EUROPEAN RESEARCH REACTOR POSITION PAPER BY CEA, IRN, NRG, RCR, SCK•CEN, POLATOM, AND TUM. 3 MARCH 2011

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Scenario FOR SUSTAINABLE MolyBDENUM-99 PRODUCTION In Europe

FOREWORD

The "Interim Report of the OECD/NEA High-level Group on Security of Supply of Medical Radioisotopes © OECD 2010" and the NEA Nuclear Development 2010 report No. 6967 on "The Supply of Medical Radioisotopes – An Economic Study of the Molybdenum-99 Supply Chain" clearly identify that market failure is the primary cause of the recent Molybdenum-99 (Mo-99) supply crisis. Regional networks of multiple purpose research reactors and processing facilities with coordinated operating schedules are important for the secure supply of ^{99}Mo. This position paper considers only the role of reactors in the Molybdenum-99/Technetium-99m(Tc-99m) supply chain. In addition to this paper, the roles of the Mo-99 processors, the Mo-99/Tc-99m Generator Producers, the central and local radiopharmacies and the medical end users must also be considered when evaluating the security of supply of these vital medical isotopes.

INTRODUCTION

The production, distribution and use of Technetium-99m (Tc-99m) is an international business, with irradiation and processing being performed in all Continents; with daily international transport of products and routine medical use in hospitals and clinics being performed worldwide. Despite the international nature of this business, the short shelf life of the main product Mo99 (more than 50% decays away every 3 days) means that the responsibility for efficient and secure supply is more local, so in the case of Europe, the responsibility is European.

The reliable supply of Tc-99m the daughter isotope of Mo-99 is an important public health issue since Tc-99m represents some 80% of all diagnostic Nuclear Medicine examinations performed in Europe. These important procedures increased to over 9 Million per Year in Europe in 2009, despite world supply problems in both 2008 and 2009. Mo-99 can not be stockpiled and is supplied from the continuous processing of highly enriched Uranium (HEU) targets irradiated in publicly owned Research Reactors. The European and World supply situation will remain critical in the medium term future because of the short term planned temporary shutdown of some Reactors for maintenance and the extended time scale associated with the replacement of the main Reactors supplying this material.

This Position Paper is proposed for the European Commission DG Energy by the European Organisations that operated Research Reactors (RR) for the production or the potential production of Mo-99. This Paper is aimed at ensuring sustainable production and distribution of Tc-99m in Europe in both the mid and long term. Some of these Organisations have already proven their ability to coordinate the scheduling of their Reactors for the benefit of the medical community and are willing to provide solutions to ensure the future sustainable high level of production that is required to meet European needs. The joint authors of this Position Paper have a common understanding on the use of Research Reactors for materials and fuels testing for nuclear energy applications as well as the production of vital medical isotopes.

In the past RR were not been build on the basis of supplying medical markets with isotopes and the investment in these facilities largely precedes this medical market. The historical market structure in Europe has therefore been built during an extended period where existing capacity has exceeded demand and where that supply has been essentially subsidised by existing governmental infrastructure investment. The market situation that has resulted is well documented by the recent NEA/OECD paper “The Supply of Medical Radioisotopes – An Economic Study of the Molybdenum-99 Supply Chain” NEA 6967 ISBN 978-92-64-99149-1.

The result has been that the pre-existing excess capacity has allowed market forces to keep irradiation prices relatively low. Taking into account investment/depreciation costs of new facilities, it is foreseen that irradiation costs must increase substantially in order to pay for the security of supply required by Medicine today. This increase in price can be accommodated when it is understood that this key part of the supply chain is presently representing only around 0.1 % of the overall cost of the medical procedure – Table 1.

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

Table 1: Allocation of the revenue to the various stages of the ^{99}Mo/^{99m}Tc supply chain and its relative part in the reimbursement rate of the medical procedure.
(Source: OECD economic study, ref. NEA 6967 ISBN 978-92-64-99149-1)

Hence, it is anticipated that the European Healthcare systems should be able to manage the required increase in costs without major disruption to services.

This Position Paper is the common opinion of the Operators of European RR, whose position is defined by their joint agreement to endorse a common set of operating and business principles. These would be applicable to both the present and the next generation of RR that are described further in this paper. Jointly they state their belief that a common approach is mandatory to secure the robust and sustainable production of Mo-99 required by the European Medical community. This should also ensure fair access to these RR at realistic costs on a fair trade basis. Appropriate investment should allow new RR to be able to progressively added to the existing Mo-99 irradiation capacity from 2014 onwards, increasing the security of supply for Europe.

BACKGROUND INFORMATION.

European Mo-99 production was until recently based on HEU target irradiation in 3 reactors: HFR (Petten, NL), BR2 (Mol, B) and OSIRIS (Saclay, F). All 3 Reactors are more than 40 years old and it is foreseen that they will all permanently leave service during the period 2015-2025. The 3 Reactors operate as a supply network within Europe in conjunction with 2 Mo-99 processing facilities operated by Covidien (Petten, NL) and IRE (Fleurus, B). The network has been added in the past year by the establishment of Mo-99 production at the MARIA (Otwock-Swierk, P) and the LVR-15 (Rez, CZ) Reactors using the same European processing facilities.

This is the only existing regional supply network in the world and as such has provided Europe with a high level of security of supply over the last decades and allowed Europe to respond positively to the recent world supply shortage. Supply elsewhere in the world is non-networked and exists as a number of single supply lines of geographically isolated Reactor/Processing Facility sets (e.g. in Australia, Canada and South Africa), where any single break in the supply chain completely stops Mo-99/Tc-99m supply.

With the ageing of the European supply network, it is necessary for Europe to now consider new reliable supply sources. The timescale to conceive, design, licence and construct in Europe a Reactor fully dedicated to isotope supply is probably more than 10 years, so production from such a source before 2020 would be unlikely. Moreover, commercial investment from individual medical companies in such an expensive “single use” facility is unlikely following the recent failure of the Canadian MAPLE project (based on 2 fully dedicated production reactors and an associated Mo-99 extraction facility). Additionally commercial companies have not expressed any interest in (co)ownership of Reactors.

The world community is mobilized through various international actions to find solutions to the present and future supply problems and various studies have identified that a unique dedicated production site is not an adequate answer and therefore should not be considered. The Tc-99m shortage both present and future is a worldwide issue; however, the NEA-OECD High Level Group on the Security of Supply of Medical Isotopes encourages integrated continental network solutions. Europe can react to this and secure its Tc-99m supply for the mid and long term through building on its present experience to ensure an effective supply network in the future encompassing FRM II (Munich, D), JHR (Cadarache, F), PALLAS (Petten or Zeeland, NL), MYRRHA (Mol, B), TRIGA (Pitesti,RO) and LVR-15 (Rez, CZ; this reference scenario would:

- Replace the aging reactors for Mo-99/Tc-99m supply progressively in Europe
- Add a significant level of additional Tc-99m supply in Europe starting from 2014.
- Increase and strengthen the existing European supply network.
- Provide appropriate reserve irradiation capacity that increases security of supply.
- Have sufficient capacity to back-up supply elsewhere in the world.

There is a consensus in the European Research Reactor community to improve the multi-site networked production scheme that is already the case now in Europe. The future improved scheme would be more resilient, providing more flexibility and defence in depth ensuring greater security of supply. The future network would further reduce the risks of supply chain disruption by fostering technical compatibility in target design, in target processing and in transport container use. This would be achieved in cooperation with other concerned parties and in accordance with both European and national safety standards. This initiative would also provide the forum for the desired future conversion to the use of low enriched Uranium (LEU) targets.

REFERENCE SCENARIO BASED ON 4 NEW RESEARCH REACTORS, ASSOCIATED PROCESSING FACILITIES & ALTERNATIVE BACK-UP TECHNOLOGY:

The only potential facilities able to produce Mo-99 at the significant levels required for the medium-term European needs must be located in Europe. An overview of a possible European irradiation network for Mo-99 production is given below:

Existing Production Facilities still operating in the medium term:

- BR2 (Mol, B) an existing Multi-purpose Research Reactor operated by SCK•CEN (maximum capacity: >100% of European needs when operating. Operates 140 days per year), expected to leave service by 2023 provided that the new MYRRHA facility is in operation
- HFR (Petten, NL) an existing Multi-purpose Research Reactor owned by the European Commission and operated by NRG, expected to leave service by 2018 provided PALLAS is in operation (maximum capacity: >100% of European needs when operating. Operates 280 days per year)
- OSIRIS (Saclay, F) an existing Multi-purpose Research Reactor operated by the CEA (maximum capacity: ~ 50 % of European needs when operating. Operates 200 days per year), expected to leave service in 2015
- MARIA (Swierk, P) an existing Multi-purpose Research Reactor operated by Institute of Atomic Energy POLATOM, who has started production in February 2010 (maximum capacity: presently 25%, foreseen to increase by 2012 to ~ 50 % of European needs when operating. Operates 200 days per year)
- LVR-15 (Rez, CZ) an existing Multi-purpose Research Reactor refurbished in 1989 and operated by RCR, who has started production in May 2010 (maximum capacity: ~ ?? % of European needs when operating. Operates 200 days per year), licensed until 2020, expected to remain in service until 2029 earliest.

New Production Facilities:

- FRM II (Munich, D) a new Research Reactor operated by TUM since 2005, able to irradiate uranium targets from 2014 (maximum capacity foreseen: ~ 60% of European needs when operating. Operates 240 days per year)

- TRIGA 14 MW (Pitesti, RO), an existing Multi-purpose Research Reactor operated by INR converted for operation with LEU fuel scheduled to operate until 2030, with possible power uprate. No production to date. Potential flexible operation connected with large hot cells allowing initial processing of irradiated targets and transportation of solution only. Suitable for future production from LEU targets and backup services (maximum capacity foreseen: ~ 5 % of European needs from 2013 onwards. Operates 250 days per year).

- JHR (Cadarache, F) a new Materials Testing Reactor under construction to be operated by CEA, start of operation foreseen 2014 (present foreseen production capacity: 35% of European needs; could be extended up to 70% of European needs when operating. Planned operation 220 days per year)

- PALLAS (Petten or Zeeland NL) a proposed Multi-purpose Research Reactor to be operated from 2017 by NRG to replace HFR (estimated capacity: >100% of the European needs when operating. Planned operation 300 days per year)

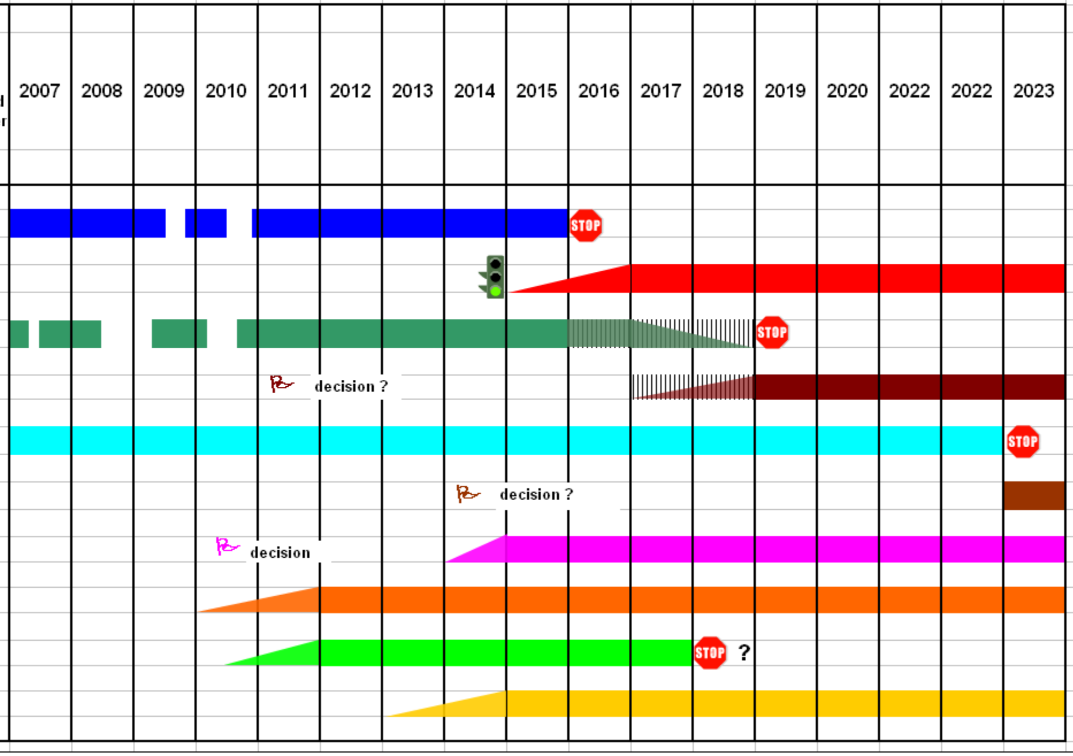
- MYRRHA (Mol, B) a proposed Accelerator Driven System (ADS) scheduled to be operated by SCK•CEN from 2022 (estimated capacity: > 100 % of the European needs when operating. Planned operation 240 days per year)

In Summary:

Subject to appropriate funding being available in due time, the 5 new production facilities could start to irradiate targets for Mo-99 production, progressively from 2014 onwards. Operating in coordinated schedules as displayed in Figure 1 below, they would cover all European needs without interruption. Their "peak capacity" to produce Mo-99 when all operating at the same time represents 200 - 250 % of European needs. However, a minimum of at least 200 % "peak capacity" is necessary to ensure continuity of production during normal scheduled Reactor refuelling and maintenance shutdown periods. In addition it also enables an important international back-up capacity to be maintained. This spare capacity needs financial support through a cost structure to be defined. Furthermore, a fair and equitable use of the available European irradiation capacity should be defined and respected. Europe will continue to require a back-up capacity from elsewhere in the world in order to manage unexpected events and likewise it will be necessary for Europe to be able to offer international back-up capacity.

European reactors producing fission Moly forecast (March 2011)

Reactor	Country	critical	Operator	P	days/year	Maximum capacity in % of present world demand (averaged over a year)
OSIRIS	France	1966	CEA	70 MW	200 days	10%
JHR	France	2014	CEA	100 MW	220 days	20%
HFR	NL	1961	NRG	45 MW	280 days	30%
PALLAS	NL	>2017	NRG	30-80 MW	300 days	50%
BR2	Belgium	1961	SCK•CEN	60 MW	140 days	25%
MYRRHA	Belgium	2022	SCK•CEN	80 MW	240 days	25%
FRM II	Germany	2005	TUM	20 MW	240 days	20%
MARIA	Poland	1974	POLATOM	30 MW	200 days	10%
LVR-15	Czech Rep	1957	NRI	10 MW	200 days	5%
TRIGA	Romania	1979	SCN/ICN	14 MW	250 days	5%



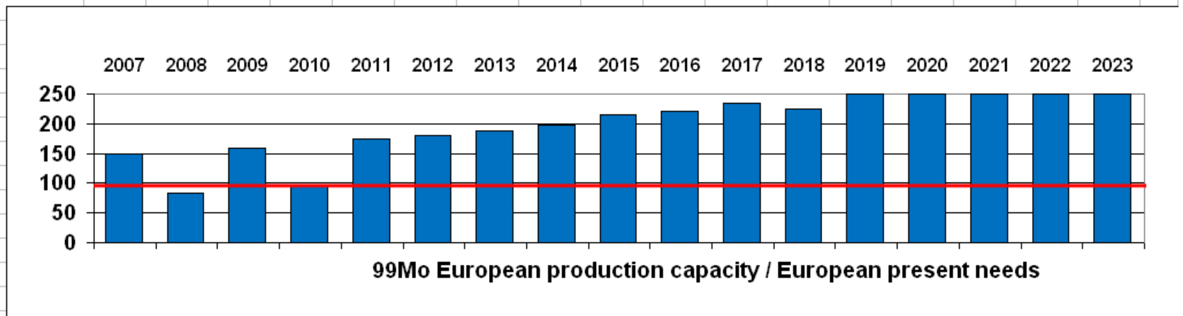


Figure 1 : Potential Reactors and Operators and European Mo-99 "peak capacity" forecast

Mo-99 processing and Tc-99m Generator production facilities:

Mo-99 processing facilities should ideally be located as near as possible to Reactor sites. The primary reasons for this are to minimise the transport of high activity fissile nuclear materials and to reduce as much as possible the decay loss of Mo-99 (the quantity of Mo-99 produced decays by 1% per hour immediately from the end of the irradiation process). However, this and the question of the provision of adequate Tc-99m Generator production capacity are not the subject of this paper. Nevertheless it should be stressed that the available processing capacity should match the reactor irradiation capacity and be networked in order to make the reactor irradiation capacity effectively and efficiently usable.

COMMON PRINCIPLES

In parallel, it will be necessary to find a suitable solution to underlying commercial issues, since the supply crisis of today is due not only to unavailability of reactors, but is also due to unfavourable economic conditions for the front end of the supply chain. Historically, these conditions have not provided the incentives needed for adequate commercial investment.

To ensure sustainable medium and long term production, each Reactor operator and Mo-99 processor should be able to recover its full costs incurred in performing their part in the network of supply (e.g. investments and/or depreciation, fair share of Reactor operating costs, Mo-99 related waste management programme, conversion to LEU targets, etc). Additionally they must be compensated for the maintenance of their share of the spare capacity required by the Medical fraternity to ensure European security of supply. The principle of solving these issues is in line with the recent NEA/OECD report.

Favouring a coordinated approach, the following common principles are agreed by the authors as a basis for a multi-year action to ensure a solid supply network for Europe:

- Agreement to fully “co-ordinate” Reactor operating programmes to ensure continuous full European supply during normal operation
- Commitment to adjust operating programmes and to “quickly” bring on line spare capacity when needed due to unplanned events
- Commitment from each Reactor to provide an agreed minimum throughput for the European market and hold open an agreed level of “on-call spare capacity”
- Provide “open access” of services to commercial parties within Europe on a “fair trade” basis
- To support the principle of “fair share” supply in the event of shortages and with regard to the supply of excess capacity to markets outside of Europe
- Irradiations to be purchased by commercial parties at a price that reflects the full costs incurred in irradiation services and to include a fair proportion of the investment cost of the reactor and associated infrastructure.
- The need to maintain adequate spare Reactor capacity must be recognised and the fair costs associated with making and maintaining the availability of spare capacity must be recovered in the overall cost/price structure.

- Develop and foster compatibility/standardisation in areas such as target design, container design and handling systems and other processes to allow full cross over use of the total network of supply within Europe
- A coordinated licensing approach between the Reactor operators and other market players with the Safety Authorities of the countries involved
- Working co-operatively in a joint funded action together with the Mo-99 processing facilities to enable the future conversion to LEU targets in an efficient, timely and sustainable way

CONCLUSION

In this Position Paper, the major European Research Reactor operators who are already producing, or who are in a position to produce Mo-99 on a commercial scale propose to work in a common way to increase the future security of supply of medical isotope by :

- Further strengthening the existing European infrastructure network approach that is supported by the position of European Research Reactors as described in the Strategic Research Agenda of the Sustainable Nuclear Energy Technology Platform.
- Working to a jointly endorsed set of common principles
- Ensuring recovery of the investment costs of new and existing infrastructure
- Ensuring availability of "on call spare capacity" and charging for it's availability

This common approach, based on existing cooperation, facilities and competencies, added to by facilities under construction and in planning and supported by common principles will ensure the conditions necessary for security of European Mo-99 supply. This cooperation and common approach will:

- Foster initiatives of compatibility in cooperation with commercial parties
- Ease the processes required to gather support for funding the necessary investments

It is believed that both the medical community and commercial parties will benefit from the increased security of supply and the fair access to services that will result from the common approach offered by Research Reactors operating to a set of common principles. These common principles will underpin and strengthen the existing European Reactor network of supply and lead to a higher level of coordination of Reactor availability and therefore defence in depth. The European medical community and in particular the speciality of Nuclear Medicine will benefit from the certainty of assured European supply.

Abbreviations:

BR2	**Belgium Research Reactor 2**
CEA	**Commissariat à l'Énergie Atomique et aux Energies Alternatives France**
FRM II	**Forschungsneutronenquelle Heinz Maier-Leibnitz (FRM II)**
HFR	**High Flux Reactor, Netherlands, Netherlands**
IEA POLATOM	**Institute of Atomic Energy, Poland**
INR	**Institute for Nuclear Research, Romania**

IRE	**Institute National des Radioelements, Belgium**
JHR	**Jules Horowitz Research Reactor, Cadarache, France**
LVR-15	**Multi-purpose Research Reactor, Rez, Czech Republic**
MARIA	**Multi-purpose Research Reactor, Swierk, Poland**
MYRRHA	**Multi-purpose Hybrid Research Reactor for High-tech Applications**
NRG	**Nuclear Research and consultant Group, Netherlands**
RCR	**Research Centre Rez, Czech Republic**
OSIRIS	**Material Testing Reactor, Saclay, France**
PALLAS	**Research Reactor, replacing HFR Petten**
POLATOM	**Institute for Atomic Energy, Poland**
SCK•CEN	**Studiecentrum voor Kernenergie, Centre d'Etude de l'Energie Nucléaire, Belgium**
TRIGA	**Multi-purpose Research Reactor, Pitesti, Romania**
TUM	**Technische Universität München, Germany**

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