# PROGRAMME



# International Workshop on Medical Radioisotopes Supply

30-31 October 2023 OECD Conference Centre Paris, France





# **Overview**

The "International Workshop on Medical Radioisotopes Supply" is organised by the Nuclear Energy Agency (NEA) and will be held at the Conference Centre of the Organisation for Economic Co-operation and Development (OECD) in Paris on 30-31 October 2023. It will explore the current status of the supply of molybdenum-99 (<sup>99</sup>Mo) as well as the actions needed to ensure it remains reliable, and will discuss the new generation of radioisotopes for diagnostics and therapy.

# Legacy of work on medical radioisotopes supply

The NEA's support for global efforts to ensure a reliable supply of medical radioisotopes, specifically <sup>99</sup>Mo, dates back to 2009, a period of substantial shortages of <sup>99</sup>Mo and its decay product, technetium-99m (<sup>99</sup>mTc). 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 stabilise supplies, although shortages of <sup>99</sup>Mo have reappeared at times.

## Workshop programme

The "International Workshop on Medical Radioisotopes Supply" will examine developments since 2019, as well as ongoing <sup>99</sup>Mo supply and demand impacts stemming from the COVID-19 crisis. Despite clear progress increasing irradiation and processing capacity, NEA countries today still rely on a relatively small number of multipurpose and ageing research reactors to meet nearly all of the world's demand for <sup>99</sup>Mo.

Moreover, recent trends in research and development and the clinical use of new diagnostic isotopes mean demand will grow in new radioisotope supply chains in coming years.

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





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# Programme – 30 October (Day 1)

# Room CC6

Arrival and check-in – 08:00-09:00 a.m.

Opening session				
9:00 (20 min)	Workshop opening			
	<ul> <li>Nick Sherman, Deputy Head of Division and Lead Technologist, Division of Nuclear Technology Development and Economics, NEA</li> </ul>			
	Welcome remarks			
	William D. Magwood, IV, Director-General, NEA			
	Special remarks			
	Jun Hatazawa, Special Advisor to the Japan Atomic Energy Commission			
Session 1:	Assessing the security of supply of <sup>99</sup> Mo and <sup>131</sup> I			
9:20 (110 min)	The COVID-19 pandemic exposed and exacerbated vulnerabilities in the supply chain for <sup>99</sup> Mo, highlighting the need for robust contingency planning to mitigate the risk of future disruptions. Session 1 will examine security of supply conditions for <sup>99</sup> Mo since 2019 and projections for 2023-2027. Presentations will survey supply-side and demand-side market conditions before and after COVID-19. This session will also highlight the supply situation of iodine-131 ( <sup>131</sup> I), for which the community as expressed supply concerns. The Chair will open a discussion on policy recommendations to ensure the adequacy of supply.			
	Relations, Lantheus			
	<ul> <li>Nick Sherman, Deputy Head of Division and Lead Technologist, Division of Nuclear Technology Development and Economics, NEA</li> </ul>			
	Introduction of NEA report: "The Security of Supply of Medical Radioisotopes: Demand and Capacity Projections for <sup>99</sup> Mo/ <sup>99m</sup> Tc for the 2023-2027 Period"			
	Kevin Charlton, former Senior Analyst, NEA			
	Current situation and challenges to supply of <sup>131</sup> I			
	<ul> <li>Jean Bonnet, Head of Strategy, Sales and Marketing, IRE</li> </ul>			

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

- Thabo Tselane, Managing Director, NTP
- Pamela Naidoo-Ameglio, Group Executive for Nuclear Operations and Nuclear Medicine, ANSTO

11:10 Sponsor showcase – Curium (10 min)

11:20 Coffee break

(15 min)

### Session 2: The current situation and challenges to supply of <sup>177</sup>Lu

11:35 Demand for <sup>177</sup>Lu is expected to grow rapidly over the next few years as (50 min) patients have high expectations for Lu-PSMA, which is effective for patients with metastatic castration-resistant prostate cancer who have no other effective treatment options, following Lu-DOTATATE for the treatment of neuroendocrine tumours (NETs).

However, like <sup>99</sup>Mo and <sup>131</sup>I, <sup>177</sup>Lu also faces the challenge of ageing irradiation reactors, and efficient production methods are still being developed.

Session 2 will provide insights from key producers of <sup>177</sup>Lu on the current supply and demand situation and future projections, and discuss issues that stakeholders should address.

<u>Chair</u>: Ira Goldman, Vice President, Global Public Policy and Government Relations, Lantheus

#### Overview of current situation of supply of <sup>177</sup>Lu by Chair

• Ira Goldman, Vice President, Global Public Policy and Government Relations, Lantheus

Current situation and challenges of supply of <sup>177</sup>Lu

- Robin Gommers, Site Head Novartis RLT Baarle-Nassau (IDB Holland BV)
- Eli Shalom, CEO, ISOTOPIA
- Harrie Buurlage, Chief Commercial Officer of Isotopes, SHINE

12:25 Lunch break
(60 min)
13:25 Sponsor showcase – Canadian Nuclear Isotope Council
(10 min)

#### Session 3: Current developments in new production

13:35 Despite clear progress increasing irradiation and processing capacity, NEA (105 min) countries today still rely on a relatively limited number of multipurpose research reactors - many of which are over 60 years of age - to produce the majority of the world's supply of <sup>99</sup>Mo. These reactors have undergone upgrades and improvements to enhance their production capacities and optimise isotope production for pharmaceutical use. However, large-scale investment in innovative production processes, new production facilities and associated infrastructure will be needed to ensure security of supply and meet expected demand. Both governments and industry stakeholders continue to face the question of how to optimise new infrastructure investments in light of technology advancements and growing demand for other radioisotopes. Session 3 will survey the effects of the development of new production facilities on supply and the challenges that the public and private sectors face, including from a financial perspective.

<u>Chair</u>: Max Postman, Foreign Affairs Specialist, Office of Material Management and Minimization, National Nuclear Security Administration, the US Department of Energy

#### Innovative <sup>99</sup>Mo production process

- Harrie Buurlage, Chief Commercial Officer of Isotopes, SHINE
- Jonathan Cirtain, Senior Vice President, Chief Development Officer, BWX Technologies, Inc. and President & CEO, BWXT Medical Ltd.

#### Plans for new radioisotope production reactors

- Ronald Schram, Director Strategic Alliances, NRG|PALLAS
- Marion Libessart, Business Development Manager, JHR PROJECT Client and Consortium Directorate, CEA
- Natalia Stankevicius, Manager of Radioisotopes Production, National Atomic Energy Commission

15:20 Coffee break (15 min)

#### Session 4: Programmes and sustainable financing models

15:35 Full cost recovery (FCR) programmes to ensure security of supply for medical (100 min) radioisotopes date back to the 1970s, with variance on specific designs and implementation across jurisdictions and organisations. Session 4 will survey the progress made 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 learnt and current best practices across jurisdictions and explore opportunities to enhance co-operation on production and supply chain security.

Chair: Jan Horst Keppler, Senior Economic Advisor, NEA

Introduction to the discussion on the realisation of the FCR

• Jan Horst Keppler, Senior Economic Advisor, NEA

Progress of policies of member countries

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

Closing remarks					
17:15 <i>(5 min)</i>	•	Diane Cameron, Head of Division, Division of Nuclear Technology Development and Economics, NEA			

18:00 Cocktail reception, with special remarks from CNIC

(90 min) George Marshall Room, Château

# Programme – 31 October (Day 2)

# Room CC6

Arrival and check-in – 08:00-08:30 a.m.

### Session 1: Innovative medical radioisotopes and radiopharmaceuticals (1)

8:30 Innovation in the diagnosis, treatment and monitoring of various medical (90 min) conditions through the use of novel medical radioisotopes and radiopharmaceuticals continues to accelerate (e.g. Theranostics, alphaemitting radionuclides, radioligands and targeted imaging). Session 1 will survey the 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.

<u>Chair</u>: Cathy Cutler, Director, Medical Isotope Research & Production, Collider Accelerator Department, Brookhaven National Laboratory

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

• Kumiko Kikuchi, Medical Radioisotopes Advisor, NEA

#### 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
- Richard Paul Baum, Curanosticum Wiesbaden-Frankfurt, Center for Advanced Radiomolecular Precision Oncology

Current work and challenges in innovative medical radioisotopes supply

- Jehanne Gillo, Director, the US Department of Energy's Office of Isotope R&D and Production
- Margarida Goulart, Head of Unit, European Commission Joint Research Centre

10:00 Coffee break (15 min)

#### Session 2: Innovative medical radioisotopes and radiopharmaceuticals (2)

10:15 Session 1 will discuss trends in innovative radioisotopes, while Session 2 will (110 min) focus on three of these radioisotopes. Firstly, the production of germanium-68 (<sup>68</sup>Ge) and its daughter nuclide gallium-68 (<sup>68</sup>Ga), which is used in theranostics in combination with <sup>177</sup>Lu, will be examined. Secondly, α -emitting <sup>225</sup>Ac and <sup>211</sup>At, which have attracted attention for their high cancer therapeutic potential and are being actively researched, will be highlighted. The focus of discussion on <sup>225</sup>Ac and <sup>211</sup>At will mainly be on how the current supply situation supports R&D of radiopharmaceuticals worldwide. Along with research reactors, accelerators are key players in innovative radioisotope production. Throughout this session, the challenges and future directions of the production of radioisotopes with accelerators will also be explored.

<u>Chair</u>: Jehanne Gillo, Director for the US Department of Energy's Office of Isotope R&D and Production

#### Production of <sup>68</sup>Ge and <sup>68</sup>Ga for diagnostics

- Roy Brown, Vice President, Government Affairs & Strategic Alliances, Curium
- Erich Kollegger, CEO, IRE

#### Production of <sup>225</sup>Ac for treatment

- Cathy Cutler, Director, Medical Isotope Research & Production, Collider Accelerator Department, Brookhaven National Laboratory
- Cornelia Hoehr, Deputy Associate Laboratory Directorm, TRIUMF
- Rachel Eloirdi, Head of Unit at the European Commission Joint Research Centre
- Shigetaka Maeda, Principal Research Engineer, Department of Experimental Fast Reactor, Oarai Research and Development Institute, JAEA
- Sven Van den Berghe, CEO, Pantera

# Development of R&D networks and production of <sup>211</sup>At radioisotopes for treatment

- Jean-Francois Gestin, Director of Research, INSERM
- Kohshin Washiyama, Associate Professor, Fukushima Medical University

12:05 *Lunch break* (75 min)

# Session 3: Pharmaceutical regulatory considerations for medical radioisotopes and radiopharmaceuticals

13:20 Pharmaceutical industry perspectives vary based on specific business (60 min) 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 bring up key regulatory challenges associated with opening new markets for the use of medical radioisotopes.

<u>Chair</u>: Aruna Korde, Radiopharmaceutical Scientist, Radioisotope Products and Radiation Technology Section, Division of Physical and Chemical Sciences, IAEA

# Aligning standards for safety, quality control, manufacturing processes and labelling requirements

- Aruna Korde, Radiopharmaceutical Scientist, Radioisotope Products and Radiation Technology Section, Division of Physical and Chemical Sciences, IAEA
- Ravindra Kasliwal, Office of New Drug Products DNDP-3, Branch-6 Office of Pharmaceutical Quality, FDA
- Rolf Hesselmann, Scientific Advisor, the Swiss Federal Office of Public Health

#### Key current challenges of pharmaceutical companies

- Roy Brown, Vice President, Government Affairs & Strategic Alliances, Curium
- Daniel Fontaine, Global Tech Steward Radio Isotopes, Novartis

14:20 Coffee break (15 min)

#### Session 4: Stakeholders panel discussion

14:35 The workshop will conclude with two breakout sessions for discussions (170 min) between governments and among companies on the keys steps needed to ensure universal access to the life-saving benefits of radiological isotopes worldwide.

#### Government panel discussion (85 min)

<u>Chair</u>: Joao Alberto Osso, former IAEA Section Head Radioisotope Products and Radiation Technology

- Jehanne Gillo, Director for the US Department of Energy's Office of Isotope R&D and Production
- Jun Hatazawa, Special Advisor to the Japan Atomic Energy Commission
- Margarida Goulart, Head of Unit at the European Commission Joint Research Centre
- Adriana Serquis, President, National Atomic Energy Commission
- Kathleen Prosser, Advisor for radioisotopes, the Uranium and Radioactive Waste Division, Natural Resources

16:00 Coffee break (10 min)

#### Specialists in medical field and private sector panel discussion (75 min)

Chair: Guy Turquet de Beauregard, Honorary President, NMEU

- 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
- Guillaume Dedet, Senior Health Economist, Employment Labour and Social Affairs, OECD
- Ira Goldman, Vice President, Global Public Policy and Government Relations, Lantheus
- Leonhard Schaetz, Global Head RLT HCS and Partnerships, Novartis
- Sven Van den Berghe, CEO, Pantera

Closing remarks					
17:25 (10 min)	Nick Sherman, Deputy Head of Division and Lead Technologist, Divisior of Nuclear Technology Development and Economics, NEA	۱			

# **Biographies – Participants**



## Richard Baum, Consultant, Curanosticum Wiesbaden-Frankfurt

Attending: Virtually

Germany

Relationship to Medical Radioisotopes:

Nuclear Medicine Diagnostic and Therapy Center

lsotope(s):

Ga-68, Lu-177, Y-90, Ac-225, Tc-99m, I-131, I-123

Richard P. Baum is President of the International Centers for Precision Oncology Academy, an ICPO Board member, Chair of the IPO Scientific Board, and Chairman of the Advanced Center for Radiomolecular Precision Oncology at Curanosticum Wiesbaden-Frankfurt. He performed in Germany the first radioimmuno-therapy (1985), the first peptide-receptor radiotherapy (1997) and the first Lutetium-177-based prostate-specific membrane antigen radioligand therapy (2013). Prof. Baum has treated over 5 000 patients with more than 15 000 radioligand applications.

He received numerous accolades such as the Mallinckrodt Award, the GLORINET Award, and the Saul Hertz Award. Currently, he holds several guest and associate professorships around the world.

He is an avid supporter of the theranostics concept – he organised the first Theranostics World Congress in 2011 (in Bad Berka) and the latest TWC-2022 (in Wiesbaden) – and the use thereof in personalised medicine for radiomolecular precision oncology.



# Jean Bonnet, Head of Strategy, Sales and Marketing, Institut des Radioélements

Attending: In person

Belgium

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

Pharmaceutical company

lsotope(s):

Mo-99; I-131;Xe-113; Ge-68; Ga-68

Jean Bonnet is a MD with a specialty in metabolic biochemistry from the University of Lyon-1. He has also received an MBA from the HEC School of Management in Paris.

After three years as a research associate at Inserm (U.189), he crossed over to the biotech business for the French start-up Immunotech, in Italy.

After his MBA in 1993, he spent 17 years in Boehringer Ingelheim, initially in various marketing roles, and then started a period of international assignments, as business head and country management in Germany, Greece and Poland.

He served at the board of Infarma, the Polish pharmaceutical industry association.

In 2010, he took a VP position first as Area Manager Europe in the imaging division of Mallinckrodt Pharmaceuticals, then as VP Strategic Execution and Business Excellence.

In parallel, he also served for five years as General Secretary of AIPES, the European association of the medical imaging and equipment supply industry.

More recently, he built up two subsidiaries for Exeltis in France and Belgium, and in early 2019 he moved back to nuclear medicine as Head of Strategy, Sales and Marketing for IRE and IRE Elit. The R&D department of IRE also reports to him.



# Roy Brown, V.P., Government Affairs & Strategic Alliances, Curium

Attending: In person

**United States** 

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

Pharmaceutical company

Distributer of medical radioisotopes

### lsotope(s):

Mo-99, I-131, Ge-68, Cu-64, Lu-177, In-111, I-123, Ga-67, TI-201, Ir-192, Re-186, Y-90, Sr-82, Sm-153, Xe-133

Roy Brown is the Vice President of Government Affairs and Strategic Alliances at Curium. His principle responsibility is assuring the long-term supply of radionuclides by working with research and test reactors and particle accelerators around the with and partnering groups developina world. new technologies. He has more than 30 years of experience in the nuclear medicine industry. Mr Brown currently serves as Curium's representative to the European Nuclear Energy Association's OECD Committee on Medical Isotope Supply. He also serves on several IAEA Committees dealing with Mo-99 and other isotope production, is on the European-based Nuclear Medicine-Europe (formerly AIPES) Security of Supply Working Group, and serves in the Nuclear Medicine-Europe General Assembly. He holds a B.S. in Radiation Biophysics and a Master's Degree in Business Administration.



# Harrie Buurlage, Chief Commercial Officer of Isotopes, SHINE Technologies

Attending: In person

**United States** 

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

#### lsotope(s):

Lu-77, Mo-99, I-131, Xe-133, Tb-161, Tb-155

In September 2023, Harrie Buurlage was named Chief Commercial Officer of Isotopes at SHINE Technologies, LLC, a next-generation fusion technology company.

Buurlage, who has been the General Manager of SHINE Europe since 2019, is now overseeing all commercial aspects of SHINE's therapeutic and diagnostic medical isotope divisions.

Buurlage's experience includes three decades in the nuclear medicine industry, encompassing management and marketing roles. He was the Chief Operating Officer at NRG in the Netherlands, overseeing key nuclear installations, and the global director for nuclear manufacturing at Covidien USA, now Curium Pharma. With 15 years at Mallinckrodt and an applied physics background from the University of Groningen, he also holds Europe's highest certification, the senior radiation safety officer from the University of Leiden, qualifying him to supervise complex nuclear sites.



# Kevin Charlton, Former Senior Analyst, Nuclear Energy Agency

Attending: In person

United Kingdom

Relationship to Medical Radioisotopes:

Consultation services concerning the development, production and distribution of medical isotopes.

#### lsotope(s):

All

Kevin Charlton is a long-term industry member working throughout the supply chain, from reactor to nuclear pharmacy, and is dedicated to the safe, secure and sustainable supply of medical radioisotopes for nuclear medicine diagnosis and therapy. He is a former NEA Senior Analyst.



# Jonathan Cirtain, Senior Vice President, Chief Development Officer, BWX Technologies, Inc. and President & CEO, BWXT Medical Ltd.

BWX Technologies, Inc.

Attending: Virtually

Canada

### **Relationship to Medical Radioisotopes:**

Producer/manufacturer of medical radioisotopes

Pharmaceutical company

Distributer of medical radioisotopes

lsotope(s):

Mo-99/Tc-99m, Ac-225. Ge-68. In-111, I-123, Sr-82

Dr Jonathan W. Cirtain is Senior Vice President and Chief Development Officer of BWX Technologies, Inc. (BWXT) and President & CEO of BWXT Medical Ltd. He is responsible for identifying and developing new technologies for the company by integrating technical expertise and resources across the enterprise. He joined BWXT as director of commercial technologies in 2017 and has also served as BWXT Advanced Technologies LLLC's President and Chief Technology Officer.

Dr Cirtain spent nine years with NASA. He received the prestigious Presidential Early Career Award for Scientists and Engineers and held positions of increasing responsibility, from astrophysicist to Science Research Office manager. He also co-founded Astraea, Inc., a machine learning and data science analytics company.

With a passion for design and innovation, Dr Cirtain has contributed to and led teams in revolutionary science and technology applications. He has developed plasma confinement systems for lab research, a solid rocket motor system for suborbital vehicles, and graphics processing unit technology for video systems.

Dr Cirtain earned his PhD in physics from Montana State. He also holds two Bachelor's degrees in physics and mathematics from the University of Memphis. Dr Cirtain has served on advisory committees for NASA, the National Science Foundation, the US Department of Commerce's National Oceanic and Atmospheric Administration, the US Office of Science and Technology Policy, the National Academy for Science and Engineering, the Royal Academy of Science, the European Space Agency and numerous universities.



# Cathy Cutler, Director of MIRP, Brookhaven National Laboratory

Attending: In person

**United States** 

Relationship to Medical Radioisotopes: Producer/manufacturer of medical radioisotopes

Dr Cathy S. Cutler is Director of the Medical Isotope Research Production and Development group (MIRP) at Brookhaven National Laboratory. Dr Cutler moved to the University of Missouri Research Reactor Centre's Radiopharmaceuticals Group in 1998. There she developed reactor processing methods for radioisotopes such as Lutetium-177, and other radiometals and developed targeting molecules such as nanoparticles for selective delivery. In order to support clinical evaluation of the radioisotopes produced at MURR she developed the quality assurance and quality control programme at MURR.

Dr Cutler's research focuses on developing production and separation methods for high specific activity theragnostic radioisotopes, creating a suite of diagnostic and therapeutic agents tailored for individual needs that has been funded by the DOE, NIH, NSF and public foundations. She brings more than 30 years of experience in the development and evaluation of radiopharmaceuticals, utilising bioinorganic and radioanalytical chemistry to develop and evaluate radiopharmaceuticals for both diagnosis and therapy. Her work has resulted in the launch of several radioisotope production lines used for applications and the issuance of patents.



# Guillaume Dedet, Senior Health Economist, OECD

Attending: In person

**Relationship to Medical Radioisotopes:** 

International organisation

Guillaume Dedet serves as Senior Health Economist at the Organisation for Economic Co-operation and Development (OECD) Health Division, where he has been leading the OECD's regular cycles of comparative analysis of health systems and the health of populations across Europe. Dedet is a lecturer at SciencesPo Paris and a former Harkness Fellow in health policy and practice. Prior to joining the OECD, he worked as medical adviser in the Health Systems Financing Department at the French Ministry of Health, and as a technical officer at the World Health Organization Regional Office for Europe.



### Rachel Eloirdi, Head of Unit, European Commission – Joint Research Centre

Attending: In person

Belgium

Relationship to Medical Radioisotopes:

R&D on Targeted Alpha Therapy

lsotope(s):

Actinium-225

Dr Rachel Eloirdi serves as the Head of the Radionuclides for Health and Innovation Unit at the Joint Research Centre in Karlsruhe, Germany. In this role, she leads a dedicated team engaged in a wide range of activities, including the development and maintenance of the Transuranus code for nuclear fuel property modelling, surface science studies using thin films as fuel models, and facilitating open access to nuclear research infrastructure at JRC Karlsruhe.

One of the aspects she has had the privilege to manage for two years is Targeted Alpha Therapy (TAT), a field that holds significant promise for advancing healthcare. Through collaborative research involving actinium-225-based radiopharmaceuticals, her team supports hospitals and research centres in their crucial work. This collaboration has contributed to the progression of TAT research.

Alberto Fernandez Fernandez, Director Nuclear Applications, Belgian Ministry of Economy and Energy Attending: In person Belgium Relationship to Medical Radioisotopes: Policymaking
Mr Fernandez Fernandez supports the Belgian government in all matters related to nuclear energy policy, LTO, radioisotopes, nuclear provisions, non-proliferation nuclear waste management and nuclear R&D (budget 250+ MEUR/year).
He holds a PhD in nuclear engineering, an MBA, a diploma in nuclear law and has pursued high studies in defence.





# Jean-Francois Gestin, Director of Research, Inserm

Attending: In person

France

**Relationship to Medical Radioisotopes:** 

Research on radiopharmaceuticals including alpha emitters

### lsotope(s):

Astatine-211

Jean-Francois Gestin obtained his PhD in 1989 after spending two years at the Brookhaven National Laboratory, United States. He joined the research group of Pr. Jean-Francois Chatal in 1991 as responsible of research (CR2 INSERM) and obtained his HDR (authorisation to direct research) in 1995. He is now Director of Research (INSERM) and head of the chemistry and radiopharmacy research group, which is part of the team 2 directed by Pr. Michel Chérel and dedicated to research in nuclear oncology, in the Centre of Research in Cancerology and Immunology Integrated Nantes Angers (CRCI2NA), France. This team integrates several fields including chemistry, radiochemistry, radiopharmacy, biology, imaging and clinical studies.

Jean-Francois Gestin is member of Nuclear Medicine Europe, Co-leader of the therapy group, and Chair of the NOAR COST Action.



# Munir Ghesani, Chief of Nuclear Medicine, Mount Sinai

Attending: Virtually

**United States** 

**Relationship to Medical Radioisotopes:** 

Academic institution-health system

#### lsotope(s):

Entire library of approved diagnostic and therapeutic radiopharmaceuticals

Munir Ghesani, MD, FACNM, FACR, is the Associate Professor of Radiology at Icahn School of Medicine at Mount Sinai and the Systems Chief of Nuclear Medicine and Molecular Imaging at Mount Sinai Health in New York. Dr Ghesani and his team have built a successful theranostics programme at Mount Sinai, benefitting patients in the Mount Sinai Health System and drawing referrals for clinically approved applications and research trials from other institutions in NYC, other regions in the North-East, and around the United States.

Dr Ghesani has numerous publications in peer-reviewed journals and is the Editor-in-Chief of a three-part book on nuclear medicine and molecular imaging. He has given more than 150 presentations at regional, national and international conferences.

Dr Ghesani held leadership roles in various societies and colleges, including as the Immediate Past President of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), Past President of the Education and Research Foundation of Nuclear Medicine and Molecular Imaging, Past Chairman of the American Board of Nuclear Medicine, Past Chairman of the Government Relations Committee and the FDA Task Force of the SNMMI, and Past Chairman of the Nuclear Medicine and PET Accreditation Committee of the American College of Radiology. In January 2020, he was named ACNM Personal Best Mentor of the Year. He has been a Fellow of the American College of Radiology (2018) and the Society of Nuclear Medicine and Molecular Imaging (2023).

Jehanne Gillo, Associate Director of Science for Nuclear Physics Attending: In person United States Relationship to Medical Radioisotopes Producer of medical radioisotopes Isotope(s)
Dr Jehanne Gillo joined the Department of Energy in 2000 and held the title of Director of Facilities and Project Management in the Office of Nuclear Physics, where she was responsible for all nuclear physics scientific user facilities and large construction projects. She further became Director of the DOE Isotope Program in 2009 and formed the DOE Office of Isotope R&D and Production in 2020. During her federal career, Dr Gillo has been awarded three awards of recognition from different Secretaries of Energy, and the Presidential Rank of Meritorious Executive Award from President Obama. Prior to DOE, she worked at Los Alamos National Laboratory.



# Ira Goldman, Vice President, Global Public Policy and Government Relations, Lantheus

Attending: In person

**United States** 

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

Pharmaceutical company

#### lsotope(s):

Mo-99/Tc-99m; F-18; Lu-177

Ira N. Goldman is Vice President, Global Public Policy and Government Relations, at Lantheus Holdings. He is Vice Chairman of the Security of Supply Working Group, Nuclear Medicine Europe, and Co-Chair of the Isotope Supply Committee and Secretary/Treasurer, Council on Radioisotopes and Radiopharmaceuticals (CORAR).

Mr Goldman is responsible for the development and execution of Lantheus's strategy and actions for public and healthcare policy, including legislative strategy and interactions with the US Congress as well as relationships with executive branch agencies. He co-ordinates Lantheus's involvement with trade associations, business and regional advocacy groups and medical societies. He also interacts with US and foreign governments and international organisations regarding medical isotope production and supply matters.



# Robin Gommers – Site Head, Novartis RLT Baarle-Nassau (IDB Holland BV)

Attending: In person

Netherlands

#### **Relationship to Medical Radioisotopes**

Producer/manufacturer of medical radioisotopes

Pharmaceutical company

#### lsotope(s):

Lu-177

#### Biography

Mr Gommers has over two decades of experience in pharmaceutical manufacturing and R&D as a leader with strong background in process improvement, transformation and organisational development both in the United States and the European Union for Amgen and Novartis.

Mr Gommers is Site Head of the Baarle-Nassau site of Novartis RLT since the beginning of 2022. This site produces GMP grade pharmaceutical isotopes based on Lu-177 used for Novartis RLT marketed and pipeline products.

His formal training is in industrial engineering (BSc) and general management (MSc).

# Margarida Goulart, Head of Unit, European Commission – Joint Research Centre

Attending: In person

Belgium

**Relationship to Medical Radioisotopes:** 

Public administration

Margarida Goulart is Head of Unit of Euratom Coordination at the Joint Research Centre of the European Commission, where she has been working for more than 10 years. Her main field of expertise includes research and policy implementation in nuclear, chemical and biological security and in nuclear science applications, particularly medical radionuclides. Dr Goulart is a medical doctor and pharmacist, and holds a doctorate in toxicology. Before joining the European Commission, she accumulated 15 years of academic experience as a researcher and professor in higher education and research institutions in health and nuclear sciences, both in Portugal and in the United States.



# Jun Hatazawa, Special Advisor, Japan Atomic Energy Commission

Attending: In person

Japan

Relationship to Medical Radioisotopes:

Policymaking

Isotope(s):

Mo-99, Lu-177, Ac-225, At-211

Jun Hatazawa is a nuclear medicine specialist, former professor and Chairman of the Department of Nuclear Medicine and Tracer Kinetics of Osaka University Graduate School of Medicine. He is the Honorary President of the Asia Oceania Federation of Nuclear Medicine and Biology. Mr Hatazawa is currently engaged in establishing the supply chain of medical use radioisotopes in Japan.





# Cornelia Hoehr, Deputy Director – Life Sciences, TRIUMF

Attending: In person

Canada

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

Cornelia Hoehr received her Ph.D. in atomic physics from Heidelberg University in Germany and the Max-Plank institute for Nuclear Physics in Heidelberg in 2004, after completing a Masters in physics at Freiburg University in Germany. After a post-doctoral research term at the Argonne National Lab, USA, she then moved to TRIUMF as a post-doctoral researcher, and subsequently took on roles in operation and facilities in isotope production and proton therapy. In 2013 she became a research scientist at TRIUMF and an Adjunct Professor at the University of Victoria, and in 2018 she became Adjunct Professor at the University of British Columbia -Okanagen and took over the role as Deputy Associated Laboratory Director - Life Sciences. Her research interests are focused on medical isotope production and proton therapy. She is a member of the steering committee for the Particle Therapy Co-Operative Group (PTCOG), consultant to the IAEA in isotope production, and was chair of the TRIUMF User Group Executive Committee (TUEC).



# Ravindra Kasliwal, Chemist, US Food and Drug Administration (FDA)

Attending: Virtually

**United States** 

Relationship to Medical Radioisotopes:

Government

lsotope(s):

Mo-99, Tc-99m, Ac-225, At211, F-18, Zr-89, etc.

### Motivation:

Regulatory and product quality

Dr Ravindra Kasliwal is a CMC expert in diagnostic and therapeutic radiopharmaceutical drug products in the Office of New Drug Products, within the Office of Pharmaceutical Quality at CDER/FDA. He has been at the FDA since 1994 and been involved in the review of many complex diagnostic and therapeutic radioactive drugs. He has served on numerous FDA committees, committees organised by national and international organisations, as well as USP standards committees dealing with radioactive drugs, where he was involved with writing regulations, guidance documents and chapters.



# Jan Horst Keppler, Senior Economic Advisor, Nuclear Energy Agency

Attending: In person

International Organisation

Relationship to Medical Radioisotopes:

Economist

Jan Horst Keppler is Senior Economic Advisor of the OECD Nuclear Energy Agency in the Division for Nuclear Energy Development and Economics (NTE). He is also professor of economics at the Université Paris Dauphine – PSL, where he co-directs the Master Energy, Finance, Carbon (EFC) and chairs the Supervisory Board of the Chair European Electricity Markets (CEEM). Professor Keppler's principal area of research is the financing and competitiveness of low-carbon technologies such as nuclear energy in the context of the energy transition. Recent publications include Achieving Net Zero Carbon Emissions in Switzerland in 2050 (2022), Ensuring the Adequacy of Funding Arrangements for Decommissioning and Radioactive Waste Management (2021) and The Costs of Decarbonisation: System Costs with High Shares of Nuclear and Renewables (2019).



# Kumiko Kikuchi, Medical Radioisotopes Advisor, NEA

Attending: In person

International Organisation

**Relationship to Medical Radioisotopes:** 

International organisation

#### lsotope(s):

All

Ms Kumiko Kikuchi has worked on the security of supply of medical radioisotopes and the social benefits of nuclear science in the medical field since joining the NEA in August 2022.

She began working at the Ministry of Education, Culture, Sports, Science and Technology of Japan in 2009, where she focused on promoting R&D in various fields and compensation for nuclear damages for the accident at the Fukushima Daiichi Nuclear Power Plant, among other topics.

When she was sent to the secretariat of the Japan Atomic Energy Commission, she worked on creating the Action Plan for Promotion of Production and Utilization of Medical Radioisotopes in 2022.



# Erich Kollegger, CEO, IRE

Attending: In person

Belgium

Relationship to Medical Radioisotopes:

Producer/manufacturer of medical radioisotopes

Erich Kollegger took over the General Management of the Institute for Radioelements (IRE) and its subsidiary IRE ELiT in early 2018. An engineer in electro-mechanics by education, his professional experience includes project management for The Jacobs Engineering Group, as well as production and plant management in chemical and pharmaceutical plants in Belgium and France. Before joining IRE, Mr Kollegger was Plant Manager of a manufacturing site for Baxter Healthcare in Lessines, Belgium. Erich is also Chairman of the Board of Directors of Transrad, a company specialised in transport of radioactive material, sharing the same site as IRE in Fleurus, Belgium.



# Aruna Korde, Radiopharmaceutical Scientist, IAEA

Attending: In person

Austria

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

#### lsotope(s):

All medical radioisotopes

Aruna Korde is a Radiopharmaceutical Scientist at the International Atomic Energy Agency (IAEA). She holds M. Pharmacy and PhD degrees from the University of Mumbai, India, and post-doctoral research fellowships in PET centres from the Yale School of Medicine and Wake Forest University, in the United States. She has over 25 years of experience in areas related to radioisotopes and radiopharmaceutical research, development and deployment for clinical use including planning and development of related facilities. In her current role at the IAEA, she is responsible for co-ordinating research projects in radiopharmaceuticals and providing technical assistance to member states for capacity building, human resource development in radioisotope production & radiopharmaceutical programmes. She has published more than 90 research papers, two IAEA books and IAEA-WHO guidance documents on GMP for radiopharmaceutical products. She is co-ordinating the WINRI "Women in Radiopharmaceutical Initiative" expert group under WiN dlobal.



# Marion Libessart, JHR Business Development Manager, CEA

Attending: In person

France

Relationship to Medical Radioisotopes:

Producer/manufacturer of medical radioisotopes

### lsotope(s):

All

Marion Libessart has been working at the CEA Cadarache as a JHR Business Development Manager within the client and consortium directorate since 2020.

In addition to consortium and marketing activities, she is involved in the preparation of the loading of the reactor and the associated business model, taking into account the voice of the customer, with a more active role on the radioisotope activities.

Before that she worked for 10 years at the ArianeGroup company in Les Mureaux as contract and sales manager for satellite and launchers equipment and engineering services, then for nuclear energy activities and as key strategic business developer.



# Shigetaka Maeda, Prinicipal Research Engineer, Japan Atomic Energy Agency

Attending: In person

Japan

**Relationship to Medical Radioisotopes:** 

Research on production of medical radioisotopes

lsotope(s):

Actinium-225

Dr Maeda has worked for 23 years in the field of nuclear engineering. His expertise spans a wide range of areas, including fast reactor physics, core design, radiation measurement and regulatory compliance.

Currently, he is involved in the licensing process for the restart of Joyo, ensuring compliance with the new regulations of Japan's NRA. He also explores the versatile applications of Joyo, such as radioisotope (RI) production. Dr Maeda is particularly enthusiastic about the production of actinium-225 and plans to conduct a production demonstration test once Joyo resumes operations.



# Pamela Naidoo-Ameglio, Group Executive, Nuclear Operations and Nuclear Medicine, ANSTO

Attending: Virtually

### Relationship to Medical Radioisotopes

Producer/manufacturer of medical radioisotopes

### lsotope(s)

Mo-99

Pamela Naidoo-Ameglio is an executive leader who has been immersed in nuclear, technology, mining, geoscience, operational and corporate roles in public and private sector corporations for over 30 years.

As Group Executive at ANSTO, she is responsible for Australia's only nuclear research reactor, OPAL, sovereign nuclear medicine production and radioactive waste operations.

Ms Naidoo-Ameglio is an Executive Director of Australian Nuclear Medicine (ANM), Science Advisory Board member of the Australian Museum, and executive committee member of Women in Nuclear-Australia.

She champions people development and diversity and is a mentor in STEM.



# Joao Alberto Osso Jr., IAEA, retired

Attending: In person

Brazil

### Relationship to Medical Radioisotopes:

Independent consultant, retired from IAEA

Mr Joao Osso, a Brazilian national, holds a PhD in nuclear chemistry from the University of Manchester, England. He had more than 34 years of experience in the field of radioisotope and radiopharmaceutical production in Brazil before joining the IAEA in February 2014, holding the position of Head of the Radioisotope Products and Radiation Technology Section from the Division of Physical and Chemical Sciences. He retired from the IAEA at the end of November 2021 and moved back to Brazil, where he acts as consultant and expert in the field of radiopharmacy in several projects.



# Max Postman, Foreign Affairs Specialist, National Nuclear Security Administration

Attending: In person

United States

Relationship to Medical Radioisotopes:

Government

lsotope(s):

Molybdenum-99

Max Postman is the Program Manager for the Domestic Molybdenum-99 Program at the Office of Defense Nuclear Nonproliferation in the US Department of Energy's National Nuclear Security Administration (DOE/NNSA). Mr Postman has over 15 years of experience at the DOE/NNSA, including in his current federal role and in previous contractor roles. His previous assignments have included nuclear export controls, nuclear cleanup, and budget and strategic planning. Mr Postman received a Bachelor's degree in political science from Grinnell College in Grinnell, Iowa, and a Master's degree in security studies from Georgetown University in Washington, D.C.



# Kathleen Prosser, Advisor, Government of Canada

Attending: Virtually

Canada

Relationship to Medical Radioisotopes:

Policy advisor responsible for radioisotopes at NRCan

Kathleen Prosser is an Advisor in the Uranium and Radioactive Waste Division with Natural Resources Canada, based out of Ottawa. Her work intersects with the federal government of Canada's policies related to radioactive waste, small modular reactors, radioisotopes, and advanced fuel cycles.





# Ronald Schram, Director Strategic Alliances, NRG|PALLAS

Attending: In person

Netherlands

Relationship to Medical Radioisotopes:

Producer/manufacturer of medical radioisotopes

### lsotope(s):

Moly-99, Lu-99, and wide range of other alpha- and beta-emitters

Ronald Schram is Director, Strategic Alliances at NRG|PALLAS, the Netherlands. NRG|PALLAS develops and delivers nuclear medicine products and contributes to energy solutions. NRG|PALLAS operates the High Flux Reactor and is building the PALLAS reactor. Dr Schram represents NRG|PALLAS on strategic files towards governments and partners. He participates in the European Nuclear Energy Association's OECD Committee on Medical Isotope Supply, the European Observatory on medical radioisotopes, and Nuclear Medicine Europe (NMEU). He has 30 years' experience in the nuclear field, working on nuclear R&D, nuclear technology and nuclear medical developments. He holds a PhD in physical chemistry.



# Eric Schutt, Chief of Staff, VP of Government of Affairs, & Mo-99 Project Director, SHINE Technologies

Attending: In person

Netherlands

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

### Isotope(s):

Mo-99, I-131, Xe-133, Lu-177

Eric Schutt joined SHINE as the Chief of Staff and Vice President of Government Affairs, responsible for planning and leading SHINE's strategic government affairs activities. He spent 25 years working in and around government at the state and federal levels, including serving as Governor Scott Walker's (R-WI) chief of staff and as an SVP of External Affairs and Head of State Government Affairs with UnitedHealth Group. Mr Schutt holds an MBA from George Washington University and a Bachelor's in history, political science and international relations from UW-Madison.



# Adriana Serquis, President, CNEA (Argentinean National Atomic Commission)

Attending: Virtually

Argentina

Relationship to Medical Radioisotopes:

Producer/manufacturer of medical radioisotopes

### Isotope(s):

Mo-99, I-131

Adriana Cristina Serquis is an Argentinean physicist, the President of the National Atomic Energy Commission (CNEA), and Principal Researcher of the National and Technical Research Council (CONICET). She graduated from the University of Buenos Aires and earned a doctorate in physical sciences at the Balseiro Institute. She did a post-doctoral fellowship at Los Alamos National Laboratory. Since 2004 she has been working at the CNEA's Bariloche Atomic Center and teaching as Professor at the Instituto Balseiro and National University of Rio Negro. She received several awards, such as the L'Oréal-UNESCO National Award for Women in Science for her contribution to the rational use of energy.





# Nick Sherman, Deputy Head of Division for Nuclear Technology Development and Economics, NEA

Attending: In person

International Organisation

**Relationship to Medical Radioisotopes:** 

Technology development and economics

#### lsotope(s):

All

Nicholas W. Sherman serves as the OECD Nuclear Energy Agency's (NEA) Deputy Head of Division for Nuclear Technology Development and Economics.

Before joining the NEA, Mr Sherman worked at the US Department of Energy (DOE) from 2009 to 2023 in the Office of International Affairs. His duties included the G7 and extensive bilateral research co-operation with the European Commission and EU member states.

In the field of energy technology, his notable accomplishments include leadership as Vice Chair of the International Energy Agency's (IEA) Committee for Energy Research and Technology (CERT), the development of multi-million dollar brick and mortar U.S.-EU Smart Grid and Electric Vehicle Interoperability Centers, drafting the first-ever DOE ioint fundina opportunity announcement (FOA) for the USD 125 million US-India Joint Centre for Research and Development (JCERDC), and oversight of the US-EU Energy Council's Technology Working Group. During his DOE tenure, Mr Sherman also served as the DOE's Energy Attaché to Brussels (2018-2019) and as the Director for International Energy and Economic Policy at the White House (2019-2021).



## Natalia Stankevicius, Radioisotopes Production and Radiation Applications Area Manager, National Atomic Energy Commission (CNEA)

Attending: Virtually

Argentina

**Relationship to Medical Radioisotopes** 

Producer/manufacturer of medical radioisotopes

Isotope(s):

At the moment: Mo-99; I-131; Sm-153.

In the Future: Lu-177; Bi-213; Ac-225.

A promoter of activities related to gender equality in the nuclear sector, Natalia Stankevicius currently works as Head of the Radioisotope Production and Radiation Applications Area – EZEIZA ATOMIC CENTER. She is responsible for co-ordinating the activities of the RA-3 Reactor, the radioisotope production plants for the national production of Mo-99, I-131 (among other radioisotopes) and other applications of nuclear technology, such as the Semi-Industrial Irradiation Plant (PISI Co-60). She plans strategic sales lines. Additionally, she is in charge of planning the new Fission Radioisotope Production Plant.

Until 2020 Ms Stankevicius worked as head of the Department of Chemical Control and Plant Engineering for the Management of the Nuclear Fuel Cycle.



# Thabo Tselane, Group Managing Director, NTP Radioisotopes SOC Ltd

Attending: In person

South Africa

**Relationship to Medical Radioisotopes:** 

Producer/manufacturer of medical radioisotopes

#### lsotope(s):

Mo-99, I-131, Lu-177

Mr Thabo Tselane is the Group Managing Director for NTP Radioisotopes SOC Ltd and also Chairperson of NTP Logistics and AEC Amersham (subsidiaries of NTP Radioisotopes). He was the Deputy Chairperson of Umgeni Water Board. Prior to joining NTP Radioisotopes, Mr Tselane was the Group Executive: Nuclear Operations and Chief Technology Officer at NECSA. Prior to his appointment at NECSA he served as a Senior Executive Manager: Nuclear Compliance and Enforcement and later Acting CEO of the National Nuclear Regulator (NNR).



# Guy Turquet de Beauregard, Honorary President, NMEU

Attending: In person

France

Relationship to Medical Radioisotopes:

European Industry Association for Nuclear Medicine

lsotope(s):

All in routine and in development

Mr Turquet de Beauregard is currently NMEU Honorary President (France) and SEVY Conseil President (France).

He was previously a physicist at CEA (Commissariat à l'énergie atomique, France) and the Los Alamos National Lab (United States).

He is also a former advisor at the Prime Minister's office (France) and a former Executive VP of CISBIO International and IBA Molecular.

# Sven Van de Berghe, CEO, Pantera

Attending: In person

Belgium

Relationship to Medical Radioisotopes: Producer/manufacturer of medical radioisotopes

Distributer of medical radioisotopes

lsotope(s):

225Ac

Sven Van den Berghe holds a PhD in physics and has a nuclear materials background with a specialty in nuclear fuel development, in particular fuel for research and test reactors. He has been the director of the Nuclear Materials Science Institute at the Belgian Nuclear Research Centre SCK CEN, where he also managed the commercial side of the radioisotope production at the BR2 reactor. Since 2022, he has moved to the role of CEO of PanTera, a spin-off of SCK CEN together with the accelerator manufacturer IBA, targeting the large-scale production of Actinium-225 as the most promising alpha-emitter for the next generation of therapeutic radiopharmaceuticals.



# Koshin Washiyama, Associate Professor, Fukushima Medical University

Attending: In person

Japan

### Relationship to Medical Radioisotopes:

Producer/manufacturer of medical radioisotopes

In-house production and clinical application of medical radioisotopes

### lsotope(s):

Cyclotron produced radioisotope

Mr Kohshin Washiyama holds a BSc (1997) and MSc (1999) in chemistry from Kanazawa University. After graduating, he worked as an assistant professor at Kanazawa University to manufacture and apply radioisotopes for medical use, especially alpha emitters, while obtaining a PhD in health science (2005). He was a visiting researcher at the University of Gothenburg, Sweden in 2012-2013, and a visiting associate professor at Duke University Medical Center in 2016-2018 to expand knowledge and experience of the targeted alpha therapy. He is currently Associate Professor at Fukushima Medical University, where he conducts research on targeted alpha therapy, focusing on cyclotron-based production of At-211 and development of its labeled compounds.



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Cover photos: Medical-isotope producing reactor (Randy Montoya/Sandia National Laboratories, CC BY-NC-ND 2.0); PET-MRI scan (Geir Mogen/NTNU, CC BY-NC 2.0); Applying radiochemistry to nuclear energy and medicine (Brookhaven National Laboratory, CC BY-NC-ND 2.0); High Flux Isotope Reactor (Genevieve Martin/Oak Ridge National Laboratory, CC BY 2.0).