international-government sponsored co-ordination agency could be developed to fulfil the co-ordination role to ensure reserve capacity for a reliable supply of ^{99}Mo/^{99m}Tc.

Communication down through the supply chain and especially to the final user of the results of this co-ordination and in the event of any unplanned outages is essential for the proper management of reserve capacity. During the current shortage situation, the communication efforts have provided for the ability for supply chain participants to respond to impending shortages. This includes hospitals who have been able to readjust patient testing schedules to match supplies and through prioritisation of those tests that are most urgent.

These demand-side management efforts (similar to load shifting in electricity terms) can actually be used as a source of reserve capacity, reducing the need for WRC and for ORC. For the former, communication allows for end customers to adjust their patient scheduling to avoid procedures during those short periods where a reactor is shutdown between cycles. For the latter, demand-side management could also been seen as a viable form of reserve capacity during times of unexpected shutdowns. Of course, in both of these cases it is not expected that demand-side management would be the only reserve capacity called upon but it could be expected to contribute to efforts and reduce the overall need for reserve capacity and the associated costs.

It is clear that co-ordination and communication is essential to ensure the appropriate use of reserve capacity and to reduce impacts of unplanned outages or longer-term planned outages. Efforts undertaken by AIPES and the industry during the current shortage have proved to be effective in these regards. The co-ordination efforts also play a role in reducing the potential negative effects on prices of having "excess" capacity available. However, these efforts do not respond to the need to pay for reserve capacity, which will be discussed in the next section.

6.3.3 Government funding of reserve capacity

As noted in the previous section, reserve capacity related to the operational constraints of the reactors (WRC) would be well handled through the effective co-ordination of reactor schedules. Funding for WRC would only be necessary in the situation where a reactor would be required to be used only for part of its normal operating cycles. The funding for reserve capacity is principally important for the provision of ORC – that reserve capacity that serves the purpose of dealing with unplanned outages.

As with the remuneration for overall capacity, the view of governments on the social contract is relevant for the discussion on funding reserve capacity. As noted, government funding in the past supported the development and maintenance of reserve capacity. If governments deem that the current social contract maintains this role, given the desire for security of supply, then they would have to commit to funding the provision of ORC at reactors and any related processing facilities. As with the overall capacity, government funding could be provided unilaterally by the national government responsible for the reactor or through a form of international government funding.

Under both of these options, funding for reserve capacity could be supported through general taxes. Under unilateral actions, a government would financially support reserve capacity in their jurisdiction, but these taxes would be supporting reserve capacity that provides security of supply for the global market. An export tax on exported ^{99}Mo could potentially be used to help offset draws on the general tax base. Under international funding, countries would support an international reserve capacity fund (which could be coupled with the international ^{99}Mo production fund discussed in Section 6.2.2) through their general tax revenues. This international fund would provide support to the ORC that is deemed necessary to ensure reliable supply based on an n-1 criterion.

Another option would be to fund reserve capacity through a form of flat charge that could be applied to the ^{99}Mo/^{99m}Tc supply chain. Under this option, a flat levy would be charged on each curie of bulk ^{99}Mo sold or each curie of ^{99m}Tc used in a nuclear medicine procedure. This could be collected by each country's government and earmarked specifically to pay for reserve capacity in their country, transferred to reactors in other countries based on a valuation of the reserve capacity or transferred to the "international reserve capacity fund". With this levy there would need to be full transparency on the amount collected and where it went to ensure its public acceptance and its effectiveness in supporting the existence of reserve capacity. Again, it is recognised that the implementation of any international funding mechanism would be extremely difficult.

Under all of these scenarios for funding reserve capacity, if a government determines that it is in their social contract to support reserve capacity they have to be able to commit to *long-term, ongoing* funding for that capacity. In addition, government must be aware that they will have entered into a social contract with the global supply chain to ensure that the capacity is available, operational, has regulatory approval and will not be used except in situations where it is necessary.

6.3.4 Commercial funding of reserve capacity

If the government decides that the social contract does not include any obligation to fund reserve capacity, the capacity will need to be supported through commercial funding. As noted in the discussion on market failures, reliability of supply is not a public good according to the economic definition as a party can be excluded from reliability efforts of other parties. As a result, it seems to be the role of the private sector to ensure that they have access to a reliable supply network and outage reserve capacity.

Patients receive a benefit to having a reliable supply system through availability of nuclear medicine diagnostic testing. Therefore, patients and their health insurance systems should demand reliable supply and be willing to support it through paying a "reliability premium". This demand and remuneration should flow back up the supply chain, resulting in the upstream providing reserve capacity and being paid for it.

However, since patients generally do not have a say in the contracting decisions of hospitals with the upstream ^{99}Mo supply chain, the positive externalities of reliable supply may not be fully captured in the market and there may be a role for government intervention. Governments could require that processors and generator manufacturers have access to reactor and processor ORC, respectively, through a reserve capacity credit system. Under this system, processors and generator manufacturers would be required to provide credits to meet deemed ORC requirements established by government, based on the n-1 criterion discussed above. In order to obtain credits, there are two options that could be considered: auctions or private contracts.

Under the auction system, ORC credits would be offered by reactors to be purchased by processors, and by processors (processing capacity) to be purchased by generator manufacturers. There could also be offerings for ORC based on demand management actions related to the use of ^{99}Mo or ^{99m}Tc.[1] To account for operational cycles of reactors these offerings could be time sensitive, only being offered for certain periods throughout the year. At any point in time, the processors and generator manufacturers would be required to be in possession of enough credits to meet their reserve capacity requirements.

Under the private contract option, ORC credits would not be offered through a centralised auction system but rather through private contracts. These contracts could be organised as capacity options, where the purchaser pays upfront for the right to access production if required but there is no obligation to do so if not required. When the purchaser uses the capacity option, an additional payment would be paid based on units produced. Again, these capacity options could be provided as potential demand management actions.

With both of the commercial options the capacity market developed would ensure that there is not an over development of reserve capacity. The price agreed in the capacity market would reflect the costs of maintaining necessary reserve capacity and not more. In addition, it would send a strong price signal to capacity providers when there is not sufficient capacity, as prices would be expected to rise through competition for the available ORC credits. These commercial options for supporting ORC are relevant even if governments have decided that the social contract defines the provision of operating capacity as their role.

6.4 Conclusion

This study explains the supply chain for ^{99}Mo production and delivery, from the reactor to the end user – the patient. The supply chain is complex, with three market models and with many issues facing each stage and low profitability throughout the full chain. The market operation is impacted by large transaction costs, differing and changing social contracts, a mix of public and private players, domestic and international market considerations and a product that decays in a short timeframe. It is also a market where technical, policy and medical factors play a significant role in final market outcomes. It is clear that there is no one silver bullet to improve supply chain reliability.

From the information provided in this report, it is clear that the historical market development has had a significant impact on the current supply chain economics. The origin of ^{99}Mo as a by-product resulted in incomplete cost assessments that set the stage for an undervaluation of the ^{99}Mo irradiation services (and in some cases processing) during the commercialisation processes. The commercialisation process also created a situation of buyer market power that reportedly maintained low

1. These demand management offerings may require a locational criterion to account for decay effects of transportation of ^{99}Mo and ^{99m}Tc.

prices and resulted in seller market power in the processing and generator components of the supply chain. The market actions observed, such as price wars, were indications of possible barriers to entry, maintaining the market power of the incumbent processors and reinforced the uneconomical pricing structures. The low prices continued down through the supply chain, both creating their own issues and providing a feedback loop that perpetuated the low prices.

Overall, this historical development had the result of creating the current economic situation where the pricing structure does not provide for sufficient financial incentive to economically support ^{99}Mo production at existing research reactors or development of new production and processing capacity, which should be based on the use of LEU targets. The historical market development and pricing structure has other undesirable effects on the current economic situation, such as the potential inefficient use of ^{99}Mo and ^{99m}Tc and no recognition of the economic value of reserve capacity. In the past, the social contract supported this uneconomical operation at the reactor level, allowing the supply chain to exist even in an economically unsustainable condition.

As the report demonstrates, there are indications of a changing social contract by some producing nations, recognising the historical burden of financially supporting an industry that benefited the global market, especially health care systems of other jurisdictions. A changing social contract implies that the government would not financially subsidise the production of ^{99}Mo, requiring either a shutdown of these operations or altering the pricing structure such that upstream ^{99}Mo production could be done in a commercial manner.

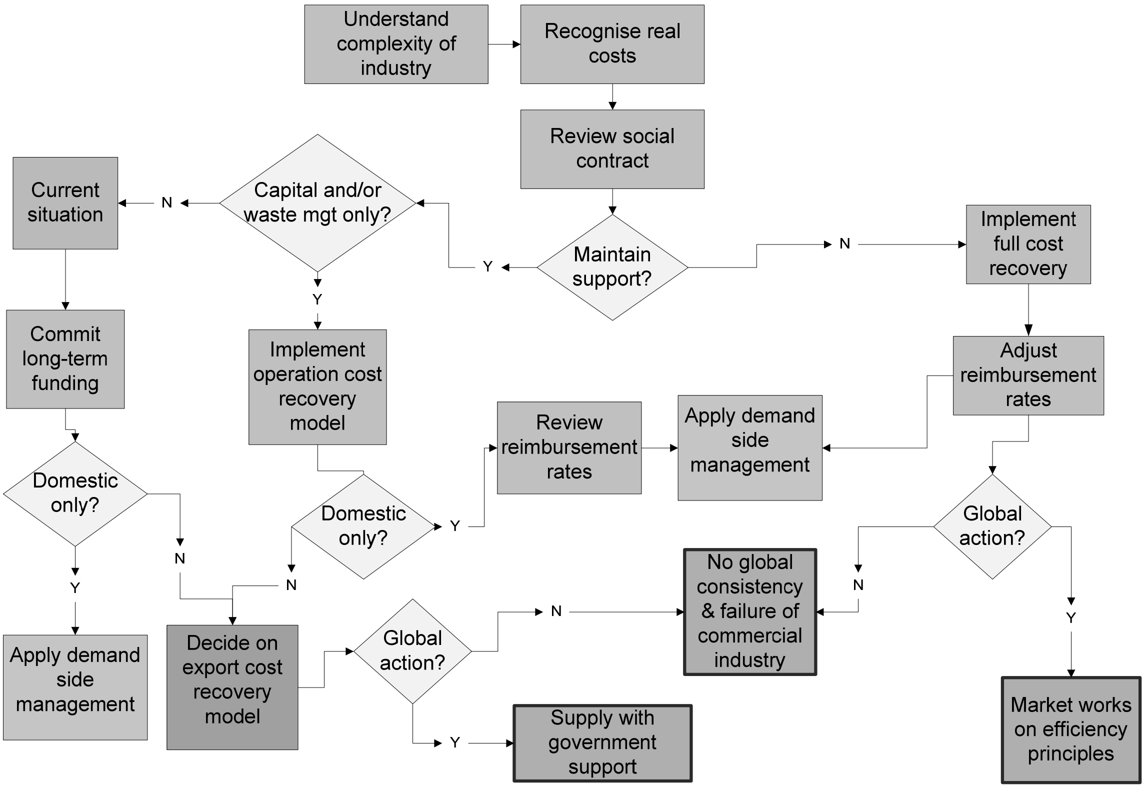
The report describes and provides an economic analysis that indicates the level of pricing increases that would be required to support ^{99}Mo production in a sustainable fashion. The analysis presented in this report demonstrates the minimal impact that rising prices would have on the end user. However, it is an impact that has to be recognised and accounted for through reimbursement rates.

The options provided in this chapter to address the economically unsustainable situation being faced by the supply chain are based on the economic assessment presented in this study. The principal question that needs to be determined before choosing which option(s) to use to fund overall capacity and reserve capacity is the direction of the social contract. Governments must decide their approach to financially supporting ^{99}Mo production and must be very clear and committed to that strategy, recognising the impact that commitment has on the market. If governments decide to continue to financially support the industry they must be willing and able to provide long-term funding, not only for the operation of the reactors for its ^{99}Mo production, but also for investment in ongoing maintenance to the current fleet of ageing reactors and finally in replacement capital for the reactors. If governments decide to change the social contract in a clear and committed manner, the current pricing structure has to be changed to set the industry on an economically sustainable footing. Figure 6.1 provides a visual representation of the decisions that need to be taken and the final expected outcomes of those decisions.

It is beyond the scope of this report to recommend to governments what form of social contract they should follow. That decision is based on economic factors certainly, but also on policy, medical and technological factors. It is up to governments to set their own priorities among these different considerations to determine the approach that they are willing and able to take. However, it should be recognised that the harmonisation of approaches would be beneficial to the long-term sustainability of the industry, reducing distortionary effects between jurisdictions.

This study was undertaken to provide a solid factual base of the ^{99}Mo supply chain, determine the failures in the market and provide options for governments to consider such that ^{99}Mo production is set on an economically sustainable path forward. The information presented in this report addresses these goals and will hopefully be beneficial by informing decision makers on the economics of the supply chain for ^{99}Mo production as they make the necessary decisions concerning this supply chain's future.

Figure 6.1: Proposed government decision tree on ^{99}Mo market sustainability



It is clear that there is no single silver bullet that will set the supply chain on an economically sustainable path to reliability. It is highly unlikely that all governments and supply chain participants will be able to quickly decide on the social contract in a harmonised fashion and take the required steps to alter the market to reflect that contract. However, the long-term goal should be to arrive at a supply chain that is economically sustainable and not reliant upon the use of HEU.

A number of step changes could be taken to move toward realising that long-term goal. Governments could set a transitional period where they would continue to financially support ^{99}Mo production and capacity development, gradually increasing the required amount of private sector contribution to these costs. Over a set period the proportion of private sector support would increase until the industry arrives at full-cost pricing. This process would provide time to allow for the market to adjust to the new pricing paradigm but would require committed government funding through the period.

At the same time, governments should undertake a review of reimbursement rates for nuclear medicine diagnostic tests. This review would be focussed on the final impacts of a transition to full-cost pricing and how to manage the communication during and after the transition (possibly including separate charging to end user for the isotope). Governments would have to decide if they wanted to shift financial support for these procedures from direct payments to reactors to increasing the reimbursement of the procedures. It is understandable that increasing reimbursement rates or hospital-specific isotope budgets takes time and, in some countries, requires the co-operation of multiple jurisdictions. As a result, the transition period to full-cost pricing is even more important to ensure continued support.

During this transition period, governments should work together to harmonise policies related to ^{99}Mo production support, reserve capacity and market models. This would be essential for being able to reach the long-term goal.

The supply chain participants need to realise that it is unlikely that the current economic model can support ^{99}Mo production in the medium to long term. Pricing models and contracts need to reflect the principles of economic sustainability discussed in this report. Supply chain participants need to support, not hinder, the required changes with the goal of sustaining the industry and ensuring a long-term reliable supply of ^{99}Mo for the benefit of patients.

The co-ordination and communication that has been going on has been essential to minimising the impacts of the current supply shortages. This needs to continue after the short-term crisis has passed. Governments and industry players need to support and participate in these efforts.

The NEA will support these efforts by playing an ongoing role in encouraging a reliable supply chain during and after the transition period. Its role is to provide important and relevant information, economic analysis and options/recommendations on the market situation. It will also continue to serve as a forum for producing nations to discuss the issues and work towards solutions through the HLG-MR.

Following up on the findings of this economic study, the NEA Secretariat will undertake further study to support the HLG-MR in discussing policy options. Through a series of background papers, the NEA Secretariat will examine different market models and approaches to ensure sufficient capacity, including reserve capacity. This would also include an evaluation of these approaches in the context of different delivery chains – large centralised systems or distributed systems – and how they could be delivered in this global market.

The changes discussed in this report are necessary for the economic sustainability of the ^{99}Mo/^{99m}Tc supply chain. There are a number of decisions that governments and industry players need to take, decisions that could have a long-term impact on the supply chain. This study provides the fact basis necessary to make informed decisions and provides options for discussion. Although big changes are necessary, a series of steps could lead the industry to the final goal of economical sustainability. However, if no further examination of the issues or if no action is undertaken, the supply chain will remain fragile and require significant, ongoing government financial support. Harmonised action is required and it seems that the supply chain and decision makers are becoming aware of the issues and are willing to take action.

This study supports the efforts to increase the reliability of the ^{99}Mo supply chain and the NEA is willing to continue its support to help ensure a reliable supply chain in the future. This study is one piece of the NEA's overall efforts on this important issue and attempts to reduce the market failure by providing information to decision makers.

Annex 1

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1. Company Association and Title at the time of input, from period of October 2009 to April 2010.

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Annex 2

METHODOLOGY

This annex provides additional detail on the calculations used to derive the numbers presented in the study. The methodologies described below cover the derivation of the current economic situation, the levelised unit cost of ^{99}Mo, the impacts of the price increases on the supply chain and the assumptions embedded in each of these derivations.

Exchange rates

For all calculations, national currencies were converted to EUR and USD using the 2009 average exchange rate[2], with EUR 1 equal to AUD 1.774; CDN 1.585; USD 1.395; ZAR 11.679; GBP 0.891; CHF 1.501.

Normalisation to six-day curies EOP

In order to be able to compare prices and values throughout the full supply chain, it was necessary to normalise all production units to ^{99}Mo six-day curies end of processing EOP. This normalisation contains a number of assumptions that will be described here. Depending on the value of the assumptions, the final values could be affected but not the final conclusions. However, it was necessary to normalise to provide a clear picture of the economics of the supply chain; often confusion between product units can affect the understanding of the supply chain and the conclusions that are drawn from that understanding. The assumptions used were based on actual experience in the supply chain but variation between participants would be expected.

In order to normalise for reactors and processors, half-life calculations were undertaken following the formula:

$$C_t = C_0 * e^{(-k*t)}$$

where $k = \ln(0.5)*(-1/t_{1/2})$ and:

C_t: number of curies at time "t";
$t_{1/2}$: the value of the half-life [65.9736 hours for ^{99}Mo and 6.0058 for ^{99m}Tc (Tuli, 2005)].

For the reactor and processing stages of the supply chain, it was assumed that the processing stage lasted 24 hours, including transportation time from the reactor and there was a 20% loss of product during processing, not including decay of product. This processing loss is not as a result of decay, but as a result of product loss during the separation and purification of the ^{99}Mo.

2. Values are taken from www.ecb.int (European Central Bank) for 2009 average.

For the generator stage, reported activity level was reported in gigabecquerels (GBq) calibrated either on the date of delivery or calibrated six days after delivery. In order to normalise to ^{99}Mo six-day curies, it was assumed that delivery of the generator occurred two days post processing (two days after the end of the processing component of the supply chain). GBq were translated to curies at the rate of 1 Ci = 37 GBq. The activity in the generators in curies then had a decay conversion factor applied to it to derive the activity for six-day EOP. For those generators calibrated on day of delivery, the curie activity in the generator was multiplied by the decay conversion factor 0.3648 recognising that delivery day was “day two” and thus a six-day curie EOP would be four days worth of decay smaller. The conversion factor is derived using the half-life formula above for t=96 hours (four days).

For those generators calibrated six days after delivery, the curie activity in the generator was multiplied by the decay conversion factor 1.6558 to account for the calibration day being “day eight” and thus a six-day curie EOP would be two days more product because six-day EOP is two days less of decay than day eight.

For the radiopharmacy stage, there are a number of assumptions that have to be made. Traditionally, when curies are discussed at this stage they are presented as curies of ^{99m}Tc. However, a curie of ^{99m}Tc is not the same as a curie of ^{99}Mo. This difference can lead to significant confusion when trying to compare the costs and revenues at this stage if a conversion is not undertaken to a common unit.

One of the most important assumptions that needs to be made is the amount of elutions that occur per day and the timing of those elutions. In addition, not all the ^{99m}Tc produced as a decay product of the ^{99}Mo can be eluted; normal elution can yield between 80 and 90% of the available ^{99m}Tc. To convert the quantity of ^{99m}Tc to ^{99}Mo we start with the following formula (from personal communication with an industry expert), which can be visually represented in Figure A.1 (assuming an elution efficiency of 90%):

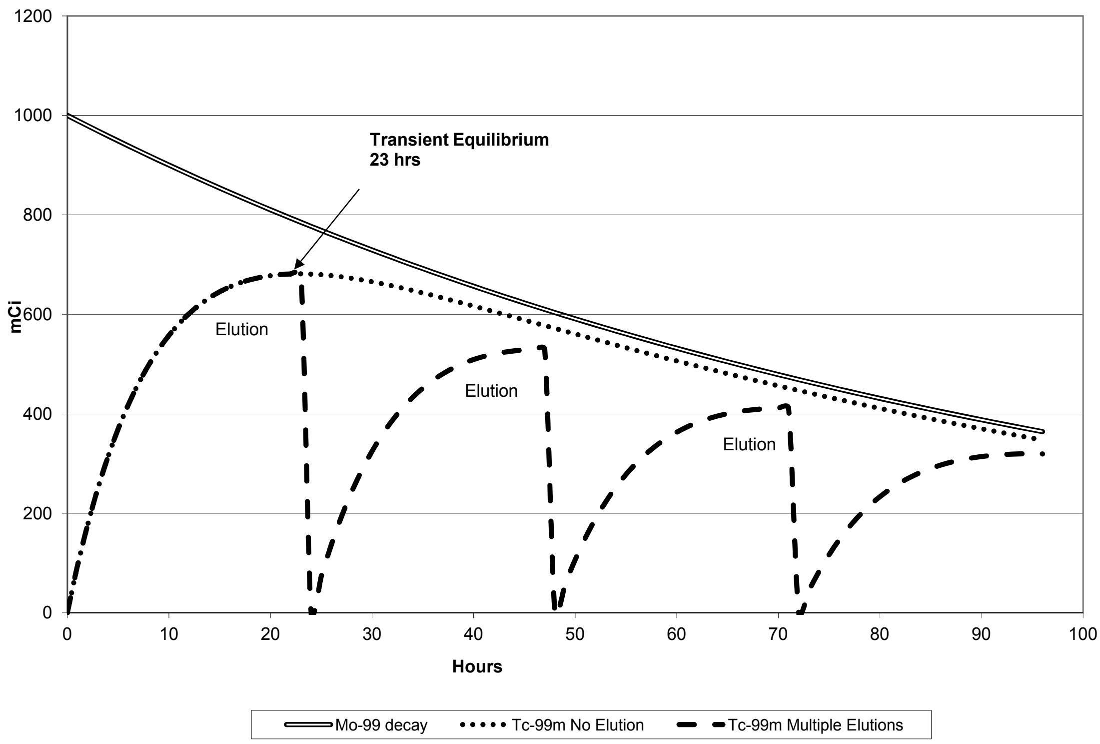
$$mCi\ {}^{99m}Tc = (mCi\ {}^{99}Mo)*(0.9537)*(1-({}^{99m}Tc\ df\ /\ {}^{99}Mo\ df))*(elution\ \%)$$

where:

mCi ^{99m}*Tc*:	amount of ^{99m}Tc eluted at any point in time;
mCi ^{99}*Mo*:	the remaining amount of ^{99}Mo at the time of elution (accounting for decay);
0.9537:	conversion ratio based on Bateman equation and ^{99m}Tc branching factor;
^{99m}*Tc df*:	decay factor based on the time from the previous elution;
^{99}*Mo df*:	^{99}Mo decay factor based on the time from the previous elution;
elution %:	elution efficiency since not all ^{99m}Tc is removed with each elution (value used was 90%).

A low estimate of potential yield is that a generator that is calibrated at noon on Friday will yield approximately 1.72 curies of ^{99m}Tc for every calibrated curie of ^{99}Mo if elutions occur once a day at six a.m., starting on Monday morning, for 12 days. At the upper end, a generator that is calibrated at noon on Sunday will yield approximately 4.65 curies of ^{99m}Tc for every calibrated curie of ^{99}Mo if elutions occur three times a day (at 2 a.m., 5 a.m. and 10 a.m.) starting on Monday morning, for 14 days. These values were confirmed by comparing with industry ^{99m}Tc generator yield charts. Of course, the high yield elution pattern described here will still result in some loss of ^{99m}Tc as not all the ^{99m}Tc that is produced will be eluted.

Figure A.1: ^{99}Mo/^{99m}Tc decay chart



These low and high values were used to convert ^{99m}Tc curies to ^{99}Mo six-day curies. The conversion process is done via two steps: 1) converting the ^{99m}Tc curies to ^{99}Mo curies calibrated in the generator, and then 2) converting the calibrated ^{99}Mo curies to six-day ^{99}Mo curies accounting for decay. These two steps are shown in the following equations:

$$X / Ef = Y \tag{1}$$

$$Y * Cf4 = Z \tag{2}$$

This becomes:

$$X*(Cf4/Ef) = Z \tag{3}$$

Where:

X: Amount of Ci of ^{99m}Tc (for example, for use in a patient dose);
Ef: The elution factor calculated above (1.72 for the low-efficiency situation; 4.65 for the high-efficiency situation);
Y: Amount of Ci of ^{99}Mo calibrated in the generator;
Cf4: Conversion factor for four days of ^{99}Mo decay (0.3647228504), based on the half-life formula presented above;
Z: Amount of Ci of six-day ^{99}Mo.

From equation (3), the value Cf4/Ef allows one to convert curies of ^{99m}Tc to six-day ^{99}Mo curies, and for the purposes of ease in this report is called the T-M conversion factor. For the low-efficiency elution scenario, the T-M conversion factor is 0.2120482; for the high-efficiency elution scenario, the T-M conversion factor is 0.078435.

As an example, if a medical procedure used 25 mCi of ^{99m}Tc eluted from a generator using the low-efficiency elution pattern, using equation (3) above, this would be equivalent to:

$$25 \text{ mCi of } ^{99m}\text{Tc} * 0.2120482 = 5.3 \text{ mCi of six-day } ^{99}\text{Mo}$$

This means that to elute 25 mCi of ^{99m}Tc, there would need to be a generator calibrated to at least 5.3 mCi of six-day ^{99}Mo.

In terms of the amount of the ^{99m}Tc eluted, it was assumed that the ^{99m}Tc was eluted three hours before the procedure to give time to prepare the radiopharmacy dose and transport it to the hospital. The half-life formula presented above was used to determine the amount of ^{99m}Tc that was required to be eluted to have the amount needed for the procedure.

The application of the normalisation process will be explained further below, where necessary.

Current economic situation

To derive the values on the current economic situation presented in Chapter 4, the starting basis was the information received by the NEA Secretariat from supply chain participants. Reactor irradiation costs were taken from reported values of operating costs per year, the proportion of those costs that were related to ^{99}Mo production and the total number of six-day curies EOP produced per year, such that:

$Costs_{reac}$ = (reporting operating costs*% related to ^{99}Mo production)/annual six-day Ci EOP

Annual six-day curies EOP either came from reported values where provided or was derived from the number of six-day curies EOP produced per week in the reactor times the number of weeks the reactor normally operated. As described above, this derivation included assumptions of 24 hours for processing (including transportation time from the reactor) and a 20% processing loss.

This calculation was done for every reactor and then the median value was taken. The median was used rather than the mean as any outlier would have a significant effect on the results if the mean was used. The limited number of data points means that one data point carries substantial weight and thus one outlier could drastically skew the results.

Reactor revenue per six-day curie was derived by using reported results for annual revenue divided by the annual six-day curies EOP. Again, for reporting in the study and for additional calculations the median value was used.

The same process was undertaken to derive the current economic situation for processors. There were some additional assumptions made given a lack of reported data. It was assumed that processors operated 52 weeks per year when deriving annual six-day curies EOP. If this is not accurate such that they process for less than 52 weeks, it would have the effect of increasing the operating costs and also the revenue per unit produced. In some cases, the values for cost or revenue per six-day curie used were reported directly and not calculated. In both of these cases, the median values of the calculated or reported results were used.

The process to derive the price of six-day curies EOP at the generator manufacturer level requires additional assumptions given differences in calibration dates. Interviewees reported the prices of various generators at different calibration levels, in gigabecquerels (GBq). These values were translated to price per curie (1 Ci = 37 GBq) at calibration date.

In order to get six-day curies, it was first assumed that the production of generators required 48 hours (including transportation time of the bulk ^{99}Mo to the generator manufacturing facility). Then the generator prices per curie had a conversion factor applied to them, derived from the half-life calculations described above. For those generators that were calibrated at the date of delivery, the conversion factor must represent the difference between the ^{99}Mo available at two days post EOP and that available six days post EOP. There is approximately 0.3647 curies of ^{99}Mo on six days EOP for each curie at two day EOP (based on decay calculations). Therefore, the price per six-day Ci is found by:

(Price/calibrated Ci)/0.36472285 = price/six-day curie EOP

For those generators that were calibrated at six days from the date of delivery, the conversion factor represents the difference between the ^{99}Mo available six days post EOP and that available eight days post EOP. There is approximately 1.656 curies of ^{99}Mo on six days EOP compared to a curie eight days EOP. Therefore, the price per six-day Ci is found by:

(Price/calibrated Ci)/1.655840548 = price/six-day curie EOP

Again, once these values were calculated for all available and provided data, the median value was taken to be used in presentation and further calculations.

For the radiopharmacy calculations, the values provided by radiopharmacy/hospital interviewees were the price of the ^{99m}Tc used in each procedure (the ^{99m}Tc does), the price of the cold kit and the ^{99m}Tc to the hospital or nuclear medicine department (the radiopharmaceutical dose) and the reimbursement rates per type of scan. For the first variable, the values were either reported directly or were derived from reported costs of generators divided by the reported normal number of patients served by the generator, along with high and low values of patients depending on the usage of the generator. For the second variable, prices were provided based on both generic cold kits and brand-name cold kits, along with different numbers of doses that can be prepared from a single cold kit vial. Calculations included both high and low values provided for doses and patients.

To calculate the value of the ^{99m}Tc used in a procedure in terms of six-day curies EOP of ^{99}Mo, it is necessary to translate curies of ^{99m}Tc to curies of six-day ^{99}Mo using the normalisation process described above. To replicate the procedures used in the industry, it was assumed that the ^{99m}Tc is eluted three hours before the procedure. The financial values provided for the ^{99m}Tc per procedure were then divided by the calculated curies of six-day ^{99}Mo.

From (3) above: X*(Cf4/Ef) = Z

(^{99m}Tc mCi$_{-3hrs}$ * T-M conversion factor)/1000 = Ci six-day ^{99}Mo

Then:

(EUR of ^{99m}Tc mCi$_{-3hrs}$ in dose/Ci six-day ^{99}Mo per dose) = EUR/Ci ^{99}Mo

T-M conversion factors are either 0.2120482 or 0.078435, depending on the assumption of elution timing. The amount of ^{99m}Tc used per procedure in the calculations range from 20 mCi to

30 mCi, which requires 28 to 42 mCi of ^{99m}Tc to be eluted to have those values three hours later. This means that each patient dose requires between 0.0022 and 0.009 six-day curies of ^{99}Mo.

These calculations were completed and the results presented in Table 4 of Chapter 4. The assumptions used in the methodology can have a very important effect on the prices calculated at every stage. For example, if there is an additional 12 hours added on to the assumed time of the processing stage, there will be an additional loss of about 12% of product, affecting the end value. Another example at the radiopharmacy stage: the amount of ^{99m}Tc obtained from a generator eluted three times a day with the first elution one day post calibration is three times that obtained from a generator eluted once a day with the first elution 66 hours post calibration (e.g. calibration at noon on Friday with first elution at 6 a.m. Monday).

Although it is recognised that the normalisation to six-day curies EOP and the determination of prices are complicated calculations and that the assumptions used can greatly affect the final results, it is necessary to do to be able to compare the economics of the full supply chain. As a result of the potential impact of the assumptions on the final economics, the numbers presented in Chapter 4 should only be considered indicative of the current situation.

For Table 5 in Chapter 5, the value of each stage of the supply chain as a segment of the final ^{99m}Tc dose provided to the hospital is presented. Then these calculated values of prices per six-day curies EOP at each stage of the supply chain were applied to the median values of reported ^{99m}Tc prices per procedure (EUR 10.20), radiopharmacy dose per procedure (EUR 39.14) and a weighted median of reimbursement rates per procedure (EUR 245.61) to demonstrate what percentage these values represent of the final ^{99m}Tc dose price, the price of the total radiopharmaceutical (i.e. the price of the cold kit and ^{99m}Tc in the dose provided for the patient) and of the final reimbursement costs. There can be a significant difference between procedures and between regions but using these median values allows for a reasonable presentation and development of conclusions.

Presenting a range of values may not provide any additional clarity to the economic situation being faced in the supply chain. For example, the median value of the price that reactors see per procedure is EUR 0.26 with a range from EUR 0.10 to 0.40. Using the full range for calculations could, in some cases, reveal information that is considered confidential given the few players in certain stages of the supply chain. In addition, it does not seem to add to the findings of the paper.

During the review of a draft version of this report, it was suggested that a simplified approach would be to take the current pre-shortage prices calculated, multiply this by the annual world demand for ^{99}Mo, then divide this value by 30 million to get the price per dose. The 30 million value is used in many texts as the number of annual ^{99m}Tc medical diagnostic procedures, with the original source being the summary of a 2007 workshop (NNSA, 2007). Using this approach would result in a price of irradiation *per procedure* of approximately EUR 0.90, which is about four times the price suggested in this report.

A problem with using this proposed approach is that behind the "simplicity" is uncertainty around the 30 million value, that could greatly affect the final results. In addition, the simplicity breaks down when one tries to apply this methodology downstream and still relies on the methodology described above.

First, the original 30 million figure is not cited so it is difficult to validate. For cardiac procedures, which are the majority of ^{99m}Tc based procedures, there are two doses required: for stress and rest tests. This immediately means that the 30 million procedures could actually mean between 30 and 48 million doses (assuming cardiac tests represent 60% of all procedures). This 48 million dose figure was derived independently by the Government of Canada and presented at the January 2009 NEA Workshop on Security of Supply of Medical Radioisotopes. At 48 million doses, the irradiation price per dose becomes about EUR 0.55 using this methodology. Other values for annual doses have also been presented, with ranges been observed from 25 million up to 65 million doses.

Applying this approach creates significant difficulties in being able to assess the full supply chain since global demand data is not readily available for each stage. If one were simply to recreate the calculation for each level of the supply chain, using the prices derived in the model for the six-day curies and then dividing by 30 million procedures, there would be an overestimation of prices since there is no accounting for the decay of the ^{99}Mo or the non-decay product loss at the various stages. This result was seen when the NEA Secretariat tried to recreate this approach, with calculated prices being significantly higher than reported prices seen in the market – pointing to an error within the assumptions of this approach.

As a result, the 12 000 six-day curies per week demand figure, which applies to the amount of six-day curies required from the reactor, would need to be replaced by global demand figures for each stage of the supply chain and then the values calculated in this report (using the methodology described above). However, while there are demand figures in regional markets, there are no comprehensive global demand figures that are currently available. They could be derived with a series of assumptions on ratios of regional consumption related to global consumption, but this again adds additional assumptions.

As a result, this proposed method adds additional layers of complexity and uncertainty on the methodology described above, without any clear indication of benefits from adding that complexity.

LUCM calculations

For the calculations undertaken for Chapter 5 the levelised unit cost of ^{99}Mo (LUCM) was developed. This methodology provides the constant real price of one six-day curie of ^{99}Mo that would be sufficient to cover the long-term average cost of producing the unit. This price is found by discounting the stream of revenue and costs associated with producing ^{99}Mo to the present (discount rates explained below). The costs that are included should reflect the full operational and capital costs of the research reactor (upgrades or replacement capital) that can reasonably be attributed to ^{99}Mo production.

The LUCM methodology is identical to Average Incremental Costs approaches used for calculating long-run marginal costs for other industries that require significant lumpy capital investments to meet incremental demand, such as the water industry (Marsden Jacob Associates, 2004). This methodology allows for the inclusion of a time period that is relevant for these types of industries where developed infrastructure lasts for an extended period of time and the payment structure must be able to adequately cover the average costs of production. The methodology used in this study follows the levelised cost of electricity methodology used in the *Projected Costs of Generating Electricity – 2010 Edition* (IEA/NEA, 2010). For the ^{99}Mo supply chain, the assumption is not a changing demand, however, but a changing supply availability.

The calculation of LUCM is based on the notion that the stream of discounted revenues must equal the stream of discounted costs, such that the investor breaks even. The discount rate used includes recognition of the necessary return on investment that would be required. In order for the investor to break even, the following formula is used:

$$\sum_t({}^{99}Mo_t * P_{99Mo} * (1+r)^{-t}) = \sum_t((Investment_t + O\&M_t) * (1+r)^{-t})$$

which is the discounted revenue on the left side, with discounted costs on the right hand side. This equation becomes the formula for LUCM through isolating the constant price variable:

$$LUCM = P_{99Mo} = \sum_t((Investment_t + O\&M_t)*(1+r)^{-t})/(\sum_t(^{99}Mo_t*(1+r)^{-t}))$$

Where:

$^{99}Mo_t$:	The amount of ^{99}Mo produced in year "t" in six-day curies EOP;
P_{99Mo}:	The constant price of ^{99}Mo in six-day curies EOP;
$(1+r)^{-t}$:	The discount factor for year "t";
$Investment_t$:	Investment costs in year "t";
$O\&M_t$:	Operations and maintenance costs in year "t".

O&M costs include the attributable portion of any O&M related to "common" infrastructure of the producing facility, including a portion of staff salaries, fuel, and repairs. Although there was no costs directly attributed to decommissioning of the research reactors, interviewees indicated that O&M costs included a set-aside for decommissioning. In addition, there is no specific variable for waste costs; interviewees indicated that short-term waste management costs were included in O&M costs reported but final waste management costs (long term) were not included as the final disposal or recycling plan was not established.

The methodology used in this study does not consider the impact of whether the infrastructure is financed through debt or equity or the impact of taxes on investment. These effects were ignored as the various structures of the supply chains and the different jurisdictions within which they operate would have created an unnecessary complication to the results. Given the point of using the LUCM within this study was to provide an indication of the necessary pricing structure for the economical production of ^{99}Mo and the effects on the end user, this approach seems acceptable.

The discounting and discount rates used in the LUCM methodology is used to reflect the opportunity cost of capital. Basically, this means that the investment must provide some form of return to the investor (whether public or private) as the invested funds cannot be used for other purposes. As a result, the discount rates can be seen to take into account the necessary financing costs.

For the reactor component of the supply chain, the discount rates used were five and 10% to reflect the lower risk-free nature of reactor investment that is often taken through some form of government enterprise. This enterprise normally provides less risk to investors and thus requires a lower risk premium than an investment by a commercial corporation.

In general, commercial enterprises operate the processing facilities for ^{99}Mo production. In these cases, there is a higher risk premium demanded to account for higher market risk. In this study, discount rates of 10 and 15% were used for the processing component of the supply chain.

In addition to investment risk, there is also demand risk that needs to be taken into account during investment decisions. This demand risk comes from the uncertainty around the long-term future of ^{99}Mo, and more specifically reactor-produced ^{99}Mo, when developing infrastructure that could potentially last 50 years or more. In a previous study a 50 year payback period was used (National Research Council, 2009), recognising the long-life of research reactors. However, during the interviews reactor operators consistently indicated that this payback was too long given the demand uncertainty. They indicated that a payback period for ^{99}Mo production must be in the range of 10 to 20 years. For the purposes of this study LUCM was calculated for payback periods of 10, 20 and 30 years.

The calculation of LUCM is based on the information received from industry participants during interviews. From the information on costs of capital and operations for various scenarios (described below) for reactors and processing a "representative" infrastructure component was developed. This was developed by using the median of values provided during the interviews. These values were sometimes based on experience with their own development plans and sometimes based on their assessments of costs. These costs and revenues of the reactor and processing facilities were determined and discounted to a common year (based on 2009 currency) and normalised to ^{99}Mo six-day curies EOP.

A number of capital investment scenarios were developed to compare different options available to the industry, based on the construction of a:

- Fully dedicated isotope reactor.
- A multipurpose reactor where 20% of operations are for ^{99}Mo production.
- A multipurpose reactor where 50% of operations are for ^{99}Mo production.
- An existing multipurpose reactor (no capital costs) with 20 and 50% of operations for ^{99}Mo production.
- The above scenarios with processing facilities.

For the reactors, it was assumed that production occurred for 37 weeks within the year. Given that capital costs are a significant portion of the LUCM, a longer production period would reduce the calculated LUCM where as a shorter production period would increase the LUCM. A 37 week production period is similar in time to that of the current largest contributors to the global supply chain.

For the investment options based on multipurpose reactors the relevant percentage was applied to the total reported operating costs and the share of the capital costs. For those options where there are no capital costs, the above LUCM formula was again used but excluding the "investment" variable.

For the reactor scenarios a development time of eight years was assumed (including upfront design work, etc.), with 5% of the funds spent in each of the first three years and 17% in each of the last five years. This follows the assumptions used for nuclear electricity costs in the IEA/NEA *Projected Costs of Generating Electricity – 2010 Edition* and is consistent with what was reported during interviews.

A further sensitivity analysis was undertaken on various production levels from the reactor: 1 500, 2 000 and 2 500 six-day curies EOP per week. The capital costs do not vary significantly between production levels with experience showing that less than EUR five million are required for the installation of additional ^{99}Mo irradiation rigs. As a result, the main impact from this analysis was that increased production reduced the LUCM costs. In the study only the results of the highest production level were reported as it was the most economically viable option and is more reflective of the major producing reactors.

For determining LUCM at the processing stage, the processing facility was assumed to be able to process the reactor output (2 500 six-day curies per week EOP for a period of 37 weeks) with additional input from other reactors to be able to undertake processing for 52 weeks of the year. The LUCM from the various reactor scenarios (at a 5% discount rate) was used as an input cost to the processor, such that the LUCM formula used is:

$$LUCM_{proc} = P_{99Mo} = \sum_t((Investment_t + (LUCM_{reac} * {}^{99}Mo_t) + O\&M_t)*(1+r)^{-t})/(\sum_t({}^{99}Mo_t*(1+r)^{-t}))$$

where:

${}^{99}Mo_t$:	The amount of ^{99}Mo produced in year "t" in six-day curies EOP;
P_{99Mo}:	The constant price of ^{99}Mo in six-day curies EOP;
$(1+r)^{-t}$:	The discount factor for year "t";
$Investment_t$:	Investment costs in year "t";
$LUCM_{reac}$:	LUCM from the various reactor scenarios (at a 5% discount rate);
$O\&M_t$:	Operations and maintenance costs in year "t".

For the supply chain participants downstream from the processing facility data was not available for investment or O&M costs. As a result, it was not possible to undertake LUCM calculations for these downstream stages. However, it was necessary for the study to provide an assessment of the effects of the economically sustainable pricing on the downstream components.

As a reasonable proxy, the price changes that were required in the upstream supply chain were applied to the "current economic situation" that was presented in Chapter 4. The difference between the current economic situation reactor or processing price and the LUCMs were applied to the downstream components to see the final effects. This proxy assumes that those price increases that were observed would be able to be passed through the supply chain prices at 100% of the absolute value increase (not the percentage increase).

These calculated LUCM values and downstream results were then applied to the various imaging procedures, reimbursement rates, dose costs, etc. to obtain the final impact on the end user, using median values.

Annex 3

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Annex 4

ACRONYMS

AECL	Atomic Energy of Canada Limited
AIPES	Association of Imaging Producers and Equipment Suppliers
ANSTO	Australian Nuclear Science and Technology Organisation
CEA	Commissariat à l’énergie atomique et aux énergies alternatives
Ci	Curie
EANM	European Association of Nuclear Medicine
EOP	End of the processing stage of the supply chain
FDIR	Fully dedicated isotope reactor
GBq	Gigabecquerels
HEU	Highly enriched uranium
HLG-MR	High-level Group on the Security of Supply of Medical Radioisotopes
IAEA	International Atomic Energy Agency
IEA	International Energy Agency
IES	Intelligent Energy Systems
IRE	Institute for Radioelements
LUCM	Levelised unit cost of ^{99}Mo calculations
LEU	Low enriched uranium
NEA	Nuclear Energy Agency
NRG	Nuclear Research & Consultancy Group
OECD	Organisation for Economic Co-operation and Development
Proc	Processing facilities
ORC	Outage reserve capacity
SPECT	Single photon emission computed topography
WRC	Weekly reserve capacity

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