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Guidance Document

Full-cost Recovery for Molybdenum-99 Irradiation Services:

Methodology and Implementation

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NUCLEAR ENERGY AGENCY

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NUCLEAR ENERGY AGENCY
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Foreword

At the request of its member countries, the OECD Nuclear Energy Agency (NEA) became involved in global efforts to ensure a reliable supply of molybdenum-99 (^{99}Mo) and its decay product, technetium-99m (^{99m}Tc), the most widely used medical radioisotope. The NEA established the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) in 2009.

Under its first mandate (June 2009-2011), the HLG-MR examined the major issues that affect the short-, medium- and long-term reliability of ^{99}Mo/^{99m}Tc supply and then developed a policy approach to move the supply chain to a sustainable basis and ensure security of supply. The objectives of the HLG-MR during its second mandate (July 2011-2013) are to work towards increasing the long-term security of supply of ^{99}Mo and ^{99m}Tc, especially through the implementation of the HLG-MR policy approach and its associated recommendations. This will entail actions to maintain transparency on global developments, continue communication with the supply chain and end users, evaluate progress toward implementation and provide additional information and analysis where necessary.

A key action under the second mandate is to provide guidance on the implementation of the HLG-MR policy approach. This document provides guidance to reactor and alternative production technology (e.g., cyclotrons, accelerators) operators on how to undertake full-cost identification and implement full-cost recovery. The document also discusses issues related to levelling the playing field between old and new reactors.

A supporting tool to this guidance document is an Excel workbook that puts the concepts and formulas described in the document into a usable format. The workbook can be accessed on the HLG-MR webpage for use by operators of research reactors and other ^{99}Mo/^{99m}Tc production technologies (see www.oecd-nea.org/med-radio).

Acknowledgements

This guidance document is a product of the HLG-MR's Full-cost Working Group (see Annex 1 for members), who developed the methodology. In addition, a significant number of supply chain participants and stakeholders including all major reactor operators, all major processors, generator manufacturers, representatives from radiopharmacies and nuclear medicine practitioners reviewed the proposed methodology and provided important comments.

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.

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Introduction

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

One of the key principles in the policy approach is:

> Principle 1: All ^{99m}Tc supply chain participants should implement full-cost recovery, including costs related to capital replacement.

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

To ensure a long-term reliable supply of ^{99}Mo/^{99m}Tc, operators of traditional multi-purpose research reactor and other ^{99}Mo/^{99m}Tc production technologies have to implement full-cost identification and recovery. This will provide the economic incentives to develop ^{99}Mo related infrastructure and to fully pay operating costs. For a consistent approach on how costs are identified, this guidance document provides a full-cost recovery methodology that identifies the essential elements that should be included when determining the full-cost of ^{99}Mo irradiation services, including a reasonable portion of facility common costs, and how these elements should be allocated between various missions in the case of multipurpose facilities.

Full-cost recovery should be implemented by all producers that supply the global market, otherwise there will be distortions that could jeopardise the long-term economic sustainability of the irradiation providers and thus jeopardise the long-term supply security of ^{99}Mo/^{99m}Tc. In addition, it should be recognised by all consumers within the global market that the price increases expected by the application of full-cost recovery should flow through the supply chain and should be reflected in the costs of the final medical procedure, to be reimbursed appropriately by the health care system. As shown in the *Economic Study* (NEA, 2010), the final impact on end-users should be reasonably small; however, the increases are necessary to ensure reliable supply.

Applying the full-cost recovery methodology ensures that there are no hidden subsidies directed towards ^{99}Mo production, allowing for a level-playing field between the world's producers. The costing methodology is flexible, recognising different situations at different reactors, but identifies the key cost elements that need to be recovered through the pricing of ^{99}Mo irradiation services. It should be noted that the full-cost recovery methodology suggested in this document should be applicable to all production technologies; however, it was written based on experience with research reactors and thus some elements may need to be adapted slightly – but in the spirit of full-cost recovery – for alternative production technologies.

Processors and generator manufacturers should already set their prices such that their costs are fully recovered, given their commercial nature. However, in cases where subsidies are provided by governments to certain processors or manufacturers, these should be removed to ensure that the move to sustainable economics can be achieved. For example, any government subsidies for the management or disposal of the wastes produced from the processing of ^{99}Mo irradiated targets should become the responsibility of the supply chain, following the notion of full-cost recovery and allowing for equal opportunities for all processors within the global supply chain.

The full-cost recovery methodology described in this document is not a price-setting mechanism; it defines the cost elements and allocation methods, but it does not dictate the value of those costs nor prices that would be expected or required under full-cost recovery. Given varying costs and ownership structures and national competition laws, international pricing-setting regulation would be difficult or impossible to implement. Nor is price-setting necessarily desirable; a full-cost recovery methodology would still allow for downstream stakeholders to benefit from improvements in efficiencies that lower production costs through offering lower prices (where sustainable).

The HLG-MR policy approach also noted that outage reserve capacity (ORC) should be sourced and paid for by the supply chain (Principle 2). The provision of ORC is not an item included in the full-cost recovery methodology as ORC could be considered a product that is offered separately from irradiation services. It is expected that the full-cost methodology described in this guidance document should also be applied to identifying the costs associated with the provision of ORC within a reactor.

The guidance document describes the methodology and how full-cost recovery could be implemented. In addition, the document discusses how the application of full-cost recovery provides for a reasonable level-playing field between old and new reactors in their provision of ^{99}Mo irradiation services. The guidance document was developed by HLG-MR's Full-cost Working Group (see Annex 1 for participants) and was approved by the HLG-MR.

It is not mandatory that a reactor operator applies this methodology exactly as described in this document. The methodology provides consistent guidance to all reactors, but some reactor operators may already be using their own full-cost identification and recovery methodology. If they can demonstrate that their methodology is compliant with the full-cost recovery principles established and described in this guidance document, such that all relevant costs are identified and recovered, that will be sufficient. However, this methodology was reviewed by global supply chain participants and deemed to be a sensible model that allows for consistency across all producing reactors.

Operators have the responsibility to adhere to the principle of full-cost recovery and to ensure it is implemented, respecting applicable domestic accounting law and competition rules. It should be recognised that there may be differences in how such analyses are performed to align with accounting standards and financial reporting. However, this guidance document is for a different purpose and should not be seen as incompatible with those other reports; they all have specific objectives and therefore do not need to be perfectly consistent.

The NEA has developed an Excel workbook that allows operators to implement the full-cost identification methodology described below. The workbook incorporates all the formulas of the methodology so that the operator would only be required to insert the costs and variables specific to their facility and the model will produce the results of the levelised unit cost of ^{99}Mo production at the facility. The guidance document describes the derivation of the whole methodology but a specific operator/user may not need to know all of the issues; the Excel workbook would guide them through calculation of the full-costs of providing ^{99}Mo irradiation services. The workbook can be accessed on the HLG-MR webpage for use by operators of research reactors and other ^{99}Mo/^{99m}Tc production technologies (see www.oecd-nea.org/med-radio).

Methodology

Any ^{99}Mo production facility that serves multiple purposes or irradiates multiple products, such as the majority of the irradiating research reactors, will need to attribute a certain portion of the general or shared costs to ^{99}Mo production, with the remaining portion of the costs being attributed to the other missions within the facility. In addition, the facility will have some specific costs that can be clearly and directly attributed to ^{99}Mo irradiation services.

This section identifies the key cost elements within the irradiating facility and then provides the methodology for each of the cost elements for apportioning the common costs and accounting for direct costs to ^{99}Mo irradiation services. As noted above, an Excel workbook is available from the NEA that provides the methodology and the necessary calculations.

The high-level cost elements within the irradiation facility identified are:

A. Capital costs:

- refurbishment costs that would be depreciated (to distinguish from maintenance): amortised over the life of the refurbished components;
- new infrastructure amortised over the life of the infrastructure, which was decided to be 40 years for a research reactor to ensure consistency[1], including any financing costs.

B. General overhead costs:

- general or shared administration, including: human resource management, financial and accounting services, legal services, IT, government relations, etc;
- site infrastructure support: roads and grounds, site and facilities maintenance.

C. General operational costs:

- reactor operation and maintenance staff, safety staff, centralised engineering, design and manufacturing services, etc;
- reactor fuel (or equivalent with alternative technologies) and other generic consumables;
- utilities: energy, water, etc;
- licensing and regulatory requirements, quality control;
- security, including staff;

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[1] In some circumstances the actual amortisation periods of financing for new capital will be shorter than 40 years, for example in the case of commercial funding. However, the HLG-MR recognised that an amortisation period of, say 20 years, would lead to significant cost differences between years 19 and 21. To ensure consistency among how full-costs are calculated and the smoothing of costs over the lifespan of the facility, the methodology recommends the use of a 40 year amortisation period, which is consistent with the life span of the research reactor. Differences between amortisation periods (or for different financing models) will have to be accounted for in the pricing of the irradiation services from the reactor, which are set by each reactor independently and are not discussed in this document beyond the fact that prices should allow for full-cost recovery.

- waste management: management of full waste streams from the reactor (or other production technology), not including legacy waste[2];
- final waste disposal provisions[3] (not including legacy waste).

D. Decommissioning costs:

- annual provisions for the decommissioning (and related final waste disposal) of the research reactor or alternative production technology.

E. Specific ^{99}Mo irradiation costs:

- irradiation device (e.g. rigs): design, construction, operation, maintenance, dismantling; specific costs associated with the device to be recouped if they were not already paid by the processor;
- handling of irradiation targets:
  - reception, storage, loading-unloading, conditioning;
  - "ex-works truck loaded" services, where provided (e.g. shipping, providing shipping containers, provision of targets); specific costs associated with these services to be recouped if they are not already provided by processor;
  - administration: specific staff, insurance, security.
- processing waste management: if the reactor operator manages waste from the processing procedure or facility;
- processing waste final disposal: if the reactor operator is responsible for the final disposal provisions for waste from the processing procedure or facility.

The overall methodology for determining the costs of ^{99}Mo irradiations services is provided by the following equation, with the methodology of each variable explained below:

$$Full\ Cost\ for\ ^{99}Mo = wA + y_m(x_rB + C) + zD + E$$

Where:

A = Capital costs
B = General overhead costs of the entire site
C = General operational costs of the reactor
D = Decommissioning
E = Specific ^{99}Mo irradiation costs

The first action is for the irradiation facility operator to identify the full costs of their facility and then allocate costs among the different high-level cost elements – a sort of "first glance" assessment of cost allocation (see Figure 1). For example, the capital costs of a ^{99}Mo irrigation rig would get

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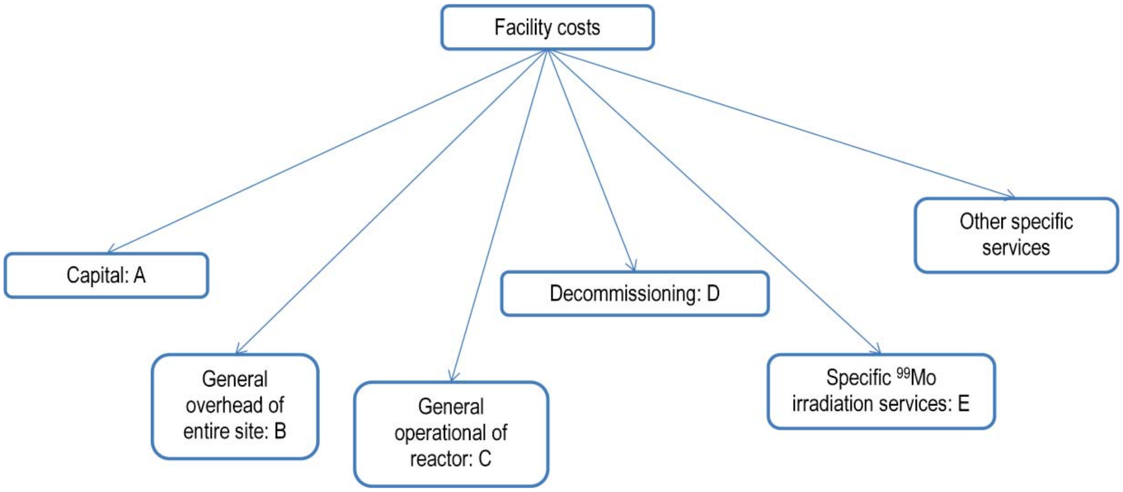
[2] Legacy wastes are the wastes from research reactors and processing facilities that occurred in the past. The HLG-MR recognises that these wastes need to be dealt with; however, they are also aware that it would be realistically impossible to ask the supply chain to pay for waste developed from past production. It is logical that full-cost recovery would be applied to those waste costs that are incurred from this point forward, but not for those wastes developed in the past.

[3] The HLG-MR recognised that not all research reactors may have final waste disposal plans at this time, but realise that all should be working on developing final disposal plans; many countries and regional governments (e.g., the European Union) are requiring the development of these plans. Regardless, many research reactors pay provisions for final disposal of radioactive wastes, even if the final disposal plan is not yet developed or finalised. These provisions should be included in the full-cost recovery methodology to ensure the removal of all hidden subsidies.

allocated to E during this first glance assessment and human resource costs that cannot be attributed to any one specific mission would be allocated to B.

In the case where a cost item is divided among different uses, the cost of the item would be divided among the appropriate variables for the uses based on percentage of time. For example, if an employee was principally a general reactor operational cost (e.g., doing maintenance 80% of the time), but spends some direct time on ^{99}Mo production (e.g., maintenance of the irrigation rig 10% of the time) and some time on general site maintenance (e.g., general maintenance 10% of the time), 80% of costs associated with the employee would be allocated to C, 10% allocated to E and 10% allocated to B.

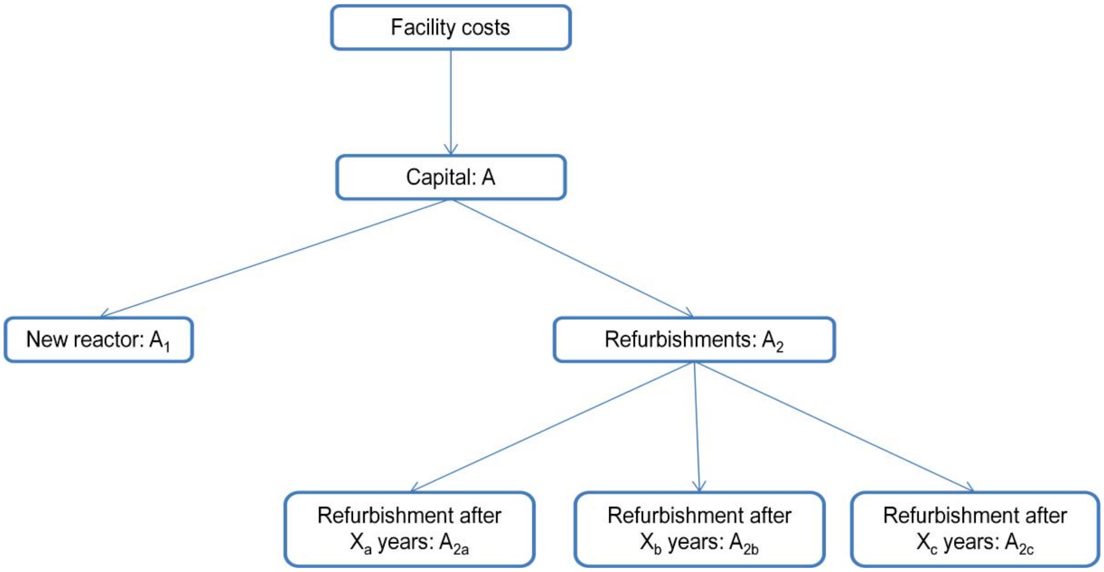
Figure 1: High-level cost elements



After the first glance assessment is undertaken, the irradiation facility operator would proceed through each of the cost elements to determine the actual apportionment to ^{99}Mo irradiation services (and other missions/services if desired).

Capital costs (wA)

Figure 2: Components of capital costs



Capital costs are the overnight capital costs of the initial infrastructure and the expected series of refurbishments that would occur during the lifespan of the irradiation facility (see Figure 2). The methodology to determine the amount to be allocated to ^{99}Mo production includes financing costs. Where costs can be directly attributed to specific missions, the value should be sent to the appropriate mission costs and the value of A adjusted (see step 1 below).

To determine the factor for the initial Infrastructure (see Figure 3 for a visual representation of the steps):

1. Determine the percentage of ancillary equipment and related site infrastructure that is directly attributable to other missions (e.g., beam lines, cold source, test loops, etc) and those that can clearly be attributed to ^{99}Mo production (e.g., irrigation rigs). Call this percentage w_1. The costs that are directly attributed to ^{99}Mo production would be included in variable E.

2. Determine a reasonable estimated percentage of reactor and facility usage that is for irradiation and handling of ^{99}Mo targets, based on business activity (% of total effort of operations related to ^{99}Mo production based on activity planning of the reactor lifetime). Call this w_2.

   A reference to actually determine w_2 could be the methodology used for y_m (see section on General Operational Costs later in this document), such that $w_2=y_m$. During the possible validation of the implementation of the full-cost recovery methodology, governments or other agencies potentially undertaking the validation could use $w_2=y_m$ to assess the implementation. Where w_2 deviated significantly from y_m, justification by the operator would have to be provided.

3. Determine the factor of A that could be applied each year based on what would need to be paid back to the lender of funds for the initial infrastructure. To ensure the inclusion of financing costs, the factor, w_3, is determined using the following amortisation formula:

$$w_3 = \frac{\left(1 + {}^{r}\!/_{t}\right)^{n\times t} - 1}{{}^{r}\!/_{t} \times \left(1 + {}^{r}\!/_{t}\right)^{n\times t}}$$

   Where:

   r = nominal interest rate
   n = the amortisation period in years (note: 40 years is a reasonable amortisation period for the reactor)
   t = number of payment periods in a year

4. By applying w_1, w_2, and w_3 to the overnight capital costs of the infrastructure following the formula presented after step 8 below, all ^{99}Mo-production related costs should be fully and fairly identified, recovered and not subsidised by national governments. This will provide an annual amount that will need to be paid by the reactor operator for the initial infrastructure in nominal currency. This value will be put in an annual payment spreadsheet[4]. Then the annual values will be discounted to determine the net present value (NPV) of the investment costs so that levelised unit cost of ^{99}Mo irradiation service costs (LUCM) and/or average cost of irradiation services (per cycle) can be determined at the end of the attribution exercise.

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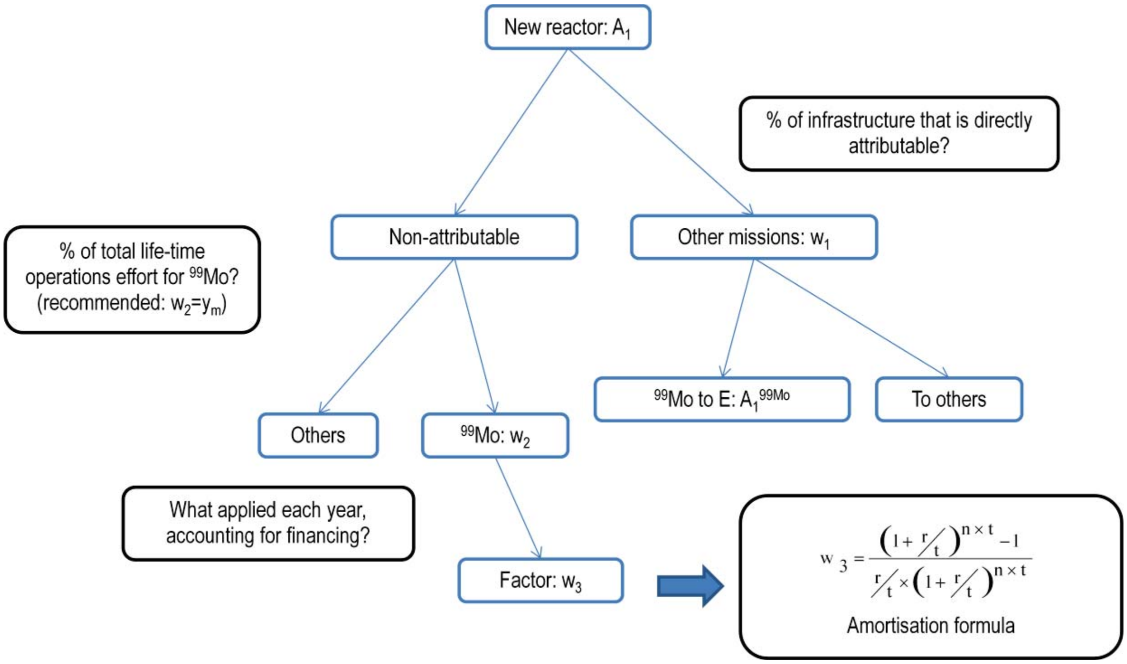
[4] See NEA Excel model of the methodology at www.oecd-nea.org/med-radio.

Figure 3: Methodology for allocation of new reactor capital costs



To determine the factor for refurbishments (see Figure 4 for a visual representation of the steps):

5. Determine the expected schedule of refurbishments and the amortisation period for each refurbishment. Note that the refurbishment costs and schedule do not need to be identical every time. The amortisation period for a refurbishment should be the expected lifespan of the refurbishment.

   From the schedule, determine the expected costs of the refurbishments (in current currency, either in absolute terms or as a proportion of initial capital costs). In order to account for inflationary effect, apply the formula to determine the amount of the refurbishment in the year to be undertaken:

$$Future\ Value = Present\ Value \times (1+i)^{k_x}$$

   Where:

   I = inflation rate
   k_x = the year in which refurbishment x takes place, from the year of construction.

   Call this value A_2; for each refurbishment, add subscripts to give A_{2a}, A_{2b}, etc.

6. Repeat steps 1 and 2 above for the refurbishments to give w_4 and w_5 respectively. If there are multiple refurbishments, add subscripts to give w_{4a}, w_{4b}, etc.

7. Using the formula below, determine the amount that would need to be paid back to the lender of funds (including financing costs) during each refurbishment period. The factor (w_{6a}, w_{6b}, etc.) is determined using the following amortisation formula:

$$w_{6x} = \frac{\left(1+{}^{r}/_{t}\right)^{v\times t}-1}{{}^{r}/_{t}\times\left(1+{}^{r}/_{t}\right)^{v\times t}}$$

Where:

r = nominal interest rate
t = number of payment periods in a year
v = the amortisation period in years for the refurbishment

8. By applying w_4, w_5 and w_6 to the costs of the refurbishment infrastructure following the formula below, all ^{99}Mo-production related costs should be fully and fairly identified, recovered and not subsidised by national governments. This will provide an annual amount that will need to be paid by the reactor operator for the refurbishments during their repayment periods, in nominal currency. This value will be put in an annual payment spreadsheet. Then the annual values will be discounted to determine the NPV of the investment costs so the LUCM of irradiation services and/or average cost of irradiation services (per cycle) can be determined at the end of the attribution exercise.

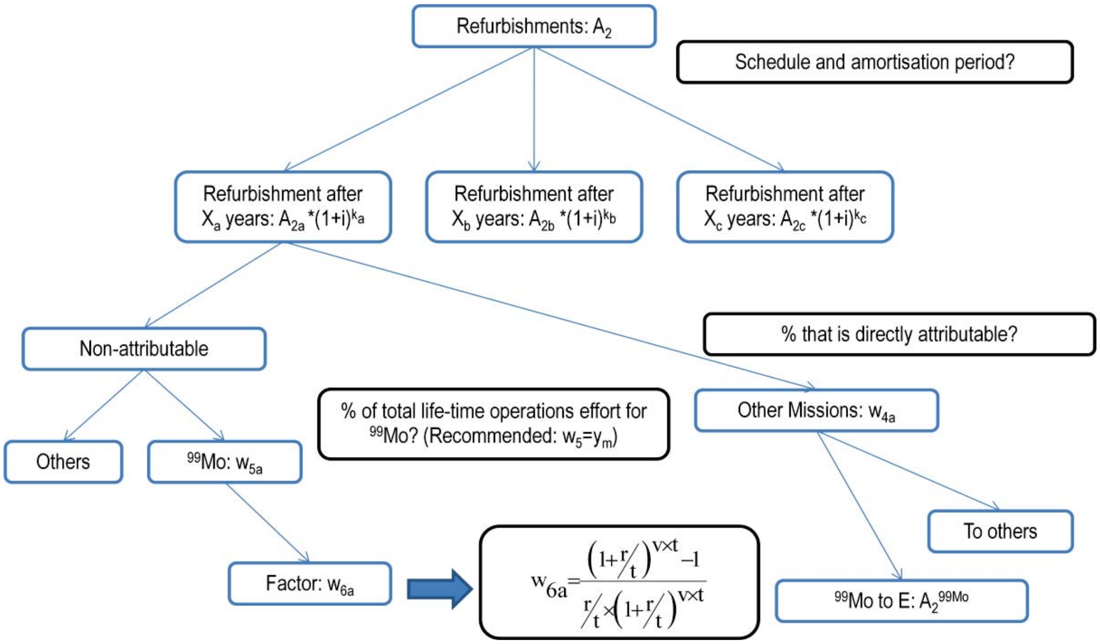
Following this process give us:

$$wA = \frac{A_1 \times \ [(1-w_1)\times w_2]}{w_3} + \sum_{x=a}^{g} \frac{[A_{2x}\times(1+i)^{k_x}]\times[(1-w_{4x})\times w_{5x}]}{w_{6x}}$$

Where:

x = the refurbishment in question, up to g refurbishments
k_x = the year in which refurbishment x takes place, from the year of construction

Figure 4: Methodology for allocation of refurbishment costs



General overhead costs (xB)

General overhead costs are the entire site indirect costs that *cannot* be traceable to a specific mission. Where an overhead costs can be directly attributable to specific facilities or missions, it should be done so and the value removed from the calculations below on the non-attributable common costs. See Figure 5 below for a visual representation of the full overhead cost methodology.

The factor to be applied to the common costs – in order to attribute the appropriate portion to ^{99}Mo production – would be the share of the facility's total operations that are related to the reactor (as opposed to other site components, like laboratories). This share would be determined based on the percentage of total effort – measured as full-time employee equivalent (FTE) – that is clearly attributable to the reactor vs. the total effort clearly attributable to all the facilities within the total site (e.g., laboratories, beam line operations). This factor would be x.

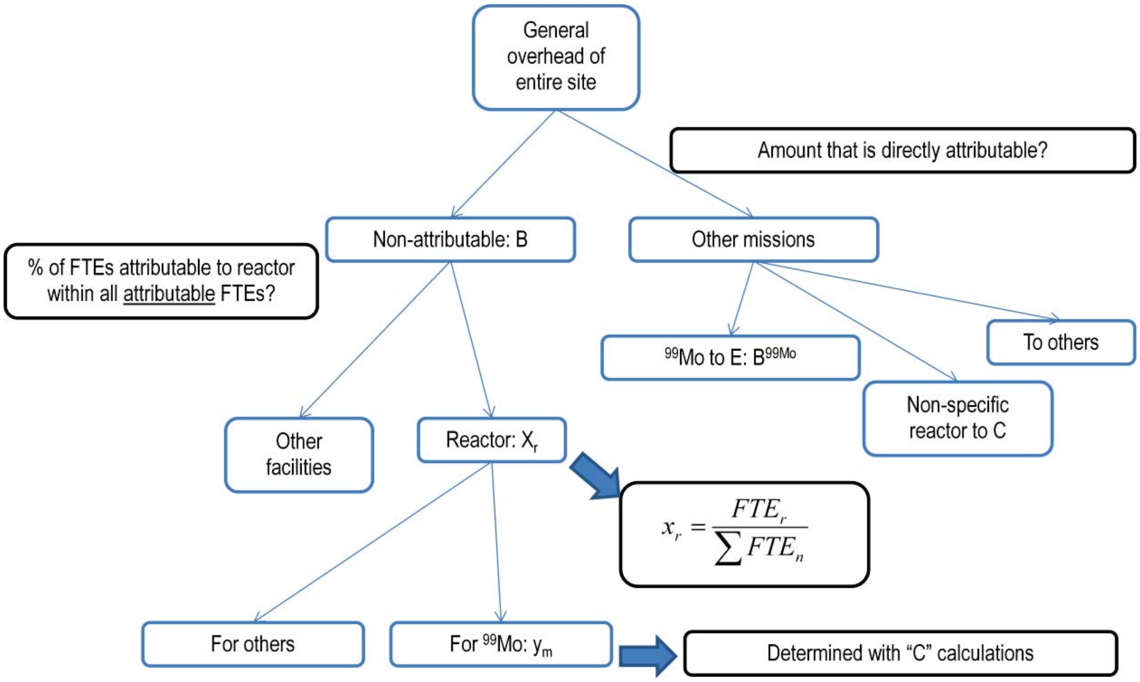
$$x_r = \frac{FTE_r}{\sum FTE_n}$$

Where:

FTE_r = full time employee equivalent clearly attributable to the reactor
$\sum FTE_n$ = full time employee equivalent clearly attributable to any and all the facilities within the total site

And FTE is measured by the total hours worked by all employees attributable to the specific facility divided by the total hours in a work year[5].

Figure 5: Methodology for allocation of general overhead costs



x_rB would then have factor y_m applied to it (see section below on general operational costs).

Applying y_m and x_r to the non-attributable overhead costs will provide an annual amount that will need to be paid by the reactor operator each year, in current currency (e.g., 2012 EUR). This value will be put in an annual payment spreadsheet. Then the annual values will be discounted (using the real interest rate) to determine the NPV of the investment costs so that the LUCM of irradiation services and/or average cost of irradiation services (per cycle) can be determined at the end of the attribution exercise.

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[5] The Full-cost Working Group discussed the possibility of normalising FTE on income levels, but concluded that there were no apparent benefits to the calculations. In many cases, FTEs are calculated with an average salary and therefore normalisation on salaries would not change the calculations.

General operational costs (yC)

General operational costs are the operational costs at the reactor that cannot be directly attributable to an end client or product. In addition, they include any costs that were attributed to the reactor from the general overhead cost methodology above.

Some activities can clearly and easily be allocated directly to a specific mission, while others cannot be so clearly delineated. Where clear allocation is possible (e.g., ^{99}Mo target loading or activities related to silicon neutron transmutation doping), these costs would be allocated to the activity (e.g., variable E in the ^{99}Mo full-cost recovery methodology) and removed from consideration under general operational costs.

Where clear allocation is not possible (e.g., reactor operations and maintenance staff, utilities, reactor fuelling costs, etc.), these common costs must be allocated to specific missions/products of the reactor using a reasonable and practical method. This allocation is necessary for full cost recovery.

In order to determine the allocation of unattributed reactor operation costs, a core impact analysis must be done to calculate the share of operations dedicated to the various services and products provided by the irradiation facility, according to the number of sites used and quality of those sites (flux level). The quality of the site determines the weighting factor to be used in assigning costs to sites in the reactor core, which have been assigned to various client activities.

Virtual sites are allocated to peripheral users (e.g., neutron beams). Unused sites within the reactor are not included in the proportional calculation to ensure that all reactor costs are attributed to users (avoiding hidden government subsidies) and to ensure that there are no stranded, unallocated or unrecovered costs. Of course, if there are too many unused sites, the costs for each service will become higher and will encourage the operator to seek out new customers to ensure that their costs remain competitive.

Specifically, the process is as follows (see Figure 8 for a visual representation of the steps):

1. Irradiation sites within the core are identified by user; unused sites should not be included, thereby avoiding stranded / unallocated costs. A few rules apply for identifying users of irradiation sites:

    a. Sites reserved for ORC should not be considered an unused site; they should be considered another use. The costs of ORC should be fully recovered through contractual agreements with processors who are paying for ORC.

    b. A fuel channel would be considered an unused site as the costs of the fuel is already calculated as a separate cost item and the site is not available for other purposes. The fuel cost would be divided among the various users based on the calculations for variable y.

    c. When a channel is used by both fuel and a specific irradiation, the fuel costs and the irradiation site would be attributed directly to the specific mission of that irradiation.

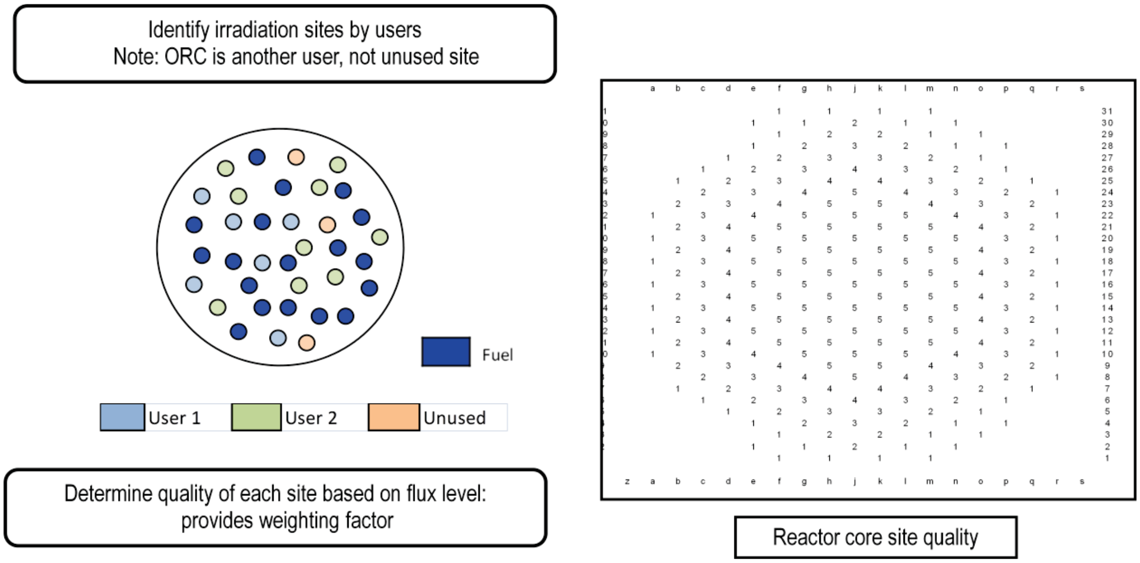
    d. If irradiation services are provided outside of the core, these sites should also be included in the calculations. Beam lines should also be considered as a user site(s).

    e. When a user's irradiation sites have an impact on other sites, such that there is an impact on the reactor configuration (e.g., some channels kept empty to ensure proper irradiation for the user), the impacted sites should be attributed to the user.

    f. Recognising that some irradiation sites have larger volumes than others, reactors could consider using the concept of a "site-equivalent" rather than specific sites. The reactor would determine a "normal site" within its reactor and this would be the reference for a "site-equivalent"; if the reactor has an irradiation site that is three times larger than the normal site, that site would be considered three "site-equivalents" and counted as such in the "number of irradiation sites by user group".

2. A quality factor for each site (ranking of 1-5) is determined based on a model of flux measurements. Figure 6 provides an example of the results of such an exercise.

Figure 6: Determination of quality factor



3. The following formula is then applied to provide a total output value for the users within the reactor:

$$U_n = \sum (S_{ni} \times Qf_{ni})$$

Where:

U_n = User n output value
S_{ni} = Site i within the reactor used by user n
Qf_{ni} = The quality factor of site i

An average taken over a typical year would be an appropriate measurement, capturing potential changes between cycles.

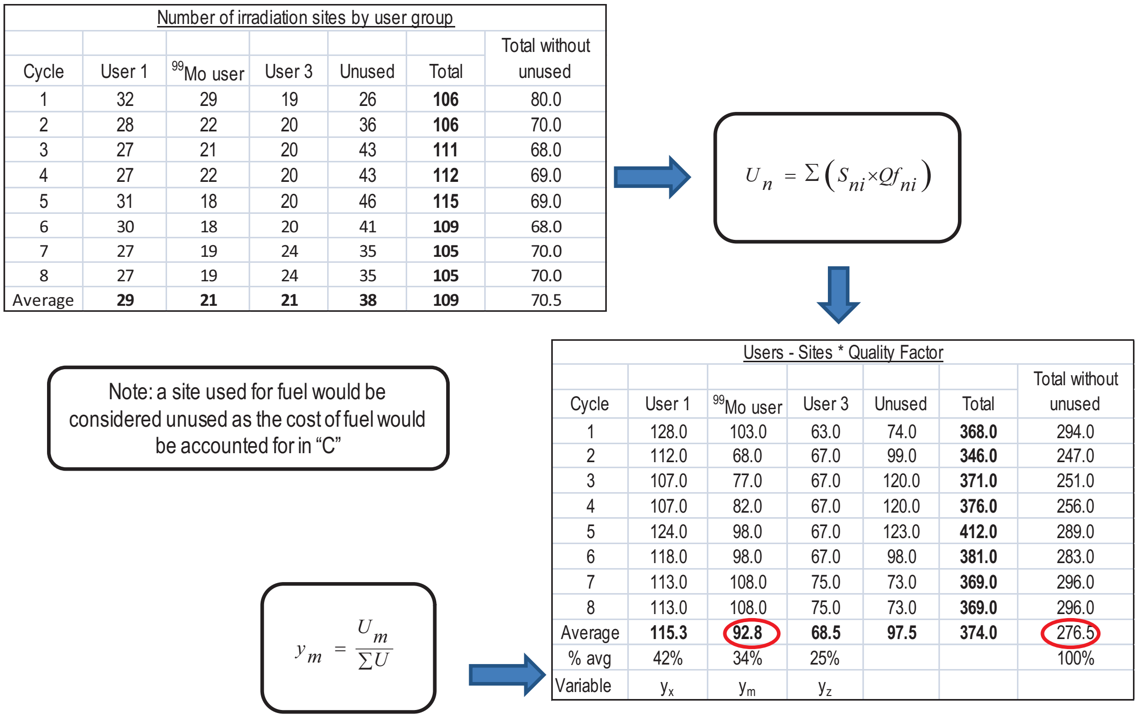
4. Group results by user and convert to percentages for allocation purposes using the total for all users within the reactor. Apply the following formula:

$$y_m = \frac{U_m}{\sum U}$$

The percentage for ^{99}Mo irradiation services becomes y_m where n=m and represents the ^{99}Mo irradiation “user”.

Figure 7 (next page) provides an example of steps 3 and 4 above.

Figure 7: Determination of y_m



Number of irradiation sites by user group

Cycle	User 1	^{99}Mo user	User 3	Unused	Total	Total without unused
1	32	29	19	26	**106**	80.0
2	28	22	20	36	**106**	70.0
3	27	21	20	43	**111**	68.0
4	27	22	20	43	**112**	69.0
5	31	18	20	46	**115**	69.0
6	30	18	20	41	**109**	68.0
7	27	19	24	35	**105**	70.0
8	27	19	24	35	**105**	70.0
Average	**29**	**21**	**21**	**38**	**109**	70.5

$$U_n = \Sigma\left(S_{ni} \times Qf_{ni}\right)$$

Users - Sites * Quality Factor

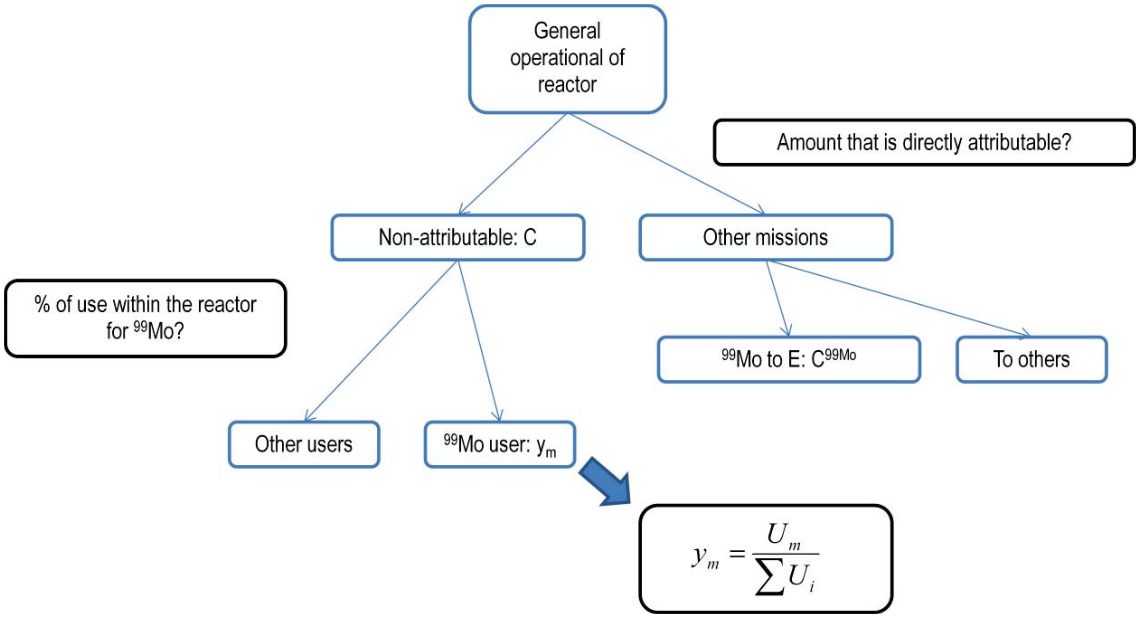
Cycle	User 1	^{99}Mo user	User 3	Unused	Total	Total without unused
1	128.0	103.0	63.0	74.0	**368.0**	294.0
2	112.0	68.0	67.0	99.0	**346.0**	247.0
3	107.0	77.0	67.0	120.0	**371.0**	251.0
4	107.0	82.0	67.0	120.0	**376.0**	256.0
5	124.0	98.0	67.0	123.0	**412.0**	289.0
6	118.0	98.0	67.0	98.0	**381.0**	283.0
7	113.0	108.0	75.0	73.0	**369.0**	296.0
8	113.0	108.0	75.0	73.0	**369.0**	296.0
Average	**115.3**	**92.8**	**68.5**	**97.5**	**374.0**	276.5
% avg	42%	34%	25%			100%
Variable	y_x	y_m	y_z			

Note: a site used for fuel would be considered unused as the cost of fuel would be accounted for in “C”

$$y_m = \frac{U_m}{\sum U}$$

At the beginning of the reactor’s life, the calculation for y_m would be done based on the expectations of the reactor’s usage. However, this component of the methodology would require regular updates to account for changes in the usage and configuration of the reactor’s irradiation facilities, such as may occur from losing a major customer for example. In order to ensure the most accurate calculations while recognising budgeting cycles within reactor, it is recommended that y_m calculations be undertaken once a year based on all the irradiation cycles within the reactor over the year, with the value for the following year’s calculations being based on the previous year’s activities.

Figure 8: Methodology for allocation of general operational costs



$$y_m = \frac{U_m}{\sum U_i}$$

Applying y_m to the non-attributable operational costs will provide an annual amount that will need to be paid by the reactor operator each year, in current currency (e.g., 2012 EUR). This value will be put in an annual payment spreadsheet. Then the annual values will be discounted (using the real interest rate) to determine the NPV of the investment costs so that the LUCM of irradiation services and/or average cost of irradiation services (per cycle) can be determined at the end of the attribution exercise.

As noted in the section on general overhead costs, this value y_m would then also be applied to x_rB in order to apportion the general overhead costs that were attributed to the reactor to ^{99}Mo irradiation services.

Decommissioning costs (zD)

Decommissioning (D) costs are those costs that *cannot* be traceable to a specific mission and include the final disposal of wastes from the decommissioning process. Where a decommissioning cost can be directly attributable to a specific mission, it should be done so and the value removed from the calculations below for the non-attributable common costs.

The process to determine zD is (see Figure 9 for graphical representation of steps):

1. Determine the value of the decommissioning fund in year 0. To do this, the value of the fund at the end of the life-time of the facility is based on a percentage of the original infrastructure investment (or an absolute amount) needed in that final year. This value must then be discounted (using the real interest rate[6]) back to year 0.
2. Determine the percentage of ancillary equipment and related site infrastructure that is clearly dedicated to other missions (e.g., beam lines, cold source, test loops, etc) and those that can clearly be attributed to ^{99}Mo production (e.g., irrigation rigs). Call this percentage z_1. The costs that are directly attributed to ^{99}Mo production would be included in variable E.
3. Determine a reasonable estimate percentage of reactor and facility usage that is for irradiation and handling of ^{99}Mo targets, based on business activity (% of total effort of operations related to ^{99}Mo production based on activity planning of the reactor lifetime). Call this percentage z_2.

   A reference to actually determine z_2 could be the methodology used for y_m (see section on general operational costs later in this document), such that z_2=y_m. During the possible validation of the implementation of the full-cost recovery methodology, governments or other agencies potentially undertaking the validation could use z_2=y_m to assess the implementation. Where z_2 deviated significantly from y_m, justification by the operator would have to be provided.
4. For decommissioning, a certain amount could be set aside every year, ensuring that there is enough in the account at the end of the amortisation period to pay for decommissioning. To determine the annual nominal amount to be put in the account, the annuity formula (below) is applied:

$$z_3 = \frac{r}{(1+r)^{n-1}}$$

5. By applying z_1, z_2 and z_3 to the decommissioning costs following the formula below, all ^{99}Mo-production related costs should be fully and fairly identified, recovered and not subsidised by national governments. This will provide an annual amount that will need to be paid into an account by the reactor operator for the decommissioning after the amortisation period, in nominal currency. This value will be put in an annual payment spreadsheet. Then the annual values will

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[6] The real interest rate is used here since the value of the decommissioning fund is known in the value of the currency at the end of the lifespan of the infrastructure. As a result, the present value of this real value in 40 years is found by discounting using the real interest rate.

be discounted to determine the NPV of the investment costs so that the LUCM of irradiation services and/or average cost of irradiation services (per cycle) can be determined at the end of the attribution exercise.

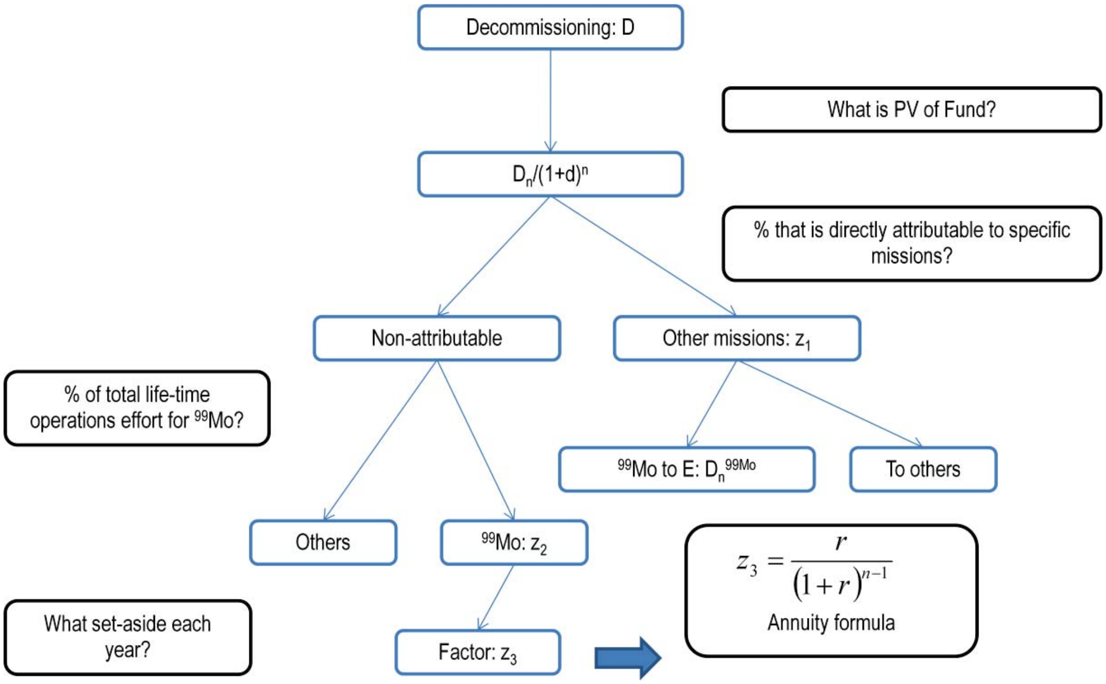
Following this process give us:

$$zD = \frac{D_n}{(1+d)^n}(1-z_1) \times z_2 \times z_3$$

Where:

D_n = the value of the decommissioning fund at the end of life of the facility, in real currency
d = is the real interest rate

Figure 9: Methodology for allocation of decommissioning costs



Specific ^{99}Mo irradiation costs (E)

Capital and operation costs that can be clearly and uniquely linked to ^{99}Mo production would be directly included into variable E and would be 100% attributed within the full-cost calculation. They should include any costs that were attributed to the reactor from the capital, general overhead, general operational and decommissioning costs.

For example, two costs that would be included in variable E and fully attributed to ^{99}Mo production are: 1) the capital cost of a ^{99}Mo target irradiation rig and, 2) costs of the time of business development staff spent directly marketing ^{99}Mo irradiation services (where clearly delineated from general business development staff time).

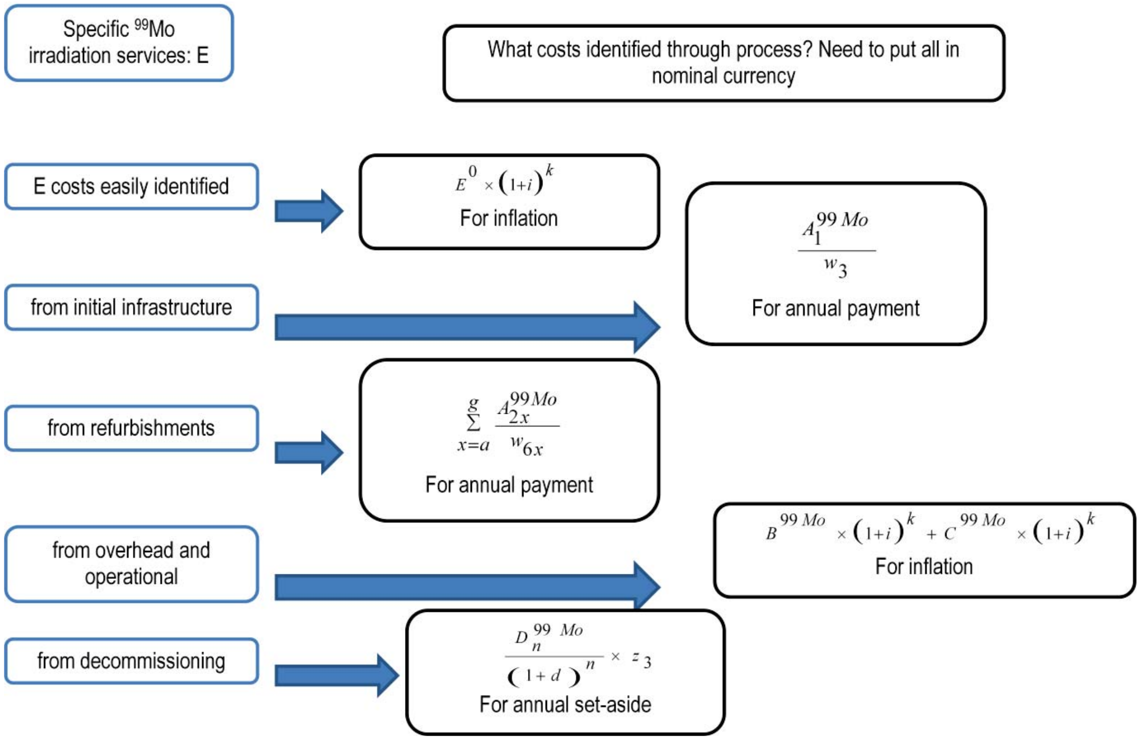
Given the cost identification process on all the other factors, where some costs could be attributed to the ^{99}Mo irradiation services directly, we need to add up all the proportions (in equivalent nominal currency values), using the formula below. Figure 10 provides a visual representation of this step.

$$E = \left(E_0 \times (1+i)^k\right) + \frac{A_1^{99Mo}}{w_3} + \left(\sum_{x=a}^{g} \frac{A_{2x}^{99Mo}}{w_{6x}}\right) + \left(B^{99Mo} \times (1+i)^k\right) + \left(C^{99Mo} \times (1+i)^k\right) + \left(\frac{D_n^{99Mo}}{(1+d)^n} \times z_3\right)$$

Where:

E_0 = is the original, clearly identifiable costs directly attributable to ^{99}Mo production services
X^{99Mo} = the component of the cost variable (where X = A, B, C or D) identified as being directly attributable to ^{99}Mo production services during the cost identification exercise
i = inflation rate
k = the year from the start of the project where the costs are incurred
d = real discount rate

Figure 10: Methodology for calculating ^{99}Mo specific costs



This will provide the annual amounts that will need to be paid by the reactor operator that are directly and clearly attributable to providing ^{99}Mo irradiation services, in nominal currency. This value will be put in an annual payment spreadsheet. Then the annual values will be discounted to determine the NPV of the investment costs so that the LUCM of irradiation services and/or average cost of irradiation services (per cycle) can be determined at the end of the attribution exercise.

The final full-cost identification methodology

Based on the discussion above, the final full-cost identification methodology will be:

$$Full\ Cost\ for\ {}^{99}Mo = wA + y_m(x_r B + C) + zD + E$$

Where

$$wA = \frac{A_1 \times \ [(1 - w_1) \times w_2]}{w_3} + \sum_{x=a}^{g} \frac{[A_{2x} \times (1+i)^{k_x}] \times [(1 - w_{4x}) \times w_{5x}]}{w_{6x}}$$

$$w_3 = \frac{\left(1 + {}^{r}/_{t}\right)^{n \times t} - 1}{{}^{r}/_{t} \times \left(1 + {}^{r}/_{t}\right)^{n \times t}}$$

$$w_6 = \frac{\left(1 + {}^{r}/_{t}\right)^{v \times t} - 1}{{}^{r}/_{t} \times \left(1 + {}^{r}/_{t}\right)^{v \times t}}$$

$$y_m = \frac{U_m}{\sum U}$$

Where m in this case is for ^{99}Mo irradiation services

$$U_n = \sum (S_{ni} \times Qf_{ni})$$

$$x_r = \frac{FTE_r}{\sum FTE_n}$$

$$zD = \frac{D_n}{(1+d)^n} (1 - z_1) \times z_2 \times z_3$$

$$z_3 = \frac{r}{(1+r)^{n-1}}$$

$$E = \left(E_0 \times (1+i)^k\right) + \frac{A_1^{99Mo}}{w_3} + \left(\sum_{x=a}^{g} \frac{A_{2x}^{99Mo}}{w_{6x}}\right) + \left(B^{99Mo} \times (1+i)^k\right) + \left(C^{99Mo} \times (1+i)^k\right) + \left(\frac{D_n^{99Mo}}{(1+d)^n} \times z_3\right)$$

This formula should then be used to determine the full costs for ^{99}Mo irradiation services in a specific given year. This value would then be put into a spreadsheet of expected costs and production over the amortisation period of the reactor and a levelised unit cost of ^{99}Mo production and/or average cost of irradiation services (per cycle) would be calculated using the NPV of the costs and production, following the model developed for the NEA economic study of the ^{99}Mo supply chain. Again, the NEA has developed an Excel workbook that allows the facility operator to undertake the full methodology.

Implementation of full-cost recovery

To implement full-cost recovery within the supply chain, governments have to require reactor operators (and other production technologies) to apply the full-cost identification methodology described above and to fully recover these costs within their pricing for ^{99}Mo irradiation services. Given the role of governments regarding nuclear activities, including the operations of their research reactors, governments generally have significant influence on the financial direction of the reactors. As a result, governments should have some form of influence with reactor operators to ensure that full-cost recovery is being undertaken at the reactor for ^{99}Mo irradiation services. Depending on the specific situation in each jurisdiction, the respective governments will have to determine the best approach to encourage reactor operators to move to full-cost recovery for ^{99}Mo irradiation services (e.g. regulations, policy directive, etc.) in their jurisdiction.

It should again be stressed that this does not mean direct price setting by governments or among different irradiation providers; it means requiring irradiation providers to implement full-cost identification and recovery. It should be noted that implementing full-cost recovery is in line with market economics; a commercial enterprise cannot survive very long if the price of the product it is selling is less than the costs to manufacture that product, including the necessary infrastructure to produce the product and bring it to market. As a result, the move to full-cost recovery will bring the current reactors into the commercial sphere regarding ^{99}Mo irradiation services. Producers that seek to negotiate the lowest prices possible for irradiation services, again, in line with normal market actions, will be faced with a new pricing paradigm. Nonetheless, they will be able to negotiate within the framework of fully paying for the costs of the services they receive.

The price increases that would be expected by the application of a full-cost recovery methodology should flow through the supply chain and should be reflected in the costs of the final medical procedure, to be reimbursed appropriately by the health care systems. Again, this is a normal market operation when the price of one input into a product increases. An input price increase may be absorbed in the short term but final product prices will eventually adapt to the increased costs. Market participants require that the revenue of a product cover the full costs of that product in order to remain in business.

Even though the *Economic Study* (NEA, 2010) demonstrated that the final impact on the end users of implementing full-cost recovery should be small, it is recognised that there is a role to ensure that there is sufficient funding within health care systems to accommodate reasonable price increases. As a result, governments should (as noted in the HLG-MR policy approach):

- in co-operation with health care providers and private health insurance companies, monitor radiopharmaceutical price changes in order to support the transparency of costs;
- periodically review payment rates and payment policies with the objective of determining if they are sufficient to ensure an adequate supply of ^{99m}Tc to the medical community;
- consider moving towards separating reimbursement for isotopes from the radiopharmaceutical products as well as from the diagnostic imaging procedures.

The HLG-MR policy approach recommends a target of June 2014 for the implementation of full-cost recovery (as well as its other recommendations). This recognises that the supply chain will require some time to prepare to move to full-cost recovery, including the time to adjust contracts within the system. This time would also allow the health community to become informed of the changes and to examine reimbursement rates and the effect of full-cost recovery on the costs of ^{99m}Tc based medical tests. The HLG-MR recognised that this transition period cannot be too long as it could affect the ability of providers of ^{99}Mo irradiation services to survive, greatly affecting long-term supply security.

A full-cost recovery methodology and the increased role of the market would not result in nuclear-related safety concerns being held "hostage" to commercial interests. None of these changes would alter the importance of compliance with health and safety regulations and commercial companies would need to continue to give the highest priority to compliance with all appropriate safety, security, safeguards and health regulations.

In addition, the move to full-cost recovery would not result in health care systems being victimised by ever increasing prices that they have no control over. Demand for ^{99}Mo/^{99m}Tc is not perfectly inelastic – if prices rise, there will be a point where changes in use patterns will reduce the amount of product demanded. These possibilities were seen during the 2009-2010 shortages, for example with changes to generator elution patterns, patient scheduling and isotopes used; these changes may in fact more than compensate for any increases that could occur as a result of implementing full-cost recovery. If prices rise too high (beyond what is justified by cost-efficiency calculations) payers will encourage the use of substitutes where feasible and the market will develop other substitutes where none exist today.

To enable the acceptance of any price increases, it will be important for ^{99}Mo/^{99m}Tc producers (reactor and alternative technology operators), processors, generator manufacturers and radiopharmacies to ensure effective communications around any forecasted price increase to help health care providers and health care systems plan budgets and manage expectations.

To ensure the effective implementation of full-cost recovery from irradiation sources and allow for transparency and trust within the supply chain, the NEA has agreed to undertake a periodic review of the supply chain. This review would indicate who is, and who is not, implementing the HLG-MR policy recommendations. Other governments may undertake their own review of irradiation facilities within their jurisdiction where there is the potential for government subsidisation of ^{99}Mo irradiation services.

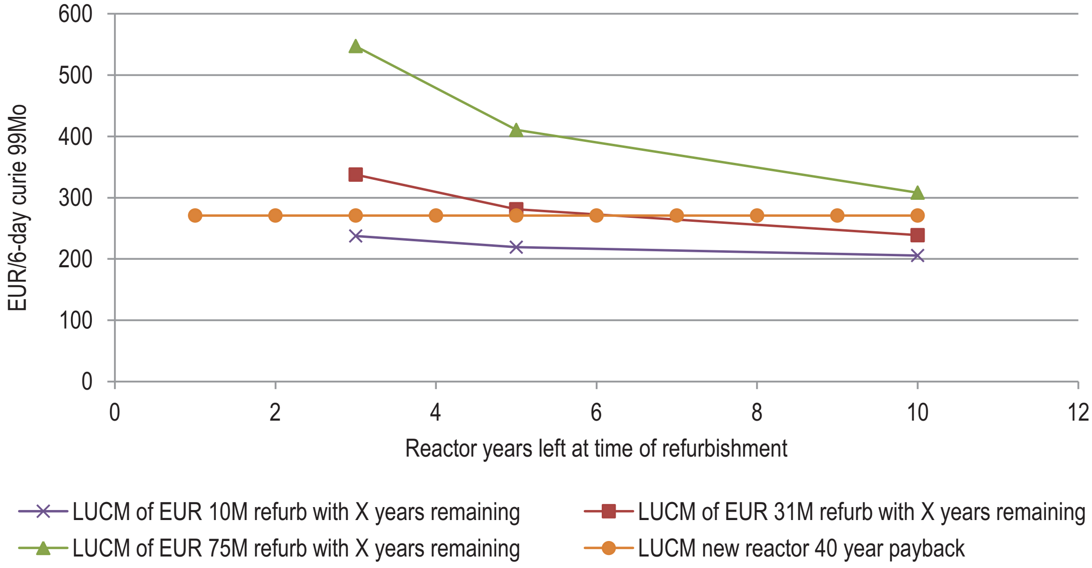
Level-playing field between old and new reactors

When proposing full-cost recovery there were some concerns that this would disadvantage new reactors. The reason given is that the capital costs would already be fully amortised for old reactors, leaving a significant cost difference between old and new reactors. This cost difference could therefore be taken advantage of by older reactors through offering lower prices for their irradiation services.

However, older reactors often require significant refurbishments and upgrades as they near their end of life, in order to be able to continue operating efficiently and safely. These refurbishments represent capital costs that need to be amortised over a much shorter time period than the original capital for the reactor, which is amortised over approximately 40 years.

Figure 11 provides various examples comparing a new reactor with a 40 year amortisation period to old reactors with the original capital completely paid but with necessary refurbishments with various years of the lifespan of the reactor remaining. The examples were derived using the full-cost methodology described in this document, with theoretical values for the various cost components. The examples are not meant to provide an accurate representation of absolute costs in 6-day curies of ^{99}Mo; the purpose is to show the relative LUCM of irradiation services between the different scenarios.

Figure 11: Example of LUCM from old vs. new reactors using theoretical example



These various scenarios show that including fully-attributed refurbishment costs in the full-cost recovery of older reactors points to an advantage for new reactors, depending on the remaining lifespan of the reactor and the amount of the refurbishment. The assumption that these late-stage refurbishment costs would be attributed fully to ^{99}Mo production is realistic given that some important recent refurbishments have been done almost exclusively for ^{99}Mo production for a few additional years. It should also be noted in the above scenarios that there is no accounting for the possible improved production efficiencies in new reactors, which would be expected to lower the LUCM of the new reactor, creating a further advantage for new reactors.

The full-cost identification and recovery methodology creates a reasonable level-playing field between these old and new reactors, recognising that costs will differ between all reactors (regardless of age). Additional work to create a level-playing field is not required.

Conclusion

In order to move toward a long-term secure supply of ^{99}Mo and ^{99m}Tc, the HLG-MR policy approach will need to be implemented by all countries that have an impact on the global market – as producers or consumers. A key recommendation of the policy approach is the implementation of full-cost identification and recovery by operators of ^{99}Mo-producing research reactors or alternative technologies. This document provides the full-cost identification methodology to be used, ensuring a consistent international approach to identifying the key cost elements and the method to allocate the costs to ^{99}Mo production.

Now that the methodology has been defined by the HLG-MR, all operators of ^{99}Mo-producing research reactors or alternative technologies should implement the methodology and move to full-cost recovery, if they are not doing so already.

As noted earlier in this document, the NEA has created an Excel model of the methodology that can be accessed on the HLG-MR webpage for use by operators of research reactors and other ^{99}Mo/^{99m}Tc production technologies (see www.oecd-nea.org/med-radio).

References

OECD/NEA (2011), *The Supply of Medical Radioisotopes: The Path to Reliability*, OECD, Paris. ISBN 978-92-64-99164-4, 169 pages.

OECD/NEA (2010), *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain*, OECD, Paris. ISBN 978-92-64-99149-1, 123 pages.

Annex 1: Full-cost Working Group participants

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