The Supply of Medical Radioisotopes

Market Impacts of Converting to Low-enriched Uranium Targets for Medical Isotope Production









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Foreword

Following the shortages of the key medical radioisotopes, molybdenum-99 (99Mo) and its daughter technetium-99m (99mTc), the OECD Nuclear Energy Agency (NEA) created the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). Since 2009, this group has identified the reasons for the isotope shortages and developed a policy approach to address the challenges to a long-term secure supply of these important medical isotopes.

In addition to the ongoing concerns related to long-term reliability, all current long-term, major ⁹⁹Mo-producing countries have agreed to convert to using low-enriched uranium (LEU) targets for the production of ⁹⁹Mo. This decision was made based on important non-proliferation reasons; however, the conversion will have potential impacts on the global supply chain, both in terms of costs and available capacity.

Recognising that conversion is important and will occur, and also recognising the need to ensure a long-term, secure supply of ⁹⁹Mo/^{99m}Tc, the NEA and its HLG-MR undertook a study to quantify the expected capacity and cost impacts of LEU-target conversion. The study also looks at potential policy options to help ensure a reliable supply of ⁹⁹Mo/^{99m}Tc produced without highly enriched uranium (HEU), consistent with the time frames and policies of the HLG-MR.

This report describes the market impact study and its findings, and briefly discusses the need for policy actions.

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 judgments 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 ⁹⁹Mo-producing reactor operators, processors and generator manufacturers. The NEA acknowledges the input and participation of the expert working group (identified in Annex 1), HLG-MR members and other supply chain participants who provided information and vetted results. Their input and participation was essential for the successful completion of this report. The NEA greatly appreciates the participation of these stakeholders.

This report was written by Chad Westmacott and Ron Cameron of the NEA Nuclear Development Division. Detailed review and comments were provided by the HLG-MR and medical radioisotope stakeholders.

Table of contents

Execut	ive summary	7
1. Intro	oduction	15
	Purpose of the study	
	HEU use in the ⁹⁹ Mo/ ^{99m} Tc supply chain	
	Overview of the NEA study on LEU-target conversion impacts	
1.4. S	Sources and uncertainties around information	18
2. Capa	acity impacts of LEU-target conversion	19
	Framework and methodology of capacity modelling	
	Reference capacity data	
	Economic- and technology-challenges situations	
	Capacity impact elements	
	Capacity impacts from converting to LEU targets	
	Comment on high-density targets	
	Conclusions regarding the expected capacity impacts from LEU-target conversion	
3. Cost	impacts of LEU-target conversion	37
	Framework and methodology of economic modelling	
3.2. E	Economic modelling scenarios	39
	Cost impact elements	
	Cost impacts from converting to LEU targets	
3.5. C	Conclusions regarding the expected cost impacts from LEU-target conversion	50
	clusions on the market impacts of converting to the use of LEU targets	- 4
	Mo production	
Referei	nces	52
Annex	res	
1. Ex	pert working group	53
2. Ca	pacity impact elements	57
3. Co	st impact elements	61
List of	figures	
	•	_
E1.	Capacity model from impacts to outcomes	9
E2.	Current and select new entrants processing production of ⁹⁹ Mo vs. demand under the economic-challenges situation	11
1.1.	Major participants and distribution channels of the ⁹⁹ Mo supply chain	
2.1.	Capacity model framework	

2.2.	Example of assessing capacity impacts from LEU-target conversion	20
2.3.	Capacity model from impacts to outcomes	21
2.4.	Current irradiator capacity vs. demand: impact scenarios	30
2.5.	Current and all potential new irradiator capacity vs. demand: impact scenarios	30
2.6.	Current and select new irradiation capacity vs. demand: impact scenarios under a technology-challenges situation	31
2.7.	Current and select new irradiation capacity vs. demand: impact scenarios under an economic-challenges situation	
2.8.	Current processing production vs. demand: impact scenarios	33
2.9.	Current and all new potential processing production vs. demand: impact scenarios	33
2.10	Current and select new processing production vs. demand: impact scenarios under a technology-challenges situation	34
2.11.	Current and select new processing production vs. demand: impact scenarios under an economic-challenges situation	35
3.1.	Example of assessing cost impacts from LEU-target conversion	38
3.2.	Non-HEU- vs. HEU-based ⁹⁹ Mo production: high infrastructure impact scenario and technology-challenges situation	49
List of	tables	
List of E1.	tables Range of percentage increases in costs of a 6-day curie of ⁹⁹ Mo from the full-cost recovery reference case as a result of LEU-target conversion	13
	Range of percentage increases in costs of a 6-day curie of 99Mo from the	
E1.	Range of percentage increases in costs of a 6-day curie of ⁹⁹ Mo from the full-cost recovery reference case as a result of LEU-target conversion	23
E1. 2.1.	Range of percentage increases in costs of a 6-day curie of ⁹⁹ Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 23
E1. 2.1. 2.2.	Range of percentage increases in costs of a 6-day curie of ⁹⁹ Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 23 24
E1. 2.1. 2.2. 2.3.	Range of percentage increases in costs of a 6-day curie of ⁹⁹ Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 23 24 25
E1. 2.1. 2.2. 2.3. 2.4.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41
E1. 2.1. 2.2. 2.3. 2.4. 3.1.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41
E1. 2.1. 2.2. 2.3. 2.4. 3.1. 3.2.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41 42
E1. 2.1. 2.2. 2.3. 2.4. 3.1. 3.2. 3.3.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41 42 44
E1. 2.1. 2.2. 2.3. 2.4. 3.1. 3.2. 3.3.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41 42 45
E1. 2.1. 2.2. 2.3. 2.4. 3.1. 3.2. 3.3. 3.4. 3.5.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41 42 45 46
E1. 2.1. 2.2. 2.3. 2.4. 3.1. 3.2. 3.3. 3.4. 3.5.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41 42 45 46
E1. 2.1. 2.2. 2.3. 2.4. 3.1. 3.2. 3.3. 3.4. 3.5. 3.6.	Range of percentage increases in costs of a 6-day curie of 99Mo from the full-cost recovery reference case as a result of LEU-target conversion	23 24 25 41 42 45 46 46

Executive summary

Key findings

- LEU-target conversion is important for long-term security of supply of the key medical isotopes molybdenum-99 and technetium-99m (99Mo/99mTc).
- LEU-target conversion does reduce the available irradiation and processing capacity, but it is not the expected cause of potential long-term shortages.
- Long-term shortages could occur if the unsustainable economic situation in the ⁹⁹Mo/^{99m}Tc supply chain does not improve. However, under a situation of ongoing economic challenges LEU-target conversion could accelerate long-term shortages.
- Converted LEU-based ⁹⁹Mo is more expensive than HEU-based ⁹⁹Mo.
- The LEU-target conversion price impact is an increase of less than 8% from the radiopharmacy, but impacts are greater upstream.
- There could be a role for governments to encourage LEU-target conversion and consumer uptake of non-HEU-based ⁹⁹Mo/^{99m}Tc to ensure long-term supply security.

Introduction

Following the shortages of the key medical radioisotopes molybdenum-99 (⁹⁹Mo) and its daughter technetium-99m (^{99m}Tc), the OECD Nuclear Energy Agency (NEA) created the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). Since 2009, this group has identified the reasons for the isotope shortages and developed a policy approach to address the challenges to a long-term secure supply of these important medical isotopes.

In addition to the ongoing concerns related to long-term reliability, all current long-term major ⁹⁹Mo-producing countries have agreed to convert to using low-enriched uranium (LEU) targets for the production of ⁹⁹Mo. This decision was made based on important non-proliferation reasons; however, the conversion will have potential impacts on the global supply chain – both in terms of costs and available capacity.

Furthermore, it is important to realise that there may not be global access to a long-term supply of highly enriched uranium (HEU) for 99Mo/99mTc production in the mid-term. As a result, long-term security of supply of these important medical isotopes requires the move to non-HEU based production, through converting to LEU targets for 99Mo production in existing (and new) producers and through the use of new technologies.

Recognising this situation and cognisant of the need to ensure a long-term secure supply of ⁹⁹Mo/^{99m}Tc, the NEA and its HLG-MR undertook a study to quantify the expected capacity and cost impacts of LEU-target conversion. In addition, the study looked at

^{1.} For example, the American Medical Isotopes Production Act of 2011 (S.99), which has passed the US Senate and was in front of the US House of Representatives at the time of writing, includes provisions to restrict the export of HEU from the United States for the purposes of medical isotope production, seven years after enactment.

potential policy options to ensure a reliable supply of ⁹⁹Mo/^{99m}Tc produced without HEU, consistent with the time frames and policies of the HLG-MR.²

The market impact study

To increase the understanding of the economic and supply chain impacts of converting to using LEU targets for ⁹⁹Mo production, the NEA examined the impact on individual facilities to develop an assessment of the impacts on the whole supply chain. A capacity model and an economic model of the supply chain were developed and used to assess the impact of conversion on global supply availability and costs, in comparison to a reference case.

Information for the assessment came from an expert working group (made up of major supply chain participants), which met for two workshops. This information was supplemented by interviews with individual supply chain participants by the NEA, and NEA's own knowledge of the supply chain.

Capacity modelling

The capacity modelling started with ⁹⁹Mo capacity and production reference data on all current and potential irradiators and processors (as of June 2012) and then applied the experienced and expected impacts of LEU-target conversion on various elements affecting capacity. The model is time and facility specific, thus the degree of the impact can vary from facility to facility. This recognises that facilities can be affected differently depending on their particular situation.

The NEA modelled three different impact scenarios on an "all-in" situation, as well as two different "challenges" situations. The three impact scenarios applied high, low and very low impacts to the reference data of the three situations. Under the high (or low) impact scenario the NEA applied the highest (or lowest) expected facility-specific impact on production capacity. The very low impact scenario assumes that the economic returns from ⁹⁹Mo irradiation services improves significantly such that reactors, where possible, displace other irradiations in order to return ⁹⁹Mo irradiation capacity to pre-conversion levels.

These impact scenarios were then applied to the three "situations":

- "All-in" situation: shows the expected impact from LEU-target conversion on all
 the current and potential irradiators and processors, according to the facilityspecific time schedules of operation, conversion (if applicable) and shutdown.
 Some current and potential irradiators and processors are already using, or will
 start operations using, non-HEU based methods and therefore they will not
 experience "conversion" impacts.
- **Economic-challenges situation:** starts from the "all-in" situation and then assumes that the unsustainable economic situation continues, such that only projects that could be constructed and operate without commercial funding proceed. This means, for example, that expected projects in the Netherlands, South Africa and the United States, among others, do not proceed. For the economic-challenges situation, the high and low impact scenarios were applied.
- **Technology-challenges situation:** starts from the "all-in" situation and then assumes that new technologies and new entrants face a higher risk in implementing their

^{2.} For more information on the HLG-MR policy approach for a long-term secure ⁹⁹Mo supply, refer to OECD/NEA (2011a).

^{3.} For more information on the economics of the supply chain, refer to OECD/NEA (2011a and 2010).

various projects. In this situation it is assumed that there is only one US project that proceeds, that Russian and Korean production are delayed, and that production from some expected projects does not occur. For this technology-challenges situation, the three impact scenarios (high, low and very low) were applied.

The capacity impact elements that were applied using the three scenarios on the three situations affected the capacity and production at the irradiators and processors (see Figure E1). The capacity and production scenarios were then compared to expected demand to determine if the impacts of LEU-target conversion affected ⁹⁹Mo supply reliability. To account for the need for outage reserve capacity⁴ (ORC), three different demand forecast situations were evaluated: one with no ORC requirements; one with low requirement for meeting ORC levels; and one with high requirements for meeting ORC levels.

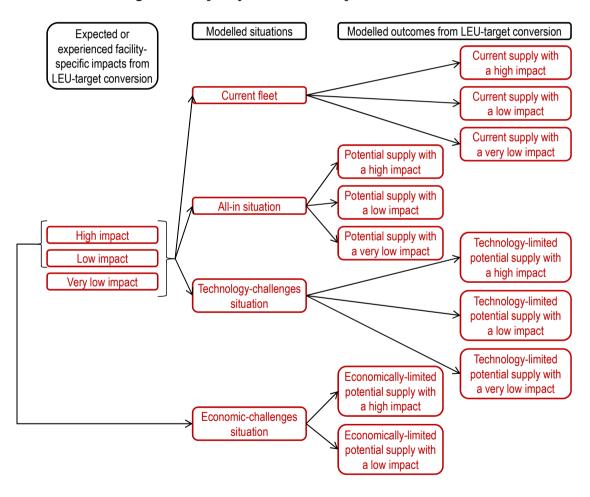


Figure E1. Capacity model from impacts to outcomes

^{4.} Outage reserve capacity is required to ensure a reliable supply chain by providing back-up irradiation and/or processing capacity that can be called upon in the event of an unexpected shutdown [see OECD/NEA (2011a) for more information]. A reduction in ORC increases the risk of supply shortages, particularly during any unplanned outage situation.

It was agreed by the expert working group that there were no incremental capacity impacts on generator manufacturers or further downstream. However, it was recognised that generator manufacturers face logistical challenges during the conversion process from keeping production of generators from HEU- and LEU-based ⁹⁹Mo separate until they receive health approvals.

For the reactors, the most important capacity element was the reduction of ⁹⁹Mo production as a result of lower uranium-235 (²³⁵U) content in the targets.⁵ The expected impacts range from no reduction in irradiation capacity up to a reduction of 50%, depending on the facility. In addition, there is a corresponding reduction in available outage reserve capacity. It is also expected that one irradiator will require one year downtime in order to convert to using LEU targets. As noted, these impacts were applied on a facility-specific basis to the reference data for the various impact scenarios to determine the impacts.

For the processors, the key incremental impact was the changed processing procedure, which requires a longer time in most cases; the lower ²³⁵U content was an effect at the reactor stage that flowed through to the processors. The changed processing procedure results in the reduction of produced bulk ⁹⁹Mo from increased decay, among other impacts. The expected reductions range from no impact up to 60%, depending on the processing facility. Outage reserve capacity will be affected at the processing stage during the conversion period since processors will generally operate both HEU- and LEU-based ⁹⁹Mo processing lines until consumer uptake allows for a switch to 100% LEU-based production. However, once production is completely from LEU targets, processing outage reserve capacity should be fully available.

Results: capacity impacts

Applying the range of expected facility- and time-specific impacts to the reference data illustrates the likely available global capacity and production of ⁹⁹Mo irradiators and processors. For both **current** irradiation capacity and processing production, conversion to using LEU targets does not create new long-term supply shortages; the shortages shown are already expected given the final shutdown of a number of the existing facilities over the next decade. However, LEU conversion does intensify the shortages by reducing available capacity.

Under the "all-in" and technology-challenges situations, supply is sufficient over the time period to 2030 for both irradiator capacity and processor production. LEU-target conversion does reduce effective capacity and production, but not to levels that are of concern (i.e. below expected demand). However, there are two periods (2014 and 2017) where processor production under the technology-challenges situation is tight compared to demand with a high ORC requirement.

Of significant concern, though, are the results of the impact scenarios on the economic-challenges situation. For both irradiation capacity and processing production, supply is not sufficient to meet demand in the long term under the economic-challenges situation (see Figure E2). Under this scenario, LEU-target conversion accelerates the expected long-term shortages, creating a significant shortfall in 2017 resulting from one

^{5.} It should be noted that the capacity study only examined the impacts of converting using "phase 1" targetry – targets that are market or near-market ready. These targets have a higher density of ²³⁵U, but are not high-density targets in the sense of "phase II" targetry (which would include such advanced target types as high-density foil targets). It may take a number of years before phase II targets are commercially viable and available. It was deemed by the expert working group that the decision to convert to phase II targetry would be a business decision based on whether the expected benefits of the added production would outweigh the expected costs of converting to using the advanced high-density targets.

irradiator that indicated that they need to be shut down to undertake conversion. After 2018 and until 2025, LEU-target conversion keeps supply below the high-demand curve; by 2027 all the scenarios (including the reference case) drop below the lowest demand curve.

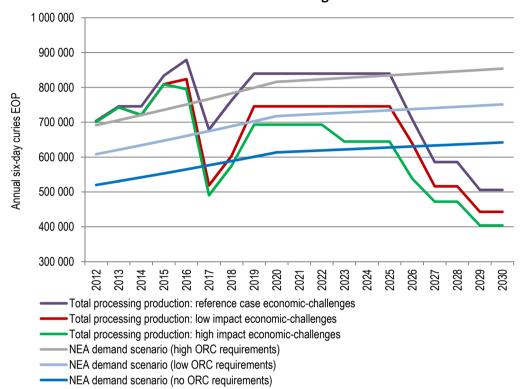


Figure E2. Current and select new entrants processing production of ⁹⁹Mo vs. demand under the economic-challenges situation

The capacity impact modelling shows that, while LEU-target conversion does reduce available capacity and production, the main concern remains the unsustainable economic condition facing the supply chain. In terms of capacity impacts, if the economic situation in the supply chain were to improve sufficiently to support adequate investment, LEU-target conversion should not create insecurities in 99Mo supply.

Cost modelling

The cost modelling, as with the capacity modelling, started with a reference case for each currently operating ⁹⁹Mo irradiation or processing facility, as well as two new entrants: the FRM-II and Russian reactors. As the point was to determine the impact on costs from LEU conversion, other new entrants were not modelled as they are planned to be non-HEU production facilities.

The facility-specific reference cases were developed with data provided by supply chain participants during the NEA economic study (OECD/NEA, 2010) and updated during this study. Where direct information was not provided, the NEA made assumptions about costs based on the results of the economic study. Using this data, the reference cases

^{6.} See OECD/NEA (2011a and 2010) for more information on the unsustainable economic situation in the upstream supply chain.

were developed using the levelised unit cost of 99Mo (LUCM) methodology used in the economic study.

The NEA modelled the impacts by applying the high and low expected cost impact values to the reference case for the specific facility, based on the specific timelines of that facility for operation, conversion and shutdown. The high and low expected values were coupled to the related capacity scenarios to undertake the LUCM modelling (which takes into account changes in production). In general, high infrastructure cost values were applied to the low capacity impact scenario, as high upfront investment should minimise the capacity impact from conversion.

Once the LUCM modelling for the various scenarios was undertaken for each facility, the top, bottom and median impact values were applied to the median of the reference cases. This provided a range to demonstrate the differences that exist in the supply chain, without publicly identifying the impacts on a specific facility.

For the processor facility-specific LUCM modelling, the irradiators' LUCMs from the various scenarios were used as an input cost (i.e. the cost of providing irradiation services) for the relevant processor scenario. The range of processors' LUCM changes was then applied down the supply chain to determine the resulting changes at each stage. As in the economic study, this assumes a 100% cost flow through down the supply chain, and allows for the clear assessment of the impacts of LEU-target conversion cost changes through the supply chain and on the end payer.

As with the capacity modelling, the expert working group determined that the main incremental cost impacts would be at the irradiator and processor stages of the supply chain.

The cost impacts started at the uranium and target supply stages, which were modelled as processing cost increases as processors are, in general, responsible for paying for targets. In this first stage, it was recognised that there would be an impact on the final cost of targets and on the research, development and qualification for these LEU targets.

For irradiators, the incremental cost impacts were related to the necessary infrastructure changes in the reactor. It was identified that either new irradiation rigs would be needed or they would have to be modified (to handle the different geometry of the new LEU targets), depending on the facility and the processor requirements. Cost impacts from reduced production (including required downtime) were calculated via the LUCM calculations, and other identified costs impacts (such as regulatory approvals) were included in processor conversion project costs as irradiators indicated that they would pass the costs on to processors.

Processors face a number of incremental cost impacts, including costs from: modifying or developing new containers for transporting irradiated LEU targets (which also includes regulatory approval costs for the containers); infrastructure changes required to process changed targets and to increase waste storage; operating impacts; and supporting generator manufacturers in obtaining health regulatory approvals. Costs for these various cost impact elements vary across facilities and sometimes within the facilities themselves (in terms of high and low expected or experienced impacts).

Results: cost impacts

Applying the range of expected facility- and time-specific cost impacts of the various impact elements to the facility reference case gives the expected results of the cost of converting to LEU targets for ⁹⁹Mo production. It should be noted that the reference case that is used for comparison is based on full-cost recovery of operations; original capital costs are assumed to be fully amortised at the reactors and processing facilities that are converting, and thus are not included.

The following table shows the range of expected impacts from the various stages of the supply chain, when compared to the reference case of full-cost recovery. It is clear from this study that LEU-based ⁹⁹Mo from a converted facility is more expensive than HEU-based ⁹⁹Mo from the same facility. The price increase, however, is less than 8% from the radiopharmacy, but is higher upstream.

Table E1. Range of percentage increases in costs of a 6-day curie of ⁹⁹Mo from the full-cost recovery reference case as a result of LEU-target conversion

	% increase in costs: range
From irradiator	3.6-36.8
From processor	6.3-42.8
From generator manufacturer	5.4-36.6
From radiopharmacy	1.1-7.8

Comparing the values in this table to those presented in the previous economic study related to the move to full-cost recovery (OECD/NEA, 2010) shows that the impacts from moving to full-cost recovery under any capital replacement scenario are expected to be larger than the impacts of LEU-target conversion. This means that LEU-based ⁹⁹Mo from a converted facility may in fact be less expensive than ⁹⁹Mo from a new facility with full-cost recovery (depending on the infrastructure scenario).

The price increases translate to a reasonably small increase in relation to the reimbursement rate of the final diagnostic procedure. Based on a reimbursement rate of EUR 245 (a weighted average of global rates), the value of the radiopharmaceutical ^{99m}Tc increases from 4.46% of the reimbursement rate up to maximum of 4.8%. This translates to less than a EUR 1 increase⁷ on a EUR 245 test. It is necessary to realise, however, that this small increase must be funded because it is important to support the changes necessary upstream. In a separate paper, the NEA has discussed how unbundling the reimbursement for the isotope from the radiopharmaceutical and the diagnostic procedure could be a tool for greater transparency on necessary price changes (OECD/NEA, 2012b).

Need for policy action

Current experience in the supply chain, unfortunately, seems to demonstrate that end payers have difficulty supporting even small changes in price. However, this support is necessary to ensure that the supply chain will have sufficient resources (and motivation) to convert to producing ⁹⁹Mo from LEU targets and to have sufficient capacity to ensure security of supply. In addition, the capacity study demonstrated that over the first few years of the conversion period, HEU-based ⁹⁹Mo will be available in sufficient quantities, and thus, with the price differences, it may be difficult to sell LEU-based ⁹⁹Mo. These two factors point to a need for governments to encourage non-HEU based ⁹⁹Mo production and consumer uptake, while always respecting the HLG-MR policy approach to ensure a long-term secure supply of ⁹⁹Mo/^{99m}Tc (OECD/NEA, 2011a).

The HLG-MR has developed a discussion paper that provides various options for governments to consider (OECD/NEA, 2012a). Broadly speaking, the policy options examined and described in that document have one of three roles: making the option of purchasing or producing non-HEU-based ⁹⁹Mo and/or ^{99m}Tc more attractive; making the

^{7.} It is important to note that these values are based on global averages; the values may vary between procedures and regions such that the isotope cost increases could be much higher for specific procedures or in certain regions.

option of purchasing or producing HEU-based ⁹⁹Mo and/or ^{99m}Tc less attractive; or limiting access to HEU-based ⁹⁹Mo/^{99m}Tc.

While countries may have differing views on the various options, given their own economic, regulatory, or political situation, the discussion paper provides a brief review of the options from the starting point of the HLG-MR policy approach to achieving a long-term reliable supply of ⁹⁹Mo/^{99m}Tc.

Conclusion

The NEA study, developed in collaboration with experts from the supply chain and with the HLG-MR, demonstrates the expected capacity and cost impacts of converting to using LEU targets for the production of ⁹⁹Mo. The findings show that LEU-target conversion will have an impact on capacity, but will not be the major factor that causes long-term shortages. The main concern is the continued economic situation in the ⁹⁹Mo/^{99m}Tc supply chain that is unsustainable for any investment, including LEU-based investment. As a result, achieving full-cost recovery pricing is a necessary (but insufficient) condition for ensuring long-term supply reliability and allowing LEU-target conversion.

LEU-target conversion does have important impacts on the availability of outage reserve capacity – in the long term for irradiation capacity, but only affecting processing capacity during the conversion period.

In addition, it is clear that ⁹⁹Mo/^{99m}Tc produced from converted facilities is more expensive that HEU-based ⁹⁹Mo. However, the increase at the radiopharmacy stage is less than 8%. This small impact on the end payer translates to an important increase upstream and the end payer will need to accommodate the increase to ensure sufficient funding for the investment required upstream in the supply chain. Evidence from the study points to an important role for governments to encourage LEU-target conversion, to help to ensure the long-term secure supply of these important medical isotopes.

Chapter 1. Introduction

1.1. Purpose of the study

Following the shortages of the key medical radioisotopes molybdenum-99 (99Mo) and its daughter technetium-99m (99mTc) the OECD Nuclear Energy Agency (NEA) created the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). Since 2009, this group has identified the reasons for the isotope shortages and developed a policy approach to address the challenges to a long-term secure supply of these important medical isotopes.

On top of the ongoing concerns related to long-term reliability, all current long-term major ⁹⁹Mo-producing countries have agreed to convert to using low-enriched uranium¹ (LEU) targets for the production of ⁹⁹Mo.² This decision was made based on important non-proliferation reasons; however, the conversion will have potential impacts on the global supply chain – both in terms of costs and available capacity.

In addition, it is important to realise that there may not be global access to a long-term supply of highly enriched uranium (HEU) for ⁹⁹Mo/^{99m}Tc production in the mid-term.³ As a result, long-term security of supply of these important medical isotopes requires the move to non-HEU based production, through converting to LEU targets for ⁹⁹Mo production in existing (and new) producers and through the use of new technologies.

Recognising that conversion is important and will occur, and also recognising the need to ensure a long-term secure supply of ⁹⁹Mo/^{99m}Tc, the NEA and its HLG-MR undertook a study to quantify the expected capacity and cost impacts of LEU-target conversion. This study seeks to fill a gap in past or ongoing analysis on LEU conversion for ⁹⁹Mo production. Most analysis has been generally technical in nature. Those studies that have examined the economic impacts have tended to focus on facility-level impacts and have not expanded the study to look at the impacts on the whole supply chain. In addition, the study looked at potential policy options to ensure a reliable supply of

Fuel elements and targets are classified as LEU, containing less than 20% of uranium-235 (²³⁵U), or HEU, which contains greater than 20% ²³⁵U. HEU targets for ⁹⁹Mo production can have up to around 93% ²³⁵U.

^{2.} All current producing countries (and expected new major entrants) agreed to the principle of converting to using LEU targets for ⁹⁹Mo production through the work plan of the Washington Nuclear Security Summit (April 2010). At the Seoul Nuclear Security Summit (March 2012), Belgium, France, the Netherlands and the United States reaffirmed their commitment to minimise the use of HEU for civilian purposes and to ensure a reliable supply of medical isotopes for patients worldwide. Australia and South Africa are already producing LEU-based ⁹⁹Mo for the global market. Canada has indicated that they will not be producing ⁹⁹Mo from its NRU reactor after 2016.

^{3.} For example, the American Medical Isotopes Production Act of 2011 (S.99), which has passed the US Senate and was in front of the US House of Representatives at the time of writing, includes provisions to restrict the export of HEU from the United States for the purposes of medical isotope production.

 99 Mo and/or 99m Tc produced without HEU, consistent with the time frames and policies of the HLG-MR. 4

The HLG-MR's main interest in understanding the impacts of LEU-target conversion is to ensure a long-term secure supply of medical radioisotopes. It is clear that HEU may not be available for ⁹⁹Mo/^{99m}Tc production in the mid to long term. Time is required to convert the irradiation and processing facilities, and to obtain the health regulatory approval necessary. As a result, it is necessary to encourage a smooth transition to using LEU targets.

This report describes the market impact study and its findings, and briefly discusses the need for policy actions.

1.2. HEU use in the 99Mo/99mTc supply chain

HEU is used in the ⁹⁹Mo/^{99m}Tc supply chain both as fuel in research reactors and as targets that are irradiated in order to produce ⁹⁹Mo. The study undertaken by the NEA and presented in this report is focused on the conversion of the targets from HEU to LEU; fuel conversion is not examined in this study.

Figure 1.1 presents the major participants and distribution channels of the ⁹⁹Mo supply chain. To understand the current situation related to HEU use, the figure shows which reactors are using HEU fuel (in orange) and which are using LEU fuel (in green). The figure also shows which processors are using HEU targets for ⁹⁹Mo production (in orange) and which are using LEU targets (in green). NTP (South Africa) is coloured both orange and green as they are in the process of converting to using LEU targets (from targets with 45% ²³⁵U); they produce both HEU- and LEU-based ⁹⁹Mo pending their customers receiving health regulatory approval to use their LEU-based ⁹⁹Mo.

As noted above, all current long-term ⁹⁹Mo-producing processors and reactors have confirmed that they will convert to using LEU targets. Covidien and Institute for Radioelements (IRE) have indicated that they expect to be converted to using LEU targets in 2015. The government of Canada has indicated that the NRU reactor will not be producing ⁹⁹Mo after 2016 and therefore will not be converting to LEU targets for ⁹⁹Mo production.

1.3. Overview of the NEA study on LEU-target conversion impacts

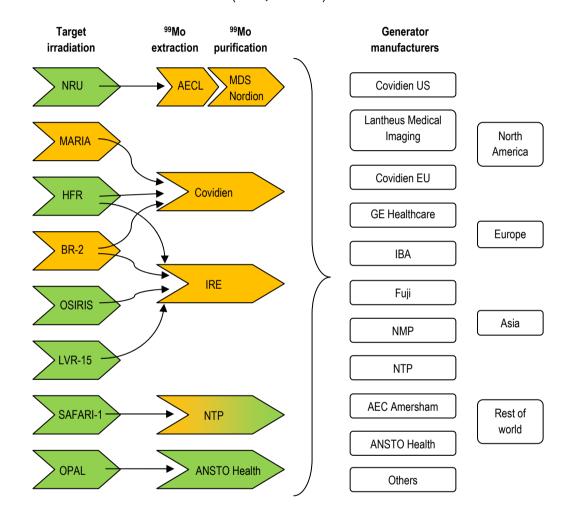
Given the current use of HEU for ⁹⁹Mo production and the agreements to convert to using LEU targets, it is important to understand the impacts on long-term security of supply. It is clear that target conversion will have an impact on producers and users of ⁹⁹Mo/^{99m}Tc; simply, ⁹⁹Mo is a fission product from ²³⁵U and therefore, if there is less ²³⁵U in each target there will be less ⁹⁹Mo produced from each target. This means that there would be a reduction in effective capacity for ⁹⁹Mo production in converting irradiators and processors. This could be expected to lead to increased costs and prices of ⁹⁹Mo/^{99m}Tc in the market since costs would be spread over less product, as well as the fact that there are investments required to be able to use LEU targets.

To improve the understanding of the expected capacity and cost impacts on the supply chain of converting to using LEU targets for ⁹⁹Mo production, the NEA examined the impact on individual facilities to develop an assessment of the impacts on the whole

^{4.} Refer to the publications, The Supply of Medical Radioisotopes: The Path to Reliability (OECD/NEA, 2011) and The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain, (OECD/NEA, 2010a) for a discussion on the economic situation in the ⁹⁹Mo/^{99m}Tc market and the HLG-MR policy approach.

supply chain. A capacity model and an economic model of the supply chain were developed and used to assess the impact of conversion on global supply availability and costs, in comparison to a reference case. The models drew from the work of the NEA economic study (OECD/NEA, 2010), especially regarding costs and end-user impacts. The models will be discussed in more detail later in the report.

Figure 1.1. Major participants and distribution channels of the ⁹⁹Mo supply chain (as of June 2011)



The study focused on examining impacts from conversion using commercially or near-commercially available targets. This is basically current targetry with slight modifications to increase density of the uranium in the target (often referred to as phase I targets for conversion). The HLG-MR agreed that it was too premature to examine the impacts on capacity and cost from phase II targetry – new advanced high-density target types (e.g. foil targets), which are still under development and some years away from deployment. As a result, any capacity and cost impact assessment on advanced targetry would contain too many uncertainties to produce credible conclusions. This report will briefly touch on the potential impacts, but no in-depth assessment was undertaken.

1.4. Sources and uncertainties around information

Information for the assessment came from an expert working group (made up of major supply chain participants, see Annex 1). The expert working group met during two workshops. The information provided at the workshops was supplemented by interviews with individual supply chain participants by the NEA, and NEA's own knowledge of the supply chain.

In order to have access to as complete information as possible, the NEA assured input providers that information that may be of a commercial nature would be kept confidential. As a result, the paper does not attribute comments, values or statements to any specific input provider where it may affect commercial undertakings. Further, the degree of some impacts of LEU conversion will not be separately provided in the report as this would be in conflict with the assurances provided by the NEA.

The capacity and cost models are facility and time specific, meaning that impacts are assessed for each facility based on the information provided for that facility and account for the timing of conversion at the specific facility. While some members of the expert working group and of the supply chain provided as much information as possible, some were unable to share information about their facility and the expected impacts of target conversion. Where information was not provided, the NEA was required to make assumptions based on the input from other participants and NEA's own knowledge of the industry.

It must be noted that for those facilities that have not yet converted to using LEU targets for ⁹⁹Mo production the values provided for their facility impacts (both cost and capacity) are based on the best available information that they have at the time of undertaking the modelling. However, in some instances there is a degree of uncertainty about the actual impact. The study accounts for this uncertainty by assessing low and high values of the expected facility-specific impacts.

In addition, since this study relies on data provided for the NEA economic study (OECD/NEA, 2010), the related uncertainties discussed in that report are relevant (see p. 61 of the economic report for a discussion on those uncertainties).

Given these uncertainties, it is clear that the values presented in this study are only approximate and do not purport to represent the situation in every region or jurisdiction. The values are meant to provide an indication of the expected trends in capacity and costs from the impacts of target conversion and to draw the key conclusions and lessons from those trends. The absolute numbers in isolation are not the important element and will not change the fundamental policy decisions that may be derived by governments based on this report. The uncertainties present in the study do not affect the final conclusions of the study.

Chapter 2. Capacity impacts of LEU-target conversion

2.1. Framework and methodology of capacity modelling

The capacity model is intended to provide a reasonable description of the capacity, product flows and availability of ⁹⁹Mo/^{99m}Tc in the global supply chain. This model establishes a reference case that is then used to undertake a time-based assessment of the impacts of conversion on the quantities of ⁹⁹Mo that can be supplied during and after conversion. The time-based reference case includes the start and stop dates and production levels from both current and expected new irradiators and processors. Additional data on the reference data are presented in Section 2.2.

The model examines capacity from uranium supply all the way through to the global market for ⁹⁹Mo/^{99m}Tc (see Figure 2.1). The model replicates the flow of product through the supply chain, for example connecting irradiators with the relevant processors. Individual supply chain participants are included in the model to allow for an assessment of different impacts at different facilities and the impact that could have on downstream players and the overall global market.

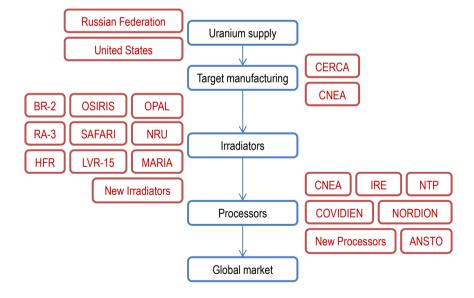


Figure 2.1. Capacity model framework

The model starts with reference data for current and all potential new entrants to set a baseline from which the supply impacts of converting to LEU targets are measured. From there, the facility- and time-specific expected impacts of LEU-target conversion were applied to the reference data to assess the supply impacts on the global market. Figure 2.2 provides an illustrative example of the process, where potential impacts at each segment of the supply chain are assessed and the expected impact would then flow through the supply chain. (In the figure, solid lines represent no expected change from target conversion and dotted lines represent an expected change.) Impacts at each stage of the supply chain were modelled to be incremental to avoid potential double-counting.

For example, a lower ²³⁵U content in the targets impacted reactor capacity and that effect flowed through to processors as lower delivered product, but was not reapplied at the processor stage.

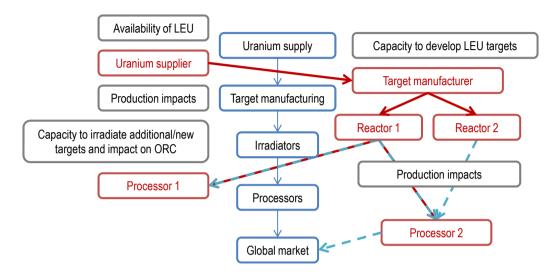


Figure 2.2. Example of assessing capacity impacts from LEU-target conversion

In order to determine the impacts, the expert working group first analysed all the potential places in the supply chain where there could be an impact on capacity or production from LEU-target conversion – called "capacity impact elements". From a list of all potential impact elements, the working group determined which were:

- important (i.e. those elements where LEU-target conversion is known to, or expected to, have an impact on ⁹⁹Mo/^{99m}Tc capacity or production);
- important but not likely (i.e. there would very likely be no impact, but if an impact were to occur it could have a large effect); and
- not relevant (i.e. there would be no impact from LEU-target conversion on the element).

Annex 2 provides a full list of the first two categories of impact elements; the "not relevant" elements are not presented as it is an extensive list that was deemed not important. The NEA modelling accounted for the important impact elements but did not model the non-relevant impact elements or the important but not likely impact elements. Some of the latter elements will be discussed in this document, but were not modelled as it was not expected that the impact would occur. However, it is important to be aware of the risk related to these elements.

The expert working group then assessed the important impact elements to set a value for the degree of the expected or experienced impact for each element, for each facility. Given that the model is time and facility specific, the degree of the impact can vary from facility to facility; in some cases a range of the expected impact for a specific element was provided for a specific facility. This resulted in the development of three impact scenarios:

- High impact scenario: the highest expected facility-specific impact on production capacity was applied to each relevant facility.
- Low impact scenario: the lowest expected facility-specific impact on production capacity was applied to each relevant facility, given normal operating and economic conditions.

Very low impact scenario: assumes that the economic returns from ⁹⁹Mo irradiation services improves significantly such that reactors, where possible, displace other irradiations in order to return ⁹⁹Mo irradiation capacity to preconversion levels.

The NEA applied the expected impacts under these three scenarios to the following three situations (see Figure 2.3):

- all-in situation;
- · economic-challenges situation;
- technology-challenges situation.

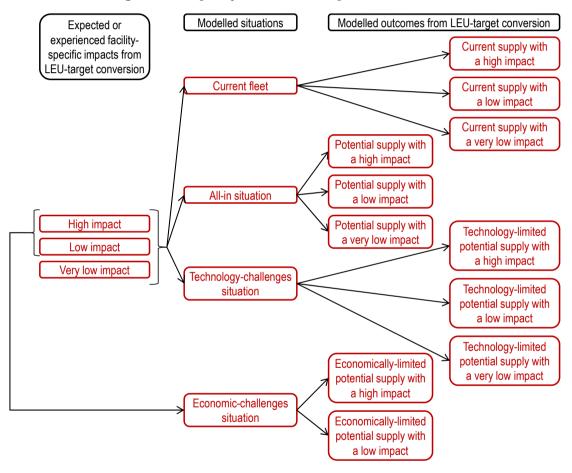


Figure 2.3. Capacity model from impacts to outcomes

For the economic-challenges situation, the modelling starts from the all-in situation and then assumes that economic conditions in the supply chain do not improve from the current unsustainable economic situation that is described in previous NEA reports (OECD/NEA, 2011a and 2010). Applying this assumption, this situation includes only those projects that can proceed in the absence of commercial funding (both irradiators and processing projects). Additional detail on the actual projects included in the economic-challenges situation is provided in Section 2.3. The NEA applied the high and low impact scenarios to the economic-challenges situation but not the very low impact scenario as that scenario assumes that the economic situation improves substantially, which is inconsistent with the economic-challenges situation.

The technology-challenges situation also starts from the all-in situation and then assumes that new technologies and new entrants face a higher risk in implementing their various projects. Under this situation, many of the potential projects do not proceed or are delayed as a result of technology reasons. Additional detail on the actual projects included in the technology-challenges situation is also provided in Section 2.3. The NEA applied the three impact scenarios discussed above to the technology-challenges situation.

Using the three scenarios and the three situations, the modelling applied the capacity impact elements to the irradiators and processors out to 2030. Given that the model is based on product flow through the supply chain, infrastructure limitations were taken into account; for example, if a processor had more capacity than the production from its irradiator suppliers, not all the processing capacity would be used. Along the same line, if there were processing limitations where a processor's irradiators could supply in excess of the processor's capacity, the processor's capacity would define the actual production of ⁹⁹Mo.

The results were then compared to expected demand to determine if the capacity impacts of LEU-target conversion affected security of ⁹⁹Mo/^{99m}Tc supply. The demand curves are based on a previous NEA study assessing long-term demand for ⁹⁹Mo/^{99m}Tc (OECD/NEA, 2011b), updated to reflect the adjustments observed in the market, resulting in a lower current demand. The previous study had current demand at 12 000 6-day curies per week, ¹ which has been revised to approximately 10 000 6-day curies per week.

In addition, the demand curves used in this study seek to reflect the need for outage reserve capacity (ORC). Outage reserve capacity is required to ensure a reliable supply chain by providing back-up irradiation and/or processing capacity that can be called upon in the event of an unexpected shutdown (see OECD/NEA, 2011a for more information). The study treats ORC as effectively increasing demand for irradiation and processor capacity, as this capacity is demanded to be "set-aside" in order to ensure security of supply. As a result, there are three demand curves used:

- future demand scenario with no ORC requirements;
- future demand scenario with low requirements to meet ORC levels;
- future demand scenario with high requirements to meet ORC levels;²

Under these three demand scenarios, 2012 demand in 6-day curies per week is, respectively: 10 000, 11 700 and 13 300.

2.2. Reference capacity data

The reference data for capacity used in this study, presented below, are the capacity of current and potential new entrants providing ⁹⁹Mo/^{99m}Tc irradiation and/or processing services. The general guideline for the inclusion of a current or potential producer was that they supply to the global market or are important for large regional markets. This means that, in general, those facilities included in the study were major producers with capacities of greater than 1 000 6-day curies a week (EOP). New entrants were included if

^{1.} A 6-day curie is the measurement of the remaining radioactivity of ⁹⁹Mo 6-days after it leaves the processing facility (end of processing, or EOP).

^{2.} The high ORC requirements demand scenario is based on a derived model that shows that a supply chain with somewhat effective, but not necessarily ideal co-ordination with a large reactor in the fleet could maintain necessary ORC levels if each irradiator kept, on average, an additional 33% of their capacity as ORC when they operate; this translates into an annual "peak" capacity of about 200% of demand. The low ORC requirements demand scenario requires the same level of reliability but is derived from a supply chain with more perfect co-ordination and more equal sized reactors. With this type of supply chain, ORC levels could be maintained if each irradiator kept an additional 17% of its capacity as ORC when operating. More information on ORC levels will be available in a forthcoming guidance document on ORC being developed by the NEA.

they seemed credible, based on public announcements, having secured funding, and/or government decisions supporting the projects. Again, it must be pointed out that the NEA did not undertake any formal assessment of the credibility of the potential projects or their reported capacity levels. The reference data represent information available to the NEA as of June 2012.

It should be noted that the timelines for some current irradiators include an assumption that licence extensions will be provided. However, licence extensions may require some refurbishments in the irradiator and the decision to proceed with those investments may be subject to the economic conditions that prevail in the market at that time. If the decision is to not proceed with the necessary refurbishments, the values in later years would be lower than presented in this study. This highlights another key reason for the need to address the economic situation in the supply chain to ensure the continued planned operation of current irradiators.

Reactor	Targets	Normal operating days	Normal available capacity per week (6-day Ci) ¹	Potential annual production (6-day Ci) ²	Estimated stop production date
BR-2	HEU	140	7 800	156 000	2026
HFR	HEU	280	4 680	187 200	2022
LVR-15	HEU	200	2 800	80 000	2028
MARIA	HEU	165	1 920	42 500	2030
NRU	HEU	300	4 680	200 600	2016
OPAL	LEU	290	1 000	41 450	>2030
OSIRIS	HEU	200	1 200	34 300	2018
RA-3	LEU	336	400	19 200	2027
SAFARI-1	HEU3/LEU	305	3 000	130 700	2025

Table 2.1. Current irradiators

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

Processor	Targets	Capacity per week (6-d Ci)	Available annual capacity (6-d Ci) ¹	Expected date of conversion to LEU targets
AECL/NORDION	HEU	7 200	374 400	Not expected ²
ANSTO HEALTH	LEU	1 000	52 000	Started as LEU
CNEA	LEU	900	46 800	Converted
COVIDIEN	HEU	3 500	182 000	2015
IRE	HEU	2 500	130 000	2015
NTP	HEU3/LEU	3 000	156 000	20134

Table 2.2. Current processors

^{1.} What is possible under normal operations, without major changes to the reactor or sacrifices to other irradiation missions.

^{2.} Based on operating days and normal available capacity - not necessarily what is actually produced currently, rounded.

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

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

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

^{4.} NTP can already produce LEU-based ⁹⁹Mo but does not expect 100% production from LEU targets until 2013, as their customers required time to obtain the necessary health regulatory approvals.

Table 2.3. Potential irradiators

Irradiation source	Targets/technology¹	Expected operating days	Expected normal available capacity per week (6-d Ci) ²	Potential annual production (6-day Ci) ³	Estimated first full year of production ⁴	Project status (19 June 2012)
NORTHSTAR ⁵ /MURR (United States)	Non-fissile in CRR	336	750/3 000	36 000/144 000	2013/2016	Phase 1 nearing completion/ phase 2 seeking financing
RIAR ⁶ (Russian Federation)	HEU in CRR7	365	800/2 000	41 700/104 300	2013/2015	Phase 1 nearing completion/ phase 2 under development
B&W MIPS (United States)	LEU solution in AHR	336	4 400	211 200	2015	Preliminary design and applications underway
CHINA ADVANCED RR	LEU in CRR	180	1 000	25 700	2015	Under construction
INR, Pitesti (Romania)	LEU in CRR	250	006	31 200	2015	Proposal
NORTHSTAR ⁵ (United States)	Non-fissile from LINAC	336	3 000	144 000	2015	Construction not yet started
FRM-II (Germany)	LEU in CRR	240	1 950	65 950	2016	Infrastructure installed, pending LEU target design
MORGRIDGE/SHINE (United States)	LEU solution with DTA and SAHR	336	3 000	144 000	2016	Preliminary design and applications underway
OPAL ⁸ (Australia)	LEU in CRR	290	3 400	140 850	2016	Available, pending processing capacity
AMIC (United States)	LEU solution with HA-HWS	336	3 000	144 000	2017	Seeking financing
Coqui (United States)	LEU in CRR	365	7 000	365 000	2017	Seeking financing
Brazil MR	LEU in CRR	290	1 000	41 450	2018	Preliminary design
KOREA	LEU in CRR	300	1 000	42 850	2018	Preliminary design
JULES HOROWITZ Reactor (France)	LEU in CRR	220	2 400	75 450	2019	Under construction
RA-10 (Argentina)	LEU in CRR	336	2 000	000 96	2019	Preliminary design
PALLAS (Netherlands)	LEU in CRR	300	7 300	312 000	2023	Design phase, additional funding required
MYRRHA (Belgium)	LEU in ADS	238	6 250	212 150	2023	Design phase, additional funding required
SAFARI-II (South Africa)	LEU in CRR	305	3 000	130 700	2026	Feasibility study underway

CRR = conventional research reactor; AHR = aqueous homogeneous reactor; LINAC = linear accelerators; DTA = deuterium-tritium accelerator; SAHR = subcritical aqueous homogeneous reactor; HA-HWS = hybrid accelerator-heavy water system; ADS = accelerator driven system research reactor.

^{2.} What is possible under normal operations, without major changes to the reactor or sacrifices to other irradiation missions.

Based on expected operating days and normal available capacity presented, rounded.

Assumed full-scale production starts one year after commissioning unless available information indicates differently, estimated by project proponents.

Produces low-specific activity ⁹⁹Mo that requires use of Northstar's generator to produce

At the HLG-MR meeting in July 2012, the Russian delegate reported approval of a plan to convert to LEU targets for ⁹⁹Mo production within 5 years. The project includes three reactors, two of which will be used to irradiate for continuous ⁹⁹Mo production, with the third being a back-up.

New production as a result of new processing capacity, "replaces" OPAL current capacity.

Table 2.4. Potential processors

Processor	Targets and (expected date of conversion)	Assumed expected available capacity per week (6-day Ci) ¹	Expected available annual capacity (6-day Ci) ²	Estimated first full year of production ³	Project status (19 June 2012)
NORTHSTAR/MURR	Non-fissile	750/3 000	36 000/144 000	2013/2016	Nearing completion/ seeking financing
RIAR/NORDION	HEU (2018)	800/2 000	41 700/104 300	2013/2015	Nearing completion/ under development
B&W MIPS	LEU solution	4 400	211 200	2015	Preliminary design and applications underway
CHINA ADVANCED RR	LEU	1 000	24 700	2015	Under construction
NORTHSTAR (LINAC)	Non-fissile	3 000	144 000	2015	Construction not started yet
ANSTO: MEGA MOLY⁴	LEU	3 400	176 800	2016	Design phase
MARIA: MOLYBDENUM 2010	LEU	1 000	52 000	2016	Seeking financing
MORGRIDGE/SHINE	LEU solution	3 000	144 000	2016	Preliminary design and applications underway
AMIC	LEU solution	3 000	144 000	2017	Seeking financing
Coqui	LEU	2 000	365 000	2017	Seeking financing
BMR	LEU	1 000	41 450	2018	Preliminary design
KOREA	LEU	1 000	42 850	2018	Preliminary design
RA-10	LEU	2 000	150 800	2018	Preliminary design

^{1.} Derived assuming an ability to process irradiated sources linked with the project, unless additional information available.

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

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

^{4.} Replaces current ANSTO processing capacity.

2.3. Economic- and technology-challenges situations

As noted in Section 2.1, the NEA modelled two "challenges" situations to recognise the fact that the all-in situation overestimates the future expected capacity as not all of the planned projects will proceed. Many of the projects may not proceed as a result of the current economic situation in the ⁹⁹Mo supply chain, because of technological or regulatory challenges that hinder the development of the project or because of the increased competition that would result if all the projects were to enter the market. As a result, the NEA modelled an economic-challenges and a technology-challenges situation. Both of these were described in Section 2.1 and were developed in consultation with the expert working group. Additional detail on the actual projects included is provided here.

For the economic-challenges situation, only the following irradiation sources and related processing facilities are included: current reactors;³ FRM-II; INR; RIAR; KOREA; CARR; BMR; and RA-10. All the other potential projects identified in Section 2.2 are assumed to not proceed under the economic-challenges situation.

For the technology-challenges situation, there is only one US project assumed to proceed, the Russian project is delayed until 2018, the Korean project is delayed until 2020, and the MYRRHA and the INR projects are assumed to not proceed.

It must be clarified that these challenges situations should not be construed as a prediction, forecast or expectation on the part of the NEA of which projects proceed and which do not. The situations were created to be illustrative of possible outcomes if economic or technical challenges were encountered. Through the use of the scenarios developed with the expert working group, the NEA is not expressing a viewpoint as to the viability of any particular project.

2.4. Capacity impact elements

As noted above, the expert working group examined the full supply chain and determined the key points along the supply chain where the conversion to using LEU targets could have an impact. The working group divided all the points, or capacity impact elements, into those that were important, important but not likely, or not relevant. The full collection of the first two categories of capacity impact elements is provided in Annex 2.

This section of the report will discuss the various important impact elements and the degree of the impacts, where possible. Where the provision of data on the degree of impact of a specific capacity impact element could reveal commercially confidential information these data will not be provided in this report. As noted earlier, many supply chain participants provided confidential information to the NEA in order to facilitate the development of this study with the understanding that the NEA would respect the confidential nature of that information.

The expert working group agreed that the key incremental capacity impact elements affected irradiators and processors. They determined that there were no incremental capacity impact elements on generator manufacturers or further downstream. However, it was recognised that generator manufacturers face logistical challenges during the conversion process as they have to keep production of generators from HEU- and LEU-based 99Mo separate until they receive health approvals.

^{3.} While all current reactors continue to operate under this situation, it is possible that some may have to stop production at some point in the future if the economic situation does not improve since they receive no or limited government funding. This possibility is not modelled in the scenarios.

Capacity impact elements affecting uranium and LEU-target supply

A key impact element for this stage of the supply chain was the availability of HEU during the period until LEU-target conversion is completed. The expert group recognised that this was a very important element – if HEU was not available for ⁹⁹Mo production during the conversion period then there could be serious implications for security of supply. However, recent assurances indicate that HEU will be made available during the conversion process, based on agreed upon timelines.⁴

An additional important impact element identified for the target supply stage of the supply chain was the ability of the supply chain to produce and supply LEU targets in quantities sufficient to meet global demand during and after conversion. The expert working group identified this as a concern as there are currently only two producers of LEU targets for the global market: AREVA-CERCA in France and CNEA in Argentina. If there are only a few suppliers, it increases the risk of supply interruptions from unforeseen circumstances. However, AREVA-CERCA indicated that they have sufficient capacity to be able to increase supplies of LEU targets to support the global market, but need firm commitments.

With the assurances provided for these two identified elements, there appears to be no specific impacts regarding uranium and LEU-target supply from converting to using LEU targets. However, the supply chain should remain vigilant to ensure that HEU and LEU targets can be supplied in the quantities necessary for a secure supply of ⁹⁹Mo/^{99m}Tc during and after LEU-target conversion.

Capacity impact elements affecting irradiation services

The most important impact element affecting irradiation services comes from the lower ²³⁵U content in the LEU targets. The lower content is not linear – moving from 93% ²³⁵U to just under 20% in the target does not mean a directly proportional reduction of absolute ²³⁵U in the target. Using current targetry, processors are able to increase the overall density of uranium in the target. NTP in South Africa converted from targets with 45% ²³⁵U but they were able to increase the density of the uranium in the target to counteract some of the reduction. Other processors do not have direct experience in conversion but their current work on conversion indicates that they also expect to be able to counteract to some degree the lower ²³⁵U content.

The expected impact on the provision of irradiation services from the lower ²³⁵U content ranges from a 0% to 50% reduction in production. The case of no impact comes from irradiators that have indicated that they have significant available space in their reactor to be able to irradiate additional targets without impacting their normal operations. In addition, under the very low impact scenario, all irradiators with additional space are assumed to be able to increase irradiation services.

For modelling this capacity impact element on LEU-target converting reactors, the reference data (as presented in Section 2.2) were used up to and including the year of conversion. From the year after conversion, the reference data were adjusted to reflect the expected impact, based on the relevant impact scenario (high, low or very low). For all new entrants, except the RIAR project, the reference data were used as the new projects are expected to start with non-HEU-based irradiation services. These impacts were applied on a facility-specific basis to the reference data, based on the timing indicated for each individual facility.

^{4.} Such as through the Belgium-France-Netherlands-United States Joint Statement: Minimization of HEU and the Reliable Supply of Medical Radioisotopes (26 March 2012), that can be found at: www.whitehouse.gov/the-press-office/2012/03/26/belgium-france-netherlands-united-states-joint-statement-minimization-he.

One irradiator indicated that a one-year shutdown period was necessary in order to convert to using LEU targets; all other research reactors indicated that target conversion was possible during normal maintenance periods and therefore no extra shutdown periods were necessary. The one year shutdown for the one facility was modelled.

Another capacity impact element that was identified as important was the impact on outage reserve capacity. Given that the LEU-target conversion will have an impact of reducing effective capacity, there will be less capacity available to be offered as ORC. The comparison of the supply scenarios and the demand scenarios later in this document will demonstrate this effect of reduced available ORC.

A related issue is the ongoing discussion on, and consideration of, moving to harmonised target design in Europe. It has been pointed out that this could have the effect of increasing flexibility in the operations of the regional network by increasing compatibility between processors and the various available irradiators. Such flexibility could help to minimise effects of reduced capacity by increasing irradiation options for processors. This issue is being discussed by the European Observatory on the Supply of Medical Radioisotopes.

Capacity impact elements affecting the distribution between irradiators and processors, and processors and generator manufacturers

The expert advisory group indicated that distribution changes between reactors and processors were possible if there was not sufficient supply from the suppliers in the current distribution channels. In addition, it was possible that there would be distribution changes between processors and generator manufacturers. However, the group also indicated that choices of distribution were much more complex and that changes could come from a number of factors, not just from impacts of LEU-target conversion. In addition, they indicated that they did not currently expect any significant distribution changes as a result of LEU-target conversion. As a result, there was no modelling done to account for changes to regional distribution.

Capacity impact elements affecting processors

As indicated above, the capacity impact elements affecting producers were to account for incremental affects at the processing stage of the supply chain. The impacts from lower ²³⁵U content in the targets were accounted for at the irradiator stage and the impacts were passed down to processors via the model, based on less product – there was no incremental impact from the lower content modelled at the processor stage.

Processors potentially still face an incremental reduction in production capacity as a result of the LEU-target conversion and the need, in some cases, to alter their processing procedures as they adjust their targets. The main incremental capacity impact element is the additional time required to extract and purify the ⁹⁹Mo from the irradiated LEU target. This additional time results in lower production from decay impacts on the available ⁹⁹Mo. In some cases, the additional time needed has an impact on transportation possibilities from the processing facility. For example, given the additional time, flights may not be available for the bulk ⁹⁹Mo until a number of hours after production completion – resulting in yet more decay of the available ⁹⁹Mo. However, this is likely to be optimised with experience.

This capacity impact element results in incremental production reductions from the processors in the range from 0% up to 60%. The case of a 0% reduction comes where a processor does not need to change their processing procedure since they are using very similar targets to their HEU targets (albeit with increased uranium density and less ²³⁵U).

For modelling this capacity impact element on the converting processors, the reference data (as presented in Section 2.2) were used up to and including the year of conversion. From the year after conversion, the reference data were adjusted to reflect

the expected impact, based on the relevant impact scenario (high, low or very low). For those processors that are either already using LEU targets or new entrants that will be based on non-HEU methods, the reference data were used. While NTP has already converted, they are currently producing ⁹⁹Mo based on both HEU and LEU targets as some of their customers have not yet received health approval to use the LEU-based ⁹⁹Mo/^{99m}Tc; as a result, the model includes a ramp-up period for full LEU-based production from NTP. The impacts were applied on a facility-specific basis to the reference data, based on the timing indicated for each individual facility.

As with irradiators, the outage reserve capacity available within processors is expected to be reduced during the conversion period: processors use their second "back-up" line during the conversion process to keep their HEU- and LEU-based production separate. However, once conversion is completed, it is expected that the processors will be able to return to their normal operations and have their second line as back-up capacity. Time will be required to adjust and increase their waste management capacity, but it should not affect their ability to supply bulk ⁹⁹Mo to the market.

An additional important capacity impact element that was identified by the expert working group was the time required for the various regulatory approvals associated with conversion. This includes the regulatory approvals to operate based on LEU targets and the related operational conditions, as well as the time needed to obtain health regulatory approvals. The main impact of the required time is that it reduces the operational flexibility of the processor – they cannot operate HEU and LEU lines at the same time and until they have health regulatory approval for their LEU production in all their customers' jurisdictions they will have to continue to operate both lines separately. However, processors have indicated that this will not have any direct impacts on their stated capacity. Given that there is no direct impact on capacity (but it is an important logistical issue), the modelling did not adjust for this impact element.

2.5. Capacity impacts from converting to LEU targets

Results for irradiation capacity

The modelling applied the range of expected facility- and time-specific impacts outlined in the previous section to the reference data for the current fleet of irradiators to determine the impact of LEU-target conversion. Figure 2.4 shows the results of the capacity modelling on current irradiators, comparing the reference case (of no LEU-target conversion) to the very low, low and high impact scenarios described in Section 2.1. These supply scenarios are then compared to demand, with various ORC requirements (again, described in Section 2.1).

Current irradiators

Under all scenarios (including the reference case), the expected exit of the NRU and OSIRIS reactors from the ⁹⁹Mo supply chain in 2016 and 2018 will drastically reduce the available irradiator capacity from the current fleet. In addition, the expected conversion to LEU targets in 2015 at most of the existing irradiators will reduce available capacity from the current fleet. During the period from 2017 to 2022, all of the scenarios, including the reference case, show that the available production from the current irradiator fleet is insufficient to meet demand and outage reserve capacity needs. During that same time period, LEU-target conversion has the impact of intensifying the supply concern, with the high impact scenario from current irradiators being lower than even the demand with no ORC requirements. By 2023, all the scenarios are very similar for the current irradiator fleet, demonstrating that long-term demand is greater than long-term supply from the current irradiator fleet regardless of the LEU-target conversion. Thus, LEU-target conversion does not create the expected long-term shortfalls, but it could intensify them and make the shortfalls arrive earlier.

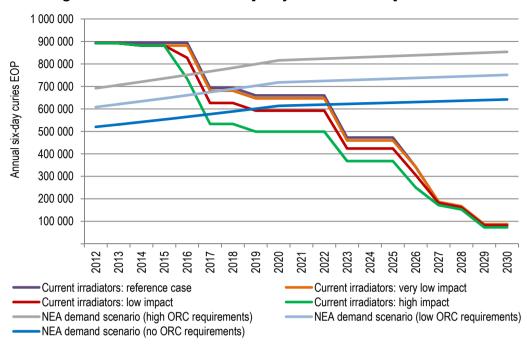
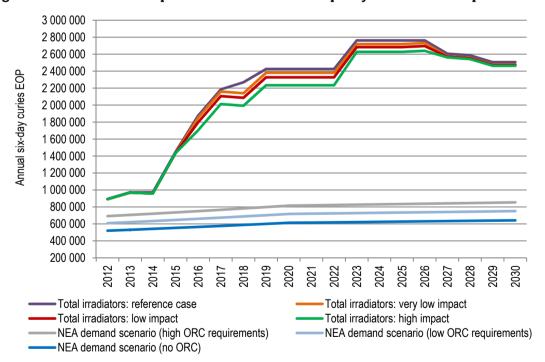


Figure 2.4. Current irradiator capacity vs. demand: impact scenarios

Figure 2.5. Current and all potential new irradiator capacity vs. demand: impact scenarios



Current and potential new entrant irradiators

As described in Section 2.2 (Table 2.3), there are many potential irradiator projects at various stages of development. Some of these projects are very well advanced, while others are in the proposal or design phase or are seeking financing or other approvals before actually advancing to construction. Figure 2.5 presents a future potential situation that includes all these proposed projects and the current fleet of irradiators. With this

"all-in" situation, LEU-target conversion under all the impact scenarios has a supply that is more than 300% of demand in the long term. LEU conversion does lower the capacity in the period from 2016 to 2022, but never to a point close to or below demand.

However, as has been noted earlier, this all-in situation includes all potential projects that have been publicly announced without any validation or assessment on the likelihood of these projects actually being successful. As with all infrastructure development not all of the projects that are planned will proceed. Many of the projects may not proceed as a result of the current economic situation in the ⁹⁹Mo supply chain, because of technological or regulatory challenges that hinder the development of the project, or because of the increased competition that would result if all the projects were to enter the market.

Challenges situations

Recognising this reality, Figures 2.6 and 2.7 present two challenges situations: the technology-challenges situation and the economic-challenges situation. Both of these situations were discussed in Sections 2.1 and 2.3. The technology-challenges situation shows that LEU-target conversion does have an impact by reducing available irradiation capacity; however, again, never to a point close to or below the future demand scenarios.

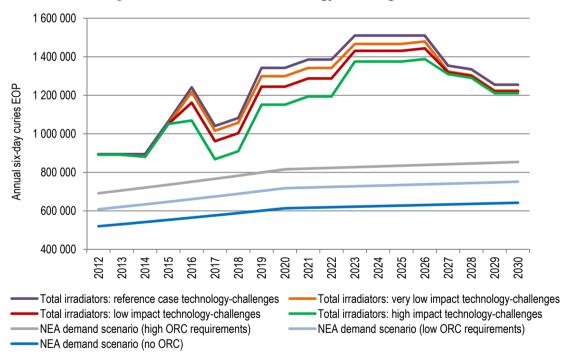


Figure 2.6. Current and select new irradiation capacity vs. demand: impact scenarios under a technology-challenges situation

Under the economic-challenges situation, LEU-target conversion creates possible shortages in 2018 where the impacts from conversion are high and only when compared to the demand curve coupled with high ORC requirements. Under this same situation, LEU-target conversion accelerates the long-term shortages expected under the reference case scenario around 2023 up to 2026. Long-term supply is less than demand for all scenarios, including the reference case scenario.

This last figure shows that LEU-conversion impacts are a secondary concern to the unsustainable economic situation in the ⁹⁹Mo/^{99m}Tc supply chain. Although LEU-target conversion may accelerate the timing of the expected long-term shortages by a few years, the

main concern is the long-term shortages. This points to the need to change the current economic situation. If the market could become more economically sound by following the HLG-MR policy approach (OECD/NEA, 2011a), LEU-target conversion does not appear to create any significant concern for irradiator capacity in relation to expected demand.

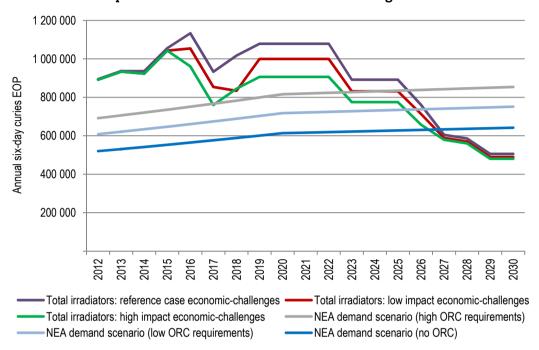


Figure 2.7. Current and select new irradiation capacity vs. demand: impact scenarios under an economic-challenges situation

Results for processing production

While irradiation capacity is essential for ⁹⁹Mo production, the future supply and demand scenarios for processor production are more indicative of potential supply, as they recognise the necessary coupling of irradiation and processing infrastructure; where one is available without the other, the potential capacity cannot be used. This was the case in the 2009-2010 shortages, when processing capacity in Canada could not be used as the NRU reactor in Canada was shut down, and at the same time available irradiator capacity in Europe could not be completely used as there was not sufficient processing capacity to offset the production losses in Canada.

While not shown here, processing *capacity* is sufficient to meet the future demand scenario – if the location of irradiators is ignored. Under all the scenarios, the global processing capacity exceeds future demand. However, processing production accounts for the necessary coupling of irradiator facilities with processing capacity.

Current processors

Figure 2.8 shows the results of the modelling on processor production from the current fleet, accounting for irradiator and/or processing capacity limitations and assuming all new irradiator entrants, but no new processing capacity. Again, this figure shows that LEU-target conversion is not the factor that creates the long-term shortage expected; that shortage is caused by insufficient irradiator and related processing capacity from the current fleet. LEU-target conversion intensifies the long-term shortages, but does not create them. Again, this demonstrates that the major concern related to long-term ⁹⁹Mo/^{99m}Tc supply security is not principally related to LEU-target conversion but rather is related to the underlying economic problems in the supply chain that hinder new infrastructure investment.

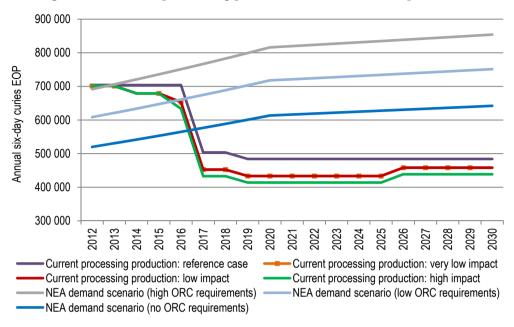


Figure 2.8. Current processing production vs. demand: impact scenarios

Current and potential new entrant processors

Figure 2.9 presents the LEU-target conversion impacts on the potential future situation where all the potential new irradiators and processors enter the market. As in the irradiator all-in situation, this figure demonstrates that while LEU-target conversion has an impact on processor production, the supply of bulk ⁹⁹Mo even under the high impact conversion scenario is approximately 250% of demand. However, this situation includes all potential projects which have been publicly announced without any validation or assessment of the likelihood of these projects actually being successful. As noted earlier, not all of the planned projects are actually expected to proceed given economic, technological and/or regulatory challenges.

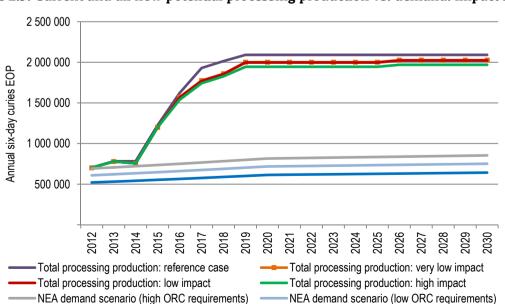


Figure 2.9. Current and all new potential processing production vs. demand: impact scenarios

NEA demand scenario (no ORC requirements)

Challenges situations

To recognise the impact of this reality on the potential projects, Figures 2.10 and 2.11 show processing production under two challenges situations: a technology-challenges situation and an economic-challenges situation. Both of these situations were discussed in Sections 2.1 and 2.3. Under the technology-challenges situation, the LEU-target conversion has the limited effect of creating two tight periods in 2014 and 2017, when compared to the demand curve with high ORC requirements. While LEU-target conversion does lower the production from the reference case, supply is above demand and therefore presents no concerns for security of supply.

Figure 2.11 presents the impacts of LEU-target conversion under an economic-challenges situation. The figure shows that LEU-target conversion accelerates the expected long-term shortages, by creating a significant shortfall in 2017 under all the LEU-target conversion impact scenarios; the reference case for 2017 drops below the demand curve with high ORC requirements but does remain above the two other demand scenarios. This drop in 2017 is a result of one irradiator indicating that they will have to be shut down to undertake the conversion process.

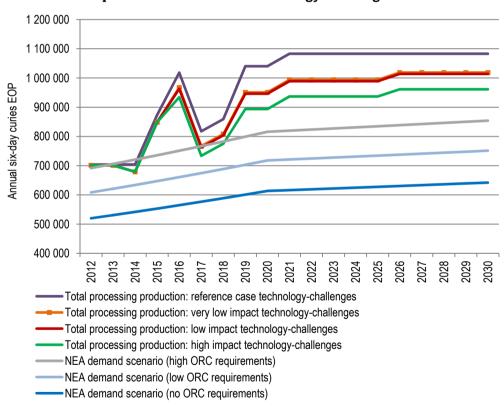


Figure 2.10. Current and select new processing production vs. demand: impact scenarios under a technology-challenges situation

From 2018 to 2025, the LEU-target conversion impacts keep supply under the economic-challenges situation below the high demand curve (with high ORC requirements), but the high and low impact scenarios are both above the lowest demand curve and the low impact scenario is above the demand curve with low ORC requirements. By 2027, all the scenarios under the economic-challenges situation drop below the lowest demand curve, again demonstrating that the long-term shortages are expected regardless of the conversion to LEU targets.

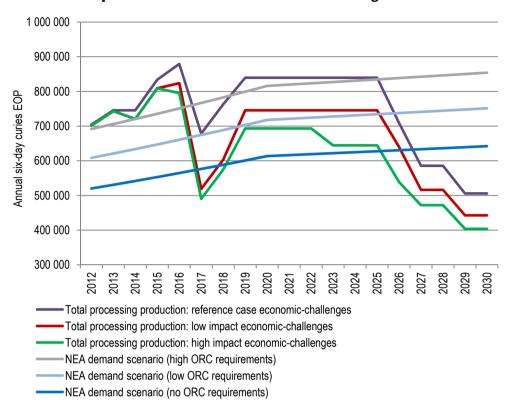


Figure 2.11. Current and select new processing production vs. demand: impact scenarios under an economic-challenges situation

These figures show that LEU-target conversion does have an impact on overall ⁹⁹Mo production but that this impact is only problematic under the economic-challenges situation. This provides support to the statement earlier in this document that LEU-target conversion is a secondary concern for long-term supply security – the primary concern is the current unsustainable economic situation that needs to be corrected to ensure sufficient incentives to develop new infrastructure.

2.6. Comment on high-density targets

The assessment undertaken through this study and detailed in this report is focused on the impact of LEU-target conversion using commercial- or near-commercial-ready target designs. This is often called "phase I targetry" and consists of adjusting the currently available targetry to increase uranium density.

However, there is also work underway to develop new advanced high-density targets, often called "phase II targetry". Much work has already been done to develop these targets and the work is ongoing.

It would be interesting to undertake a similar assessment of capacity (and cost) impacts based on using phase II targetry; however, such targets are currently not market ready and there are indications that these types of targets may not be ready for commercial use in the next seven years or so. As a result, any attempts to model capacity and cost impacts would be highly speculative given the outstanding uncertainties related to target design, dissolution methodologies, infrastructure needs and related cost impacts.

Given the uncertainty, the NEA and its HLG-MR agreed that modelling would not be done using an assumption of advanced targetry. However, it was recognised that advanced targetry could theoretically have the effect of counteracting all capacity effects of LEU-target conversion, at least returning capacity to the reference levels presented in Section 2.2.

The related costs are currently too uncertain to even speculate as to the expected outcomes. Once more detail is known about the advanced targetry, individual companies will be able to decide whether the advantages of moving to advanced targets will be greater than the expected costs.

2.7. Conclusions regarding the expected capacity impacts from LEU-target conversion

From the modelling undertaken to assess the capacity impacts from converting to LEU targets, it is clear that while there is a reduction of effective irradiation capacity and processor production from the conversion, this impact is a secondary concern to the economic situation already identified and discussed by the HLG-MR (OECD/NEA, 2011a and 2010). LEU target conversion does not create the expected long-term supply shortfalls. However, these long-term shortfalls could start earlier as a result of LEU-target conversion under the economic-challenges situation, when compared to the high ORC requirements demand curve. There are shortages expected in 2017 as a result of LEU-target conversion, coupled with the shutdown of the NRU reactor, under the economic-challenges situation.

From the modelling, LEU-target conversion only creates supply shortages under the economic-challenges situation. Under all the other situations, LEU-target conversion does lower the expected production from the reference case scenario, but not to levels where security of supply is threatened. As a result, LEU-target conversion should not create supply concerns **if the economics of the** ⁹⁹**Mo/**^{99m}**Tc supply chain were to improve**. The HLG-MR policy approach (OECD/NEA, 2011a) discusses how the supply chain economics could be improved to ensure long-term supply security.

Chapter 3. Cost impacts of LEU-target conversion

3.1. Framework and methodology of economic modelling

As with the capacity model, the economic model is intended to provide a reasonable description of the costs of producing and supplying ⁹⁹Mo/^{99m}Tc through the entire supply chain and the impacts of converting to LEU targets on those costs. The model started by creating a reference case for each currently operating ⁹⁹Mo irradiation and processing facility, as well as two new entrants: the FRM-II and the RIAR project. Given that the point of the modelling was to determine the impact on costs from LEU-target conversion, other new entrants were not modelled as they are planned to be non-HEU ⁹⁹Mo production facilities and thus do not face "conversion" costs. In addition, it was deemed very difficult to delineate "new infrastructure" costs from "LEU-related" costs for new entrants.

The economic model is a facility- and time-specific model, allowing for each facility to have different cost impacts and different times, according to their own situation, timing and infrastructure needs. The facility-specific reference cases were developed with data provided by supply chain participants for the NEA economic study (OECD/NEA, 2010) and updated where necessary during this study. Where direct information was not provided, the NEA made assumptions about costs based on the results of the economic study. Using these data, the reference cases were developed using the levelised unit cost of ⁹⁹Mo (LUCM) methodology used in the economic study.¹

Figure 3.1 provides an overview of the framework of the economic model. The reference case for each facility provides the baseline from which the cost impacts of converting to LEU targets are measured. The reference case is based on a situation where no LEU-target conversion occurs. Facility- and time-specific expected impacts of LEU-target conversion were applied to the reference case to assess the cost impacts on the full supply chain, with the facility cost impacts flowing down through the supply chain, eventually changing the cost to the end payer (i.e. health insurer or patient). Impacts at each stage of the supply chain were modelled and passed through to the next stage of the supply chain.

In order to determine the expected cost impacts, the expert working group followed a very similar procedure as was undertaken for the capacity modelling. They first analysed all the potential places in the supply chain where there could be an impact on cost (either on capital or operations) from LEU-target conversion – called "cost impact elements". From the list of all potential impact elements, the group again determined which were important, important but not likely, or not relevant. Annex 3 provides the full collection of the first two categories of the cost impact elements.

Again, the NEA modelling does not account for those cost impact elements that were deemed to be not relevant or important but not likely. Some of the latter elements will be discussed in this document but were not modelled as it was not expected that the cost impacts would occur. However, it is important to be aware of the risks related to these cost elements.

^{1.} For a detailed discussion of the LUCM methodology, refer to Annex 2 of OECD/NEA, 2010.

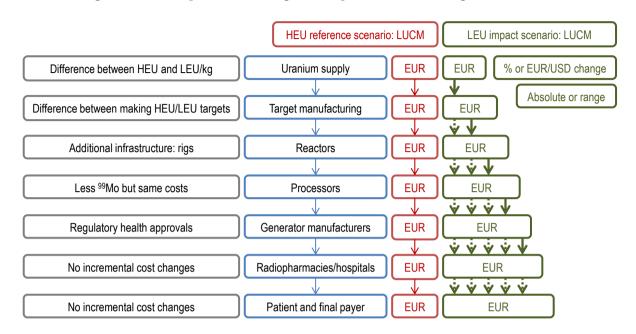


Figure 3.1. Example of assessing cost impacts from LEU-target conversion

Through the expert working group and interviews with supply chain participants, the NEA determined the degree of the relevant cost impacts for specific facilities. In many instances, the expected impacts were provided to the NEA as a range for a specific facility, representing high and low expected values for the cost impact. Where information was not provided by a specific facility representative, the NEA was required to make certain assumptions on the degree of the impact based on other participants' expectations or experience and NEA's own knowledge of the supply chain.

The NEA modelled the impacts by applying the high and low expected values to the reference case for the specific facility, based on the specific timelines of that facility for operation, conversion and shutdown. The high and low expected values were coupled to the related capacity scenarios to undertake the LUCM modelling (which accounts for changes in production). In general, high infrastructure cost values were applied to the low capacity impact scenario, as high upfront investments should minimise the capacity impact from conversion. The scenarios will be explained in the next section.

Once the LUCM modelling for the various scenarios was undertaken for each irradiation facility, the resulting top, bottom and median impact values were applied to the median reference case to obtain an "input price" of irradiation services for processors. This provided a range to demonstrate the differences that exist in the supply chain, without publicly identifying the impacts on a specific facility.

For the processor facility-specific LUCM modelling, the irradiators' LUCMs from the various scenarios were used as an input cost (i.e. the cost of providing irradiation services) for the relevant processor scenario. In addition, the ranges of various processor facility-specific cost impacts were applied to the relevant processor. Again, the LUCM modelling accounts for reduced production and the resulting cost impacts on a per unit basis.

The range of processors' LUCM changes were then applied down the supply chain to determine the resulting changes at each stage. As in the economic study, this assumes a 100% cost flow through down the supply chain, and allows for the clear assessment of the impacts of LEU-target conversion cost changes through the supply chain and on the end payer.

3.2. Economic modelling scenarios

The next section will discuss the cost impact elements and the expected or experienced degree of impact for those various elements. For the purposes of discussing the scenarios used to model the economic impacts, it is important to bring one point forward – the expert working group agreed that the key incremental cost impact elements were those that affected the irradiators and processors. This means that economic modelling scenarios were developed only for irradiators and processors.

The reference case used for both irradiators and processors assumes that no target conversion occurs. As a result, there are no conversion capacity or cost impacts applied. In addition, to accurately reflect the current supply chain, the reference case assumes that capital costs are fully amortised and that operational costs are fully recovered. For both irradiators and processors, the operating costs used were those reported to the NEA for the economic study; where data were not reported, the 20% multipurpose reactor scenario was applied for the irradiator facility and the processor cost scenario was applied for processors (refer to OECD/NEA, 2010 for more information). The ⁹⁹Mo production used to develop the reference case LUCM is based on the reference case in the capacity model except where there are weekly processing limitations; in that case the available processing capacity was used.

For irradiators, two cost scenarios were developed: a high infrastructure impact scenario and a low infrastructure impact scenario. The high infrastructure impact scenario includes high conversion costs for the irradiator, such as the costs related to the development of new irradiation rigs to accommodate a new geometry for the irradiation target. It also assumes low capacity impacts. The logic is that if irradiators make additional investments, they should be able to reduce the capacity impacts. Irradiators indicated that operating costs do not change significantly from using LEU targets and therefore, are modelled not to change from the reference case.

The low infrastructure scenario for irradiators includes low conversion costs for the irradiator, such as applying costs for modifying irradiation rigs instead of developing new rigs. However, this was assumed to result in high capacity impacts; spending less would result in less flexibility to minimise the capacity impacts of LEU-target conversion. Again, operating costs were unchanged from the reference case.

For processors, two cost scenarios were also developed along the same logic as for the irradiators. The only addition is that under the processor high infrastructure impact scenario, the costs of irradiation services are assumed to be high and under the processor low infrastructure impact scenario the irradiation service costs are assumed to be the low irradiator LUCM value.

Under the reference case and cost scenarios, production and costs are assumed to continue until the shutdown date of the facility or 2030, whichever is first, as in the capacity study.

3.3. Cost impact elements

As noted above, the expert working group examined the full supply chain and determined the key points along the supply chain where the LEU-target conversion would have an impact on the costs of production (either through capital or production costs). The working group divided all these cost impact elements into those that were important, important but not likely or not important. The full collection of the first two categories of cost impact elements is provided in Annex 3.

This section will discuss the various important cost impact elements and the degree of the impact, where possible. Similarly to the note in the section on capacity impact elements, where the provision of data on the degree of impact of a specific cost impact element could reveal commercially confidential information these data will not be provided in this report. As noted earlier, many supply chain participants provided confidential information to the NEA in order to facilitate the development of this study with the understanding that the NEA would respect the confidential nature of that information.

The expert working group agreed that the key incremental cost impacts would be applied to irradiators and processors. In some cases, there were costs in other segments of the supply chain but they were borne by either the irradiator or the processor (e.g. target development). As a result, all increment cost impacts were modelled for irradiators and processors and the cost were then passed down through the supply chain.

The working group recognised that there were incremental costs to generator manufacturers to seek health regulatory approvals for the non-HEU-based ^{99m}Tc. These costs include manufacturing of generators (labour, overhead, operations and cold parts) to be supplied to health regulators, related waste disposal, administration and regulatory costs, co-ordination and planning, legal reviews, etc. These costs are required to be paid by each generator manufacturer for each new supplier (processor) of non-HEU-based ⁹⁹Mo/^{99m}Tc. These costs can be important for a generator manufacturer (in the range of EUR 200 000-500 000). However, these costs could not be modelled in this assessment as the data provided to the NEA from generator manufacturers did not allow for LUCM calculations to be developed for this stage of the supply chain. As a result, the cost impacts are mentioned here, but not specifically modelled.

Cost impact elements affecting uranium and LEU-target supply

Four cost impact elements were identified as important at this stage of the supply chain: the cost difference between HEU and LEU (including the difference from more stringent requirements to secure HEU); research, development and qualification for LEU targets; cost differences between HEU and LEU targets; and the cost of shipping additional non-irradiated targets. The expert working group noted that it was difficult to provide specific data on the cost difference between HEU and LEU, but that regardless, the cost differences would be accounted for in the costs of targets and were not required to be modelled separately.

Research, development and qualification of LEU targets were modelled as an impact on processor costs: under most situations it would be the responsibility of the processors as they tend to be the purchasers of targets. Reported values for R&D and qualification of targets range from EUR 500 000 up to EUR 3.4 million, depending on the facility. The reported costs were applied in the LUCM modelling for the specific facility two years before the conversion year.

The difference between HEU and LEU targets, including the cost difference between the uranium, was also considered to be a cost impact on processors as they are responsible for the purchasing of targets in most cases. The values provided range from EUR 450 000 to EUR 2.65 million additional per year, depending on the facility. These additional costs were applied every year after conversion for each facility based on their facility-specific reported costs.

While the expert working group identified the cost of shipping additional non-irradiated targets as being an important cost impact element, the NEA was unable to model this potential cost. Processors were divided on whether additional containers would be required for shipping non-irradiated targets and were unable to provide any data that would allow for the modelling of this cost impact.

Cost impact elements affecting irradiation services

An important cost impact element identified for irradiation services was the cost of infrastructure changes required in the irradiator to be able to irradiate the LEU targets. These

infrastructure changes were related to potential changed geometry of the target and/or the need to irradiate additional targets. The changes were based on whether there was a need for: new irradiation rigs, modifications to existing irradiation rigs or no changes at all. These three different needs made a significant difference in the cost of the infrastructure. In addition, the placement of the rigs made a difference, with rigs placed in the core of the reactor costing more than rigs placed "poolside". Based on the value reported in an infrastructure case study and discussions with experts, the following table shows the costs per rig used to determine the values used for infrastructure changes in the irradiator.

Table 3.1. Cost per rig for irradiator infrastructure changes

New rig in core	New rig poolside	Rig modification in core	Rig modification poolside
EUR 1.09M	EUR 395 000	EUR 50 000	EUR 5 000

These costs were applied to the irradiation facilities, with the final value varying depending on whether the facility had multiple rigs to modify or replace and the placement of the rigs within the reactor. In general, under the high infrastructure impact scenario the cost for new rigs was applied during the year of conversion; under the low infrastructure impact scenario the cost for modified rigs was applied. In some cases, it was determined that new rigs were always needed.

Another important cost impact element was the reduced ⁹⁹Mo irradiation capacity as each target produces less ⁹⁹Mo. The key concern is that the operation and infrastructure costs are spread out over less overall production. This element was accounted for in the modelling by the use of the LUCM methodology.

The expert working group also identified the cost of regulatory approvals (for using changed targets, from changed infrastructure, and/or from changing the number of target irradiations) as an important impact element. Input from the supply chain indicated that this cost element would be incorporated into processor LEU-target conversion project costs as the irradiator would charge these costs to the processor. As a result, it was modelled in the processor LUCM calculations (which will be discussed later).

Finally, one irradiator indicated that a shutdown would be necessary to convert to using LEU targets. The LUCM modelling accounts for this facility-specific effect by removing production for that year; however, the modelling maintained operating costs at the facility during that year as the reactor would still have activities that would continue (such as staffing, security, etc).

Cost impact elements affecting transportation between irradiators and processors

The expert working group identified as important, cost impacts related to the containers used for transporting irradiated LEU targets from the irradiator to the processor. Specifically, these were costs for:

- designing and developing new containers;
- purchasing new containers;
- · modifying existing containers; and
- the related regulatory approval costs.

Processors indicated that they could likely modify their existing containers. However some processors indicated that they may also require additional containers to transport more irradiated targets (to counter the lower ²³⁵U content per target). Those processors provided a range of additional containers needed (2 to 12, depending on the processor). The range provided for these various container-related costs are provided in the following table.

Table 3.2. Cost range related to containers, including regulatory approvals

Designing and developing new containers, if necessary	Purchasing new containers, per container	Modifying containers, fleet costs
EUR 300 000-1 M	EUR 200 000-300 000	EUR 1 M-1.6 M

For the high infrastructure impact scenario, the assumption was that the processor would be able to handle more targets (as they invest more in infrastructure) and thus would require additional containers to ship the irradiated targets (where the processor indicated that additional containers could be necessary). This scenario also included the cost to modify the existing fleet of containers.

The low infrastructure impact scenario assumed that throughput in processors would be restricted (as they spent less on infrastructure changes) and therefore would not require any additional containers; they would only modify their existing fleet.

Under both of these scenarios, the costs related to container changes were applied during the year of conversion. The costs provided included the cost of obtaining transportation regulatory approvals.

Two other important cost impact elements were identified for this stage of the supply chain: the cost of shipping additional targets as a result of changes to irradiation sourcing patterns; and the cost of transportation regulatory approvals for new routes. Neither of these elements was modelled. For the former element, the supply chain indicated that the cost of shipping additional targets was not related to changes in irradiation sourcing patterns but rather the need for sending additional targets in general; however, no data on cost increases were provided to the NEA and therefore the impact could not be modelled. For the latter, the experts indicated that regulatory approval for new routes was an important issue, but that the use of new routes was not necessary related to LEU-target conversion and therefore should not be modelled.

Cost impact elements affecting processors

Processors faced the most incremental cost impacts of all the different levels of the supply chain. The important cost impact elements identified for processors were:

- conversion infrastructure project costs (operating and capital) and waste infrastructure;²
- operating cost increases resulting from using LEU targets;
- cost impacts related to providing information necessary for generator manufacturers to obtain health regulatory approvals.

In addition, the expert working group had identified the cost impact of obtaining regulatory approvals for changes to gaseous emissions as important. However, during subsequent conversations the experts agreed that there should be no important changes to isotope release amounts from conversion. The experts also agreed that although there is an increase in plutonium from the use of LEU targets (compared to HEU targets), the amount of the increase is very minor and therefore there is no significant change over the full volume of the waste. Therefore, there is no increased concern. It was clearly noted by supply chain participants that there was always prudent management of all wastes regardless of the type of targets used.

^{2.} At this stage, it is not possible to determine final waste disposal costs as such disposal routes are not yet implemented. Waste costs were reflected in both the estimates for infrastructure changes and ongoing operating costs. These impacts may need to be re-examined when more details on final waste costs are known.

The costs related to the LEU-target conversion project are predominately associated with the need to modify the hot cells to process the changed targets and to increase waste storage within the hot cells. The reported values include the expected costs of the regulatory approvals necessary to convert the processing facility and to operate it using LEU targets:

- high infrastructure impact scenario: around EUR 8 million, with one value much higher;
- low infrastructure impact scenario: around EUR 7 million, with one value much higher.

These values were applied on a facility-specific basis.

In addition, processors face incremental impacts related to operating costs from using LEU targets. The move to LEU targets is expected to result, in most cases, in more processing steps, longer processing time (and thus more resulting decay of the ⁹⁹Mo), higher waste volumes and yield losses from the targets. This latter impact is captured through the LUCM modelling and therefore not modelled as a separate impact. However, the other impacts are modelled with reported values of expected production reductions for all the remaining impacts varying between 1 to 20% for the high infrastructure impact scenario and from 1 to 50% for the low infrastructure impact scenario. The logic is that as more investment is made in the conversion process, the expected production impacts from target conversion should be minimised as the changed process is optimised to operate most efficiently. The facility-specific impact to operating costs is applied to the facility from the year after the conversion (as the first full year of operating as a converted facility).

Finally, the cost impacts for providing information necessary for the generator manufacturer(s) to obtain health regulatory approval is another important cost impact element. In general, generator manufacturers are required to submit three separate sets of "tens of generators" to health regulatory authorities as part of the LEU-based ⁹⁹Mo approval process for each market and from each processor. The ⁹⁹Mo used in those generators must come from commercial-sized LEU-based batches.

LEU-based processors have indicated that in order to facilitate their customers' efforts to seek health regulatory approval, the processors have provided the LEU-based ⁹⁹Mo free to the generator manufacturer for the required amount of generators. However, if processors are not yet selling LEU-based ⁹⁹Mo, they are required to develop a commercial-sized batch in order to supply the "tens of generators" based on the requirements of the health regulatory authority.

The NEA modelled this cost assuming a scenario of needing to produce the three commercial-sized batches of LEU-based ⁹⁹Mo in two markets. The scenario assumes that once approval is received in two markets, the processor could extract enough LEU-based ⁹⁹Mo from production runs for those markets to support the "tens of generators" required in a third (fourth, fifth, etc.) market. The modelling assumes that a commercial-sized batch is 300 6-day curies and would be offered free of charge, representing a cost to the processor of those curies at the full-cost recovery reference case price for the market (as foregone revenue). This cost was applied to processors during the year of conversion.

It should be pointed out that the model does not include the possibility that an existing processor would build a new processing facility rather than converting their current facility. A new processing facility can cost EUR 80 million or greater. As noted in Section 3.1, the model does not evaluate the impacts of new infrastructure costs as it is very difficult to delineate "new infrastructure" costs from "LEU-related" costs for new infrastructure. The effects of such an investment cost on prices have been determined in the NEA economic study (OECD/NEA, 2010).

3.4. Cost impacts from converting to LEU targets

The LUCM modelling was undertaken to provide a sense of the direction and magnitude of the expected price changes that would take place as a result of LEU-target conversion. Applying the range of expected facility- and time-specific cost impacts of the various impact elements to the facility-specific reference cases gives the expected results of the cost of converting to LEU targets for ⁹⁹Mo production. It should be reiterated that the reference case that is used for comparison is based on full-cost recovery of operations; original capital costs are assumed to be fully amortised at the reactors and processing facilities that are converting and thus are not included. A non-full-cost recovery reference case is also shown to allow comparison between the impact from moving to full-cost recovery and the additional costs impacts from LEU-target conversion.

While absolute values will be presented in this section, the reader must be aware that the values are meant to be illustrative and should not be construed as representing the absolute true value seen, or expected to be seen, in the market. The important lessons from the modelling results are the direction and degree of the price changes expected from LEU-target conversion through the supply, including the final impact on the patient.

Price increases resulting from LEU-target conversion

The first results from the LUCM modelling to discuss in this report are related to the expected impact on costs through the supply chain, from irradiators down to the radiopharmacy or nuclear medicine department. Table 3.3 presents the absolute values derived from the modelling of cost impacts. As noted above, the table includes two reference cases: without and with full-cost recovery being applied. These two cases are consistent with the values presented in the NEA economic study (OECD/NEA, 2010), with the latter aligned with the results for a situation with full-cost recovery for operations, but no capital for either the irradiator or the processor.

Table 3.3. Costs in the supply chain including the impa from LEU-target conversion in EUR	ct

	LUCM (EUR/6-day Ci) ¹ from:				
Impact scenario	Irradiator	Processor	Generator manufacturer	Radiopharmacy/nuclear medicine department	
Reference case without FCR ²	45	315	375	1 810	
Reference case with FCR ²	60	330	390	1 825	
High infrastructure	68	400	457	1 894	
Low infrastructure	74	418	474	1 911	
Full range	60-80	353-474	409-530	1 845-1 967	

^{1.} Values rounded and medians presented for all except "full range". Values are meant to be illustrative of the situation and should not be construed as being the absolute true value in the market.

Table 3.4 shows the percentage increase in costs expected from the modelling results. The percentage increase for the "reference case with full-cost recovery" is the increase from moving to full-cost recovery only (thus the increase from the "reference case without full-cost recovery"). All the other percentage increases presented in the table show the expected cost increase compared to the "reference case with full-cost recovery", thus isolating the cost impacts of the LEU-target conversion.

These two tables demonstrate that LEU-based ⁹⁹Mo from a converted facility is more expensive than HEU-based ⁹⁹Mo from the same or a similar facility. While this is not surprising, the values also show that the final cost impact from moving to LEU targets

As noted in Section 3.1, the reference case is the economic situation where no LEU-target conversion occurs.FCR = full-cost recovery.

from the radiopharmacy stage is less than 8%. The cost impacts upstream are higher however, reaching a cost increase of about 43% under the worst case situation for processors. The impact of these cost increase on the end payer will be discussed in the next section.

Table 3.4. Percentag	e increase in cos	ts resulting from	LEU-target conversion

Impact scenario	% increase as a result of LEU-target conversion ¹ (% increase from reference case with FCR)			
impact scenario -	Irradiator Proces		Generator manufacturer	Radiopharmacy/nuclear medicine department
Reference case without FCR				
Reference case with FCR	32.8%2	4.5% ²	$3.9\%^{2}$	0.8%2
High infrastructure	16%³	20.7%3	17.7%³	3.8%3
Low infrastructure	26.8%3	26%3	22.2%3	4.7%3
Full range	3.6-36.8%3	6.3-42.8%3	5.4-36.6% ³	1.1-7.8% ³

- 1. Medians presented for all except "full range". Values are meant to be illustrative of the situation and should not be construed as being the absolute true value in the market.
- 2. Percentage increase from reference case without FCR, thus increase necessary to move to FCR for operating costs.
- 3. Percentage increase from reference case with FCR, isolating the effects of the LEU-target conversion.

An interesting result from the modelling presented in Tables 3.3 and 3.4 is that the cost impact under the high infrastructure impact scenario is actually less than the cost impact under the low infrastructure impact scenario. This may seem counterintuitive since the high infrastructure impact scenario includes higher infrastructure costs for the irradiator and the processor. However, as discussed in Section 3.2, an additional element of the scenario is that the high upfront infrastructure spending results in lower capacity impacts. This means that there is greater ⁹⁹Mo production under the high infrastructure scenario, which allows the high costs to be spread out over more product, and results in an overall lower LUCM. Thus it appears beneficial for an individual facility to invest in optimal infrastructure during conversion in order to realise long-term savings from lower operating costs and higher production.

Another interesting comparison is between the expected LUCM from a converted facility and the expected LUCM from new infrastructure. The previous NEA economic study presented the expected impacts from moving to full-cost recovery for various infrastructure scenarios. Table 3.5 presents the expected cost increase from the reference case without full-cost recovery scenario, duplicated from the economic study (Table 5.5, p. 83, of OECD/NEA, 2010). The values demonstrate that the impacts from moving to full-cost recovery under almost all capital replacement scenarios are expected to be larger than the impacts of LEU-target conversion. This means that LEU-based ⁹⁹Mo from a converted facility (with full-cost recovery) may be less expensive than ⁹⁹Mo from a new facility with full-cost recovery, depending on the infrastructure scenario.

The values presented in Table 3.5 do not include the costs of converting to using LEU targets. It was indicated by the expert working group that in general new infrastructure should not face important cost differences from target conversion if it was still in very early stages of design. In this case, the irradiator and/or processor would be able to include the necessary adjustments in the design without imposing significant costs on the overall project. However, where a new project is already well advanced there will likely be a cost impact on a curie of ⁹⁹Mo produced since the project may not be able to alter its design significantly (e.g. to make more irradiation space available). This means that the new project would produce less ⁹⁹Mo with LEU targets compared to its originally planned quantity from HEU targets.

Table 3.5. Expected costs in the supply chain from moving to full-cost recovery, from 2010 NEA economic study

	LUCM (EUR/6-day Ci) ¹ as a result of moving to full-cost recovery, from:				
Impact scenario	Irradiator	Processor	Generator manufacturer	Radiopharmacy/nuclear medicine department	
Reference case without FCR	45	315	375	1 810	
FDIR with no processing	400	670	730	2 165	
MP 20% with no processing	145	415	475	1 910	
MP 50% with no processing	355	625	685	2 120	
FDIR with processing	400	855	915	2 350	
MP 20% with processing	145	600	660	2 095	
MP 50% with processing	355	810	870	2 305	
MP 20% - no capital + processing	55	510	570	2 005	
MP 50% – no capital + processing	140	595	650	2 090	

^{1.} Values are meant to be illustrative of the situation and should not be construed as being the absolute true value in the market

To model the expected impacts from such a situation, the NEA started with the same assumptions for the new infrastructure as used in the economic study and applied an expected reduction of capacity of 20% to account for the lower quantity of ²³⁵U in the targets. This value is consistent with the range of "low impacts" used earlier in the study. Table 3.6 provides the results of this modelling for two scenarios:

- a multipurpose reactor where 20% of its operations are for 99Mo production;
- a multipurpose reactor where 50% of its operations are for ⁹⁹Mo production.

For both of these situations, the assumptions used (to be consistent with the economic study) were: the payback period for the new infrastructure was 20 years; the original planned production was 2 500 6-day curies per week; the reactor is planned to operate 37 weeks in a year.

Based on the results presented in Table 3.6, a new multipurpose reactor where 20% of its operations are for ⁹⁹Mo production, with the assumptions outlined above, could require a cost increase of about 20% to account for the reduced production. We would expect this impact to be lower for projects that are earlier on in the planning stage since they may be able to adjust their project design.

Table 3.6. Expected costs of target conversion for fully-cost recovered new infrastructure, based on 2010 NEA economic study

Impact scenario	LUCM (EUR/6-day Ci) ¹ as a result of target conversion, from the irradiator	Percentage increase from FCR scenario with no conversion, from irradiators
MP 20% with no processing	175	20%
MP 50% with no processing	440	24%

^{1.} Values are meant to be illustrative of the situation and should not be construed as being the absolute true value in the market.

Overall, these results support the need to move the market to full-cost recovery for irradiators (under the assumption that processors and down the supply chain are already implementing full-cost recovery as they are commercial operations). LEU-based ⁹⁹Mo will likely be more expensive than HEU-based ⁹⁹Mo from the same or a similar facility, and even more expensive than subsidised HEU-based ⁹⁹Mo. If the irradiation of targets for

⁹⁹Mo production continues to be subsidised in some facilities, not only will long-term supply security be threatened from the unsustainable economic situation, it will also be threatened by hindering the LEU-target conversion process.

Cost impacts on patients resulting from LEU-target conversion

It is important to understand the impact of the expected cost increases on the end payer, as they are the ones that will see the final impact. Drawing from the data from the economic study,³ the modelling applied the cost impacts upstream to determine the expected impacts on the ^{99m}Tc used in the patient procedure. From the global data and based on a weighted average of ^{99m}Tc-based procedures, NEA based its assessment on the following starting values:

- cost of a dose of ^{99m}Tc from the radiopharmacy per imaging procedure: EUR 10.86;
- reimbursement rate for the imaging procedure: EUR 245.

It is important to remind the reader that these values are only meant to be indicative as there could be a large range depending on the medical procedure and the jurisdiction. The prices used were normalised to ⁹⁹Mo 6-day curies in order to facilitate the comparison across the supply chain.⁴

Table 3.7 presents the results of applying the cost impacts from LEU-target conversion on the price of the ^{99m}Tc dose from the radiopharmacy or hospital nuclear medicine department. Applying the cost increases upstream to the end user, the modelling shows that the price of the procedure dose of ^{99m}Tc from the radiopharmacy is expected to increase less than EUR 1, from the full-cost reference case value of EUR 10.94 to EUR 11.79 under the worst case cost impact scenario. Within a reimbursement rate of EUR 245, this translates to the ^{99m}Tc dose increasing its share from 4.46% up to 4.8% (see Table 3.8). While this increase of less than EUR 1 on EUR 245 to pay for the costs of LEU-target conversion is a very small increase, it is important to realise that this increase must be paid for and the payment must flow upstream to support the necessary changes.

Table 3.7. (Cost impact of	LEU-target conversi	on of the ^{99m} Tc dose
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Impact scenario	Value from each supply chain segment (in EUR) within the cost of the ^{99m} Tc radiopharmacy dose (cumulative for each stage of the supply chain) ¹			
Impact scenario	Irradiator	Radiopharmacy/nuclear medicine department		
Reference case without FCR	0.26	1.90	2.24	10.86
Reference case with FCR	0.35	1.99	2.33	10.94
High infrastructure	0.41	2.40	2.74	11.35
Low infrastructure	0.44	2.51	2.84	11.46
Full range	0.36-0.48	2.11-2.84	2.45-3.18	11.07-11.79

^{1.} Values are meant to be illustrative of the situation and should not be construed as being the absolute true value in the market.

^{3.} While there were concerns presented about the radiopharmacy and end-payer data in the economic study, especially related to fact that there is little US data included, additional data were not provided to the NEA despite numerous attempts to obtain the data. As a result, the NEA undertook the LEU-target conversion assessment with the data it had.

^{4.} For a full discussion of the methodology to normalise the prices of 99 mTc to 6-day curies of 99 Mo, refer to Annex 2 of OECD/NEA, 2010.

Table 3.8. Impacts of LEU-target	conversion as sha	re of reimbursement rate
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Impact scenario	Percentage of the 99mTc radiopharmacy dose within the reimbursement rate (cumulative for each stage of the supply chain) ¹			
impact scenario	Irradiator	Processor	Generator manufacturer	Radiopharmacy/nuclear medicine department
Reference case without FCR	0.11%	0.78%	0.91%	4.42%
Reference case with FCR	0.14%	0.81%	0.95%	4.46%
High infrastructure	0.17%	0.98%	1.11%	4.62%
Low infrastructure	0.18%	1.02%	1.16%	4.67%
Full range	0.15-0.19%	0.86-1.16%	1.00-1.16%	4.51-4.8%

^{1.} Based on a reimbursement rate of EUR 245.

Cost impacts on the overall supply chain resulting from LEU-target conversion

As noted in the previous section, the cost impact on the end payer is very small but it is very important that it is paid in order to account for the costs of target conversion upstream. In order to understand the overall cost impacts on the supply chain and on individual facility operators, the NEA modelled the potential cost to the supply chain by applying median values to the range of converting facilities. Table 3.9 presents the results from this analysis.

Table 3.9. Cost to supply chain on LEU-target conversion

Impact scenario	Total incremental capital costs (EUR)		Incremental operating costs over two years (EUR)		Cost to supply chain (EUR)
	Irradiator	Processor	Irradiator	Processor	Total
High infrastructure	3 000 000	12 009 000	633 000	5 812 000	93 081 000
Low infrastructure	2 500 000	10 658 000	1 681 000	7 154 000	96 335 000
Full range	0-7 615 000	9 291 000-26 574 000	0-2 932 000	2 675 000-12 881 000	55 865 000-198 652 000

Table 3.9 shows that on a facility basis, the costs are significant. While the previous section indicated that the impacts on the end payer were less than EUR 1 per procedure, the incremental capital costs for irradiators can be up to EUR 7.6 million, and EUR 26.6 million for a processor, under the worst case. Incremental operating costs are only calculated for two years, as after that time all the global players should be converted and the operating cost impacts would be incorporated into market prices as the new norm. However, during the conversion process and while the market is not 100% based on non-HEU-based ⁹⁹Mo and/or ^{99m}Tc, the operating costs impacts are relevant for converted irradiators and processors.

Applying these incremental costs over the converting reactors and processors gives the total cost to the supply chain. To convert the full supply chain to use LEU targets for ⁹⁹Mo production, the cost to the supply chain will be close to EUR 100 million (higher under a worst case situation).

Given that these costs are significant to the facility and to the supply chain overall, and that the decision to convert to using LEU targets is an externality imposed on the market players, there could be a possible role for governments to ensure that costs are manageable or compensated somehow.

Need for policy action to encourage LEU conversion because of cost impacts

The previous sections demonstrated that LEU-based ⁹⁹Mo is expected to be more expensive than HEU-based ⁹⁹Mo, especially compared to subsidised HEU-based ⁹⁹Mo. In addition there would be cost impacts throughout the supply chain, but the expected impact on the end user would be very small.

Current experience in the supply chain seems to indicate that end payers have difficulty supporting these small changes in end user prices. However, the support is necessary to ensure that the supply chain will have sufficient resources (and motivation) to convert to producing ⁹⁹Mo from LEU targets.

Figure 3.2 shows a possible future of ⁹⁹Mo production, comparing non-HEU-based production to HEU-based production under a technology-challenges situation. The point to this figure is to show that in the next few years HEU-based ⁹⁹Mo production should be sufficient to meet global demand. Since HEU-based ⁹⁹Mo is expected to be less expensive than non-HEU-based production (such as that from LEU-target converted facilities), it may be difficult for non-HEU-based producers to sell their product. This difficulty could result in delaying decisions to convert to using LEU targets or to develop other non-HEU production sources.

Given these results, and the issues raised in the previous section, there may be a need for governments to encourage non-HEU-based ⁹⁹Mo/^{99m}Tc production and consumer uptake, always respecting the HLG-MR policy approach to ensure long-term supply security.

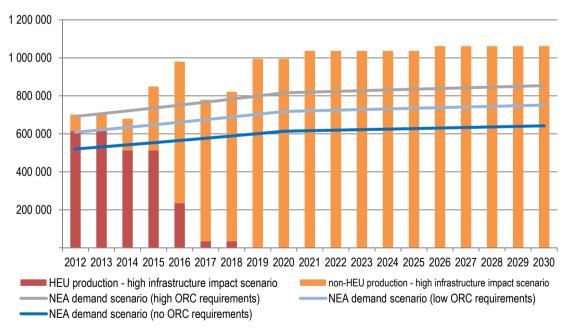


Figure 3.2. Non-HEU- vs. HEU-based ⁹⁹Mo production: high infrastructure impact scenario and technology-challenges situation

The NEA has developed a discussion paper that provides various options for governments to consider for encouraging non-HEU-based production and consumer uptake (OECD/NEA, 2012a). Broadly speaking, the policy options examined and described in the document have one of three roles: making the option of purchasing or producing non-HEU-based ⁹⁹Mo and/or ^{99m}Tc more attractive; making the option of purchasing or producing HEU-based ⁹⁹Mo and/or ^{99m}Tc less attractive; or limiting access to HEU-based ⁹⁹Mo/^{99m}Tc.

While countries may have differing views on the various options, given their own economic, regulatory, or political situation, the paper provides a brief review of the options from the starting point of the HLG-MR policy approach to achieving a long-term reliable supply of 99Mo/99mTc.

3.5. Conclusions regarding the expected cost impacts from LEU-target conversion

From the modelling undertaken to assess the cost impacts from converting to using LEU targets, it is clear that conversion will result in increased costs for the supply chain. LEU-based ⁹⁹Mo, given the increased capital and operating costs, including the impact from reduced production, is expected to be more expensive than HEU-based ⁹⁹Mo from the same or a similar facility. However, the overall move to full-cost recovery, coupled with the need for new irradiation and related processing infrastructure, should have a larger price impact on the market than the move to converting existing facilities to use LEU targets.

The impact on the end user is expected to be very small, increasing the radiopharmacy dose by less than 8% and having less than a 0.4% impact on the final overall procedure costs. However, this small impact is very important upstream, where total cost of LEU-target conversion could be close to EUR 100 million for the whole supply chain.

Given the externality nature of the decision for ⁹⁹Mo irradiators and processors to convert to using LEU targets, and the costs imposed on the market without any specific benefits for end users, there may be a role for governments to encourage non-HEU-based production and consumer uptake.

Chapter 4. Conclusions on the market impacts of converting to the use of LEU targets for ⁹⁹Mo production

The NEA study, developed in collaboration with experts from the supply chain and with the HLG-MR, demonstrates the expected capacity and cost impacts of converting to the use of LEU targets for the production of ⁹⁹Mo. The findings show that LEU-target conversion will have an impact on capacity, but will not be the major factor that produces long-term shortages; the main concern is the continued economic situation in the ⁹⁹Mo/^{99m}Tc supply chain that is unsustainable for any investment, including LEU-based investment. As a result, full-cost recovery is a necessary (but insufficient) condition for long-term supply reliability and LEU-target conversion.

LEU-target conversion does have important impacts on the availability of outage reserve capacity – in the long term for irradiation capacity, but only during the conversion period for processing facilities.

In addition, it is clear that ⁹⁹Mo/^{99m}Tc produced from converted facilities is more expensive than HEU-based ⁹⁹Mo. However, the increase at the radiopharmacy stage is less than 8%. This small impact on the end payer translates to an important increase upstream though, and the end payer will need to accommodate the increase to ensure sufficient funding for the upstream supply chain. Evidence from the study points to a role for governments to encourage LEU-target conversion, helping to ensure a long-term secure supply of this important medical isotope.

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Annex 1. Expert working group

Below is the list of people who attended the NEA workshops of the LEU-target conversion impact assessment project and/or who provided expert advice during interviews with the NEA between workshops.

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Annex 2. Capacity impact elements

Below is the final list of capacity impact elements identified by the expert working group to be important or important but not likely:

- An important element is one that is expected to have a significant impact on capacity as a result of the conversion process.
- An important but not likely element is one that could have a significant impact if it
 were to come true, but it is not expected that the element will be a concern. This
 element will not be quantified in the model, but the concern will be noted in the
 report.

The expert working group also identified those possible capacity impact elements that were not important. The group agreed that these capacity-related elements were not expected to be impacted significantly either during or after the conversion to using LEU targets.

Important capacity impact elements

Proposed capacity impact element

Uranium supply

1. Availability of HEU for period until conversion completed.

Reactor (irradiation services)

- 99Mo irradiation capacity impacts if there were no significant changes to the current reactors.
 Group 2: Standardised EU target not optimised for each reactor, therefore impact on capacity.
- 3. Time (including downtime) required for infrastructure changes that would be required as a result of moving to LEU targets. For example, will additional cooling be necessary? Additional irradiation rigs? A reconfiguration of reactor? Others?
- 4. Reduced availability of ORC during conversion (would available outage reserve capacity positions be used in order to allow for the simultaneous production of HEU and LEU-based ⁹⁹Mo?).
- 5. Reduced availability of ORC after conversion (would additional positions be used after the conversion process, which may have been used for ORC?).

Reactors → processors distribution issues

- 6. Distribution changes between reactors and processors to account for:
 - Reactor shutdown periods for conversion.

Processors

- 7. Time (including downtime) required for infrastructure changes that would be required as a result of moving to LEU targets. For example, during the conversion process are additional processing lines necessary? Other infrastructure?
- 8. 99Mo production capacity impacts.
- 9. Reduced availability of backup capacity after conversion.
- 10. Time for regulatory approvals, including approval application data and process management, for using changed targets.

- 11. Time for regulatory approvals, including approval application data and process management, for changed number of targets processed per week and/or year.
- 12. Time for regulatory approvals, including approval application data and process management, for changed infrastructure (e.g. new processing line).
- 13. Time for regulatory approvals, including approval application data and process management, for changes in isotope release amounts resulting from using LEU targets.

Processors → generator manufacturer distribution issues

- 14. Distribution changes between processors and generator manufacturers to account for:
 - Generator manufacturer purchasing choices that are not compatible with production from previous processors (e.g. generator manufacturer using LEU but traditional processors have not converted).

Capacity impact elements identified as "important but not likely"

Proposed capacity impact element

Uranium supply

1. Availability of LEU during and after conversion.

Target supply

- Time for required R&D to develop LEU targets.
- 3. Capacity to produce LEU targets.
- 4. Time to develop infrastructure capacity to fabricate LEU targets at sufficient quantities.

Target supply → reactors transportation issues

- 5. Time for transportation regulatory approval for changed container design.
- 6. Time for transportation regulatory approval for new routes for sending targets (e.g. to reactors/processors that previously did not buy from target developer).

Reactor (irradiation services)

- 7. Time for regulatory approvals, including approval application data and process management, for using changed targets.
- Time for regulatory approvals, including approval application data and process management, for using changed infrastructure (e.g. new irradiation rigs installation).
- 9. Time or capacity impacts from providing information necessary for generator manufacturer to obtain health regulatory approvals (which requires three full batches to be developed).
- 10. Time to develop fresh target storage capacity for the transition period.

Reactors → processors distribution issues

- 11. Distribution changes between reactors and processors to account for:
 - Reduced product so new reactors used or use pattern changes.
 - Reactor infrastructure changes that are not compatible with all previous processors (e.g. reactor changes irradiation rigs for new target geometry from denser targets from one processor, but other processor not converted).
 - Processor infrastructure changes that are not compatible with all previous reactors (e.g. processor converted but reactor cannot irradiate the LEU targets).

Reactors → processors transportation issues

- Time of designing and developing new containers for shipping irradiated LEU targets.
- 13. Capacity to transport the additional targets/containers.
- 14. Time for transportation regulatory approvals for additional containers.

- 15. Time for transportation regulatory approvals for changed container design to handle changed geometry of targets.
- 16. Time for transportation regulatory approvals for new routes for sending irradiated targets (e.g. from different reactors to account for reduced production capacity).
- 17. Time for transportation regulatory approvals for sending additional irradiated targets/containers along existing routes.

Note: more analysis may be required on whether need additional transportation.

Processors

- 18. Reduced availability of backup capacity during conversion.
- 19. Additional staff requirements during conversion process.
- 20. Additional staff requirements after conversion process.
- 21. Time to develop additional waste management infrastructure or processes.
- 22. Time or capacity impacts from providing information necessary for generator manufacturer to obtain health regulatory approvals (which requires three full batches to be developed).

Generator manufacturers

23. Time or capacity impacts from providing information necessary for generator manufacturer to obtain health regulatory approvals (which requires three full batches to be developed); could include impact of regulatory approvals on inputs and product distribution: LMI had LEU produced but it was not approved for use in Canada therefore had to do two product runs.

Annex 3. Cost impact elements

Below is the final list of cost impact elements identified by the expert working group to be important or important but not likely:

- An important element is one that is expected to have a significant impact on cost as a result of the conversion process.
- An important but not likely element is one that could have a significant impact if it
 were to come true, but it is not expected that the element will be a concern. This
 element will not be quantified in the model, but the concern will be noted in the
 report.

The expert working group also identified those possible cost impact elements that were not important. The group agreed that these capacity-related elements were not expected to be impacted significantly either during or after the conversion to using LEU targets.

Important cost impact elements

Proposed cost impact element

Uranium supply

1. Cost difference between HEU and LEU.

Target supply

- 2. Cost for required R&D to develop LEU targets.
- 3. Cost difference between HEU and LEU targets per unit.

Target supply → reactors transportation issues

Cost of shipping additional containers.

Reactor (irradiation services)

- 5. Cost impacts from reduced ⁹⁹Mo irradiation capacity if there were no significant changes to the current reactors.
- 6. Cost required for infrastructure changes that would be required as a result of moving to LEU targets. For example, will additional cooling be necessary? Additional irradiation rigs? A reconfiguration of reactor? Others?
- 7. Cost for regulatory approvals, including approval application data and process management, for using changed targets.
- Cost for regulatory approvals, including approval application data and process management, for using changed infrastructure (e.g. new irradiation rigs installation).
- Cost for regulatory approvals, including approval application data and process management, for changed number of target irradiations.

Reactors → processors transportation issues

- 10. Cost of designing and developing new containers for shipping irradiated LEU targets.
- 11. Cost of purchasing new containers to transport irradiated LEU targets.
- 12. Cost of shipping additional targets to processors as a result of changes to irradiation sourcing patterns.

- 13. Cost for transportation regulatory approvals for changed container design to handle changed geometry of targets.
- 14. Cost for transportation regulatory approvals for new routes for sending irradiated targets (e.g. from different reactors to account for reduced production capacity).

Processors

- 15. Costs (capital/operating) of infrastructure changes that would be required as a result of moving to LEU targets. For example, during the conversion process are additional processing lines necessary? Other infrastructure?
- 16. Cost impacts from reduced ⁹⁹Mo processing capacity given less ⁹⁹Mo attainable from each target.
- 17. Additional staff requirements after conversion process.
- 18. Cost to develop additional waste management infrastructure or processes.
- Cost for regulatory approvals, including approval application data and process management, for using changed targets.
- Cost for regulatory approvals, including approval application data and process management, for changed number of targets processed per week and/or year.
- 21. Cost for regulatory approvals, including approval application data and process management, for changed infrastructure (e.g. new processing line).
- 22. Cost for regulatory approvals, including approval application data and process management, for changes in isotope release amounts resulting from using LEU targets.
- 23. Cost impacts from providing information necessary for generator manufacturer to obtain health regulatory approvals (which requires three full batches to be developed).

Cost impact elements identified as "important but not likely"

Proposed cost impact element

Target supply

1. Cost to develop infrastructure capacity to fabricate LEU targets at sufficient quantities.

Target supply → reactors transportation issues

2. Cost of purchasing new containers for LEU non-irradiated targets.

Reactor (irradiation services)

- Cost of downtime for infrastructure changes, including lost revenue from other irradiation services that could not be provided.
- 4. Storing fresh HEU/LEU targets (space and security).
- 5. Cost impacts from standard target not being optimal for each.

Processors

6. Additional staff requirements during conversion process.

Processors → generator manufacturer distribution issues

- 7. Distribution changes between processors and generator manufacturers to account for:
 - Reduced production so different distribution pattern (e.g. focusing on more profitable markets).
 - Generator manufacturer purchasing choices that are not compatible with production from previous processors (e.g. generator manufacturer using LEU but traditional processors have not converted).

Generator manufacturers

Cost impacts from providing information necessary for generator manufacturer to obtain health regulatory approvals (which requires three full batches to be developed).

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