International Workshop on Medical Radioisotopes Supply

Current status and future action to ensure the reliable supply for molybdenum-99 (^{99}Mo)
And conversation on a new generation of innovative radioisotopes for diagnostics and therapy

Overview

The Nuclear Energy Agency (NEA) will host an *International Workshop on Medical Radioisotopes Supply* on the current status and future action to ensure the reliable supply for molybdenum-99 (^{99}Mo), as well as a discussion of a new generation of innovative radioisotopes for diagnostics and therapy. The workshop will take place at the Organization for Economic Development (OECD) headquarters in Paris on October 30-31, 2023.

Legacy of Work on Medical Radioisotopes Supply

NEA support for global efforts to ensure a reliable supply of medical radioisotopes, specifically ^{99}Mo dates back to 2009 during a period of substantial shortages for ^{99}Mo and its decay product, technetium-99m (^{99m}Tc). This led to the establishment of the High-Level Group on the Security of Supply of Medical Radioisotopes (HLG-MR) comprised of experts representing 18 countries (including some non-NEA member countries), the Euratom Supply Agency and the International Atomic Energy Agency (IAEA). Work by the High-Level Group helped inform policy decisions to stabilize supplies, although shortages of ^{99}Mo have reappeared at times.

Workshop Programme

The International Workshop on Medical Radioisotopes Supply will examine developments since 2019, as well as ongoing supply and demand impacts stemming from the COVID-19 crisis on ^{99}Mo. Despite clear progress on increased irradiation and processing capacity, OECD countries today still rely on a relatively small number of multipurpose and aging research reactors to supply nearly all of the world's demand for ^{99}Mo.

Moreover, recent trends towards research and development and clinical use of new diagnostic isotopes mean growing demand on new radioisotope supply chains in coming years.

The workshop will also highlight developments in approved and proposed therapeutic radioisotopes such as lutetium-177 (^{177}Lu), actinium-225 (^{225}Ac) and astatine-211 (^{211}At) which are expected to see significant future demand growth. Discussion to ensure reliable supplies of these therapeutic radioisotopes will be examined in the context of ongoing investments by governments and the private sector.

International Workshop on Medical Radioisotopes Supply
October 30-31, 2023
Paris, France

Day 1: October 30, 2023

Arrival and check-in (8:30-9:30 am)

Opening remarks by Diane Cameron, NEA Head of Division for Nuclear Technology Development and Economics (9:30-9:40 am)

Keynote address by NEA Director-General William D. Magwood, IV (9:40-10:00 am)

Sponsor showcase (10:00-10:30 am)

Session 1: Assessing the Security of Supply for ^{99}Mo and Other Reactor-based Radioisotopes Supply (10:30-11:45 am)

The COVID-19 pandemic exposed and exacerbated vulnerabilities in the supply chain for ^{99}Mo, highlighting the need for robust contingency planning to mitigate the risk of future disruptions. Session 1 will examine security of supply conditions for ^{99}Mo since 2019 with forward projections for 2023-2027. Presentations will survey supply-side and demand-side market conditions pre- and post-COVID-19. This session will also highlight the supply situation of iodine-131 (^{131}I), for which the community as expressed supply concerns, and lutetium-177 (^{177}Lu), for which demand is expected to increase rapidly for approved radiopharmaceuticals. The Chair will then open a discussion on policy recommendations to ensure the adequacy of supply.

Chair：Ira Goldman, Vice President, Global Public Policy and Government Relations, Lantheus *(Confirmed)*

- Introduction of NEA report: The Supply of Medical Radioisotopes: 2023 Medical Isotope Demand and Capacity Projection for the 2023-2027 Period

  -Kevin Charlton, former Senior Analyst, the NEA of the OECD *(Confirmed)*

- Current situation of supply of ^{131}I and ^{177}Lu

  -TBD

- Production and supply chain disruptions of the COVID-19 pandemic

  -Thabo Tselane, Managing Director, NTP (South Africa) *(Confirmed)*
  -Pamela Naidoo-Ameglio, Group Executive for Nuclear Operations and Nuclear Medicine, ANSTO (Australia) *(Confirmed)*

- Q&A on potential policy recommendations

Sponsor showcase (11:45 am-12:15 pm)

Lunch Break (12:15-1:30 pm)

Session 2: Current developments on new production (1:30-3:10 pm)

Despite clear progress on adding irradiation and processing capacity, OECD countries today still rely on a relatively limited number of multipurpose research reactors—many of which are nearing 50 years of age—to produce the majority of the world's supply of ^{99}Mo. These reactors have undergone upgrades and improvements to enhance their production capacities and optimize isotope production for pharmaceutical use. However, large scale investment in innovative production process, new production facilities and associated infrastructure will be needed to ensure security of supply and meet projections of future demand. Both governments and industry stakeholders continue to face the question of how to optimize new infrastructure investments in light of technology advancements, growth of new demand centres, and supply-side competition. Session 1 will survey the effects of the development of new production facilities on supply and the challenges that the public and private sectors have, including from a financial perspective.

Chair: Max Postman, Foreign Affairs Specialist, Office of Material Management and Minimization, National Nuclear Security Administration, the U.S. Department of Energy *(Confirmed)*

- Innovative ^{99}Mo production process without HEU

  -Harrie Buurlage, Chief Commercial Officer of Isotopes, SHINE (U.S.) *(Confirmed)*
  -Jim Harvey, Senior Vice President & Chief Science Officer, NorthStar (U.S.) *(Confirmed)*
  -The representative from a ^{99}Mo production company (TBD)

- Plans for new radioisotope production reactors

  -The representative from Pallas (Netherlands) *(Confirmed)*
  -Marion Libessart, Business Development Manager, JHR PROJECT Client and Consortium Directorate, CEA (France) about JHR *(Confirmed)*
  -The representative from the new reactor planner (TBD)

- Q&A on promotion of developing innovative ^{99}Mo production process and setting up new production facilities

Coffee break (3:10-3:40 pm)

Session 3: Progress of Full Cost Recovery (FCR) Programmes and sustainable financing models (3:40-5:05 pm)

FCR programs to ensure security of supply for medical radioisotopes date back to the 1970s with variance on specific designs and implementation across jurisdictions and organisations. Session 3 will survey progress on transparent and sustainable FCR programmes as financing mechanisms that support the production, availability, and affordability of radioisotopes while maintaining high standards of quality and safety. Participants will discuss lessons learned and current best practices across jurisdictions and explore opportunities to enhance cooperation on production and supply chain security moving forward.

Chair: Jan Horst Keppler, Senior Economist at the NEA *(Confirmed)*

- Introduction to the discussion on the realisation of the FCR

  - Jan Horst Keppler, Senior Economist at the NEA *(Confirmed)*

- Progress of policies of member countries

  - Max Postman, Foreign Affairs Specialist, Office of Material Management and Minimization, National Nuclear Security Administration, the U.S. Department of Energy *(Confirmed)*
  - Eric Schutt, Chief of Staff, Vice President Government Affairs, Mo-99 Project Director, SHINE (U.S.) *(Confirmed)*
  - Alberto Fernandez Fernandez, Director/ Nuclear Applications, FPS Economy, SMEs, Self-Employed and Energy (Belgium) *(Confirmed)*
  - Sven Van den Berghe, CEO of Pantera (Belgium) *(Confirmed)*

- Q&A on potential policy recommendations

Closing Remarks by Diane Cameron, Head of Division, Division of Nuclear Technology Development and Economics, the NEA (5:05-5:15 pm)

Day 2: October 31, 2023

Arrival and check-in (8:30-9:30 am)

Session 1: Innovative Medical Radioisotopes and Radiopharmaceuticals (1) (9:30-10:50 pm)

Innovation in the diagnosis, treatment, and monitoring of various medical conditions through the use of novel medical radioisotopes and radiopharmaceuticals continues to accelerate (e.g. Theranostics, alpha-emitting radionuclides, radioligands, and targeted imaging). Session 1 will survey most recent trends and breakthroughs in R&D and supply networks to support research activities. Participants will discuss opportunities to further enhance the effectiveness and impact of these medical successes.

Chair: Cathy Cutler, Director, Medical Isotope Research & Production, Collider Accelerator Department, Brookhaven National Laboratory *(Confirmed)*

- Nuclear medicine: uses, products, technologies and key players

  -Kumiko Kikuchi, Medical Radioisotopes Advisor, the NEA of the OECD*(Confirmed)*

- Recent trend of innovative radiopharmaceuticals

  -Munir Ghesani, Chief of nuclear medicine and molecular imaging at Mount Sinai Health System and associate professor of radiology at Mount Sinai Hospital, Immediate Past President of SNMMI *(Confirmed)*
  -The specialist in radiopharmaceutical therapy (TBD)

- Current work and challenges on innovative medical radioisotopes supply

  - Jehanne Gillo, Director for the U.S. Department of Energy's Office of Isotope R&D and Production *(Confirmed)*
  - The representative from the EU (TBD)

- Q&A on opportunities to further enhance the effectiveness and impact of medical success

Coffee break (10:50-11:20 am)

Session 2: Innovative Medical Radioisotopes and Radiopharmaceuticals (2) (11:20 am-12:45 pm)

Session 1 will discuss trends in innovative radioisotopes, while Session 2 will focus on three of these radioisotopes. Firstly, the production of germanium-68 (^{68}Ge), whose daughter nuclide gallium-68 (^{68}Ga) is used in theranostics in combination with ^{177}Lu, will be examined. Secondly, α-emitting ^{225}Ac and ^{211}At, which have attracted attention for their high cancer therapeutic potential and are being actively researched, will be highlighted. The focus of discussion on ^{225}Ac and ^{211}At will mainly be on the current supply situation that support R&D of radiopharmaceuticals worldwide. Along with research reactors, accelerators are also important key players in innovative radioisotope production. Through this session, the challenges and future directions of efforts regarding production of radioisotopes by accelerators will also be explored.

Chair: Jehanne Gillo, Director for the U.S. Department of Energy's Office of Isotope R&D and Production *(Confirmed)*

- Production of ^{68}Ge

  - Erich Kollegger, CEO, IRE (Belgium) *(Confirmed)*

- Production and networking of α-emitting radioisotopes

  - Cathy Cutler, Director, Medical Isotope Research & Production, Collider Accelerator Department, Brookhaven National Laboratory *(Confirmed)*
  - Cornelia Hoehr, Deputy Associate Laboratory Directorm TRIUMF (Canada) *(Confirmed)*
  - Shigetaka Maeda, Principal Research Engineer, Department of Experimental Fast Reactor, Oarai Research and Development Institute, JAEA (Japan) *(Confirmed)*
  -Jean-Francois Gestin, University of Nantes (France) *(Confirmed)*
  -Koshin Washiyama, Associate Professor, Fukushima Medical University (Japan) *(Confirmed)*

- Q&A on opportunities to further enhance the effectiveness and impact of medical success

Lunch Break (12:45-2:00 pm)

Session 3: Pharmaceutical regulatory considerations for medical radioisotopes and radiopharmaceuticals (2:00-3:25 pm)

Pharmaceutical industry perspectives vary based on specific business interests, regulatory considerations, and market dynamics. General advocacy efforts include priorities such as streamlined approval processes and coherent regulatory frameworks, domestically and internationally. Session 3 will provide an opportunity for industry participants to voice key current regulatory challenges associated with opening new markets for the use of medical radioisotopes.

Chair: Aruna Korde, Radiopharmaceutical Scientist, Radioisotope Products and Radiation Technology Section, Division of Physical and Chemical Sciences, IAEA *(Confirmed)*

- Aligning standards for safety, quality control, manufacturing processes, and labeling requirements

  - Aruna Korde, Radiopharmaceutical Scientist, Radioisotope Products and Radiation Technology Section, Division of Physical and Chemical Sciences, IAEA*(Confirmed)*

- The representative from FDA (TBD)
- The specialist in radiopharmaceutical regulation in the EU (TBD)

- Key current challenges of pharmaceutical companies

  -Roy Brown, Vice President, Government Affairs & Strategic Alliances, Curium *(Confirmed)*
  -The representative from a pharmaceutical company (TBD)

- Q&A on balancing harmonised and appropriate regulation of radiopharmaceuticals with accelerated promotion of their use

Coffee break (3:25-3:45 am)

Session 4: Stakeholders Panel Discussion (3:45-5:45 pm)

The workshop will conclude with two breakout sessions for candid discussions between governments and among companies on the keys steps necessary to ensure universal access to the life-saving benefits of radiological isotopes worldwide.

- Government panel discussion

  Chair: Joao Alberto OSSO, former IAEA Section Head Radioisotope Products and Radiation Technology

  - Jehanne Gillo, Director for the U.S. Department of Energy's Office of Isotope R&D and Production (U.S.) *(Confirmed)*
  -Jun Hatazawa, Special Advisor to the Japan Atomic Energy Commission (Japan) *(Confirmed)*
  - The representative from the EU (TBD)
  - The representative from the government of South American Country (TBD)
  - The representative from the government of North American Country (TBD)

- Specialists in medical field and private sector panel discussion

  Chair and panellists: TBD

Closing Remarks by Diane Cameron, Head of Division, Division of Nuclear Technology Development and Economics, the NEA (5:45-5:55 pm)