令和6年第23回原子力委員会 参考資料第2-1号

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INTERNATIONAL SYMPOSIUM ON TRENDS IN RADIOPHARMACEUTICALS

177Lu

#ISTR2023

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IAEA Headquarters Vienna International Centre Austria

225AC

17 – 21 April 2023





iaea.org/events/istr-2023

	Monday APRIL 17	Tuesday APRIL 18	Wednesday APRIL 19	Thursday APRIL 20	
08:00–16:00	Registration and Badging				
09:00–10:30	Opening Session M PLENARY 09:30–10:30	S.4 Production of PET Radiopharmaceuticals I M PLENARY	S.7 Production of Tc-99m Radiopharmaceuticals M PLENARY	S.11 Production of Radioisotopes and Radiopharmaceuticals: Facilities M PLENARY	T
10:30–11:00		Coffee Break			
11:00–12:30	S.1 Production of Mo-99 M PLENARY	S.5 Production of Therapeutic Medical Radioisotopes M PLENARY	S.8 Production of PET Radiopharmaceuticals II M PLENARY	S.12 Radiopharmaceutical Industry M PLENARY	
12:30–14:00		12:30–13:30 Panel Discussion: Spotlight on Partnerships in Radiopharmaceuticals CONFERENCE ROOM M2	Lunch Break		
14:00–15:30	S.2 Production of Medical Radioisotopes: Generators M PLENARY	Poster Session POSTER AREA M02 SECOND FLOOR	S.9 Production of Radiopharmaceuticals: Therapy M PLENARY	Poster Session POSTER AREA M02 SECOND FLOOR	#
15:30–16:00			Coffee Break		
16:00–17:30	S.3 Production of PET Radioisotopes M PLENARY	S.6 Academia Meets Industry (PRISMAP experience) M PLENARY	S.10 Radiopharmaceuticals Development: Factors and Considerations M PLENARY	S.13 Production of Emerging Radioisotopes M PLENARY	
	Welcome Reception M BUILDING GROUND FLOOR 18:00–20:00	The Status and Prospects of Radiopharmecutical Science, Education and Industry in Russia CONFERENCE ROOM M2 17:30–18:30	TRIUMF's Experiences with the Research to Commercial Pipeline CONFERENCE ROOM M2 18:00–19:00	Speed Mentoring and Networking for Young Radiopharmaceutical Professionals PRESS ROOM 18:00–19:00	INTE SYM IN R



Young Investigator Award

To engage and encourage the young generation of professionals in the field, 5 selected young participants will receive this award during an "Award Ceremony"



IAEA Radioisotopes and Radiopharmaceuticals Series

Copper-64 Radiopharmaceuticals: Production, Quality Control and Clinical Applications

Presenting theranostic capabilities of copper-64 Describes:

- Biochemical and radiopharmaceutical aspects
- Clinical applications

Provides production guidelines for copper-64 chloride, peptide and monoclonal antibody radiopharmaceuticals.



S.14 TC Success Stories **M PLENARY**

S.15

Regulatory, Education and Pharmacopeia **M PLENARY**

Coffee Break

S.16 Closing Session **M PLENARY**

09:00-9:40

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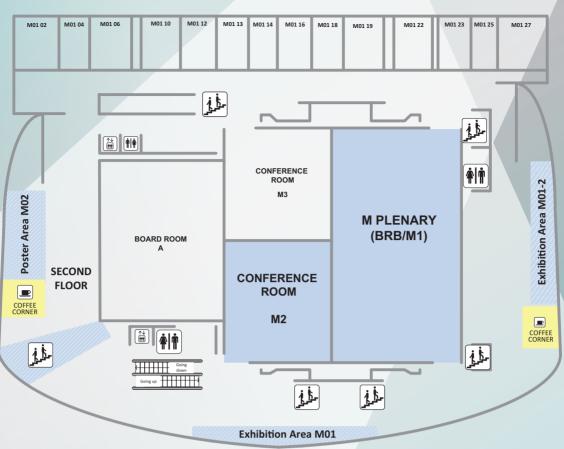
Guidance for Preclinical Studies with Radiopharmaceuticals

Provides a guide for preclinical evaluation of radiopharmaceuticals

- Facility requirements
- Constituent scientific activities
- Guidelines for biological assessment of candidate compounds

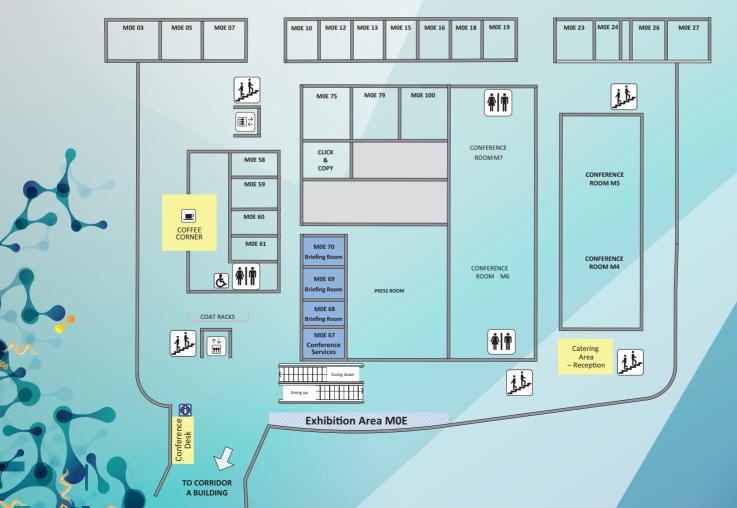


www.iaea.org/publications



M Building – First Floor – M01/M02

M Building – Ground Floor – M0E



EXHIBITORS/CONTRIBUTORS

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"WiN Global as Women in Radiopharmaceuticals"



11th International Conference on Isotopes

LIMMAN

THE REPORT OF

Abstract Book

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International Workshop on Medical Radioisotopes Supply

Current status and future action to ensure the reliable supply for molybdenum-99 (⁹⁹Mo) 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 (⁹⁹Mo), 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 ⁹⁹Mo dates back to 2009 during a period of substantial shortages for ⁹⁹Mo 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 ⁹⁹Mo 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 ⁹⁹Mo. 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 ⁹⁹Mo.

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 (¹⁷⁷Lu), actinium-225 (²²⁵Ac) and astatine-211 (²¹¹At) 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 (8:00-9:00 am)

Workshop opening by Nick Sherman, Deputy Head of Division and Lead Technologist, Division of Nuclear Technology Development and Economics (9:00-9:05 am)

Opening remarks by NEA Director-General William D. Magwood, IV (9:05-09:10 am)

Special Remarks by Jun Hatazawa, Special Advisor to the Japan Atomic Energy Commission (9:10-9:20 am)

Session 1: Assessing the Security of Supply for ⁹⁹Mo and ¹³¹I (9:20-11:10 am)

The COVID-19 pandemic exposed and exacerbated vulnerabilities in the supply chain for ⁹⁹Mo, highlighting the need for robust contingency planning to mitigate the risk of future disruptions. Session 1 will examine security of supply conditions for ⁹⁹Mo 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 (¹³¹I), for which the

community as expressed supply concerns. The Chair will 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 the past NEA's work on ⁹⁹Mo Security of Supply

-Nick Sherman, Deputy Head of Division and Lead Technologist, Division of Nuclear Technology Development and Economics, the NEA of the OECD (*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 and challenges of supply of ¹³¹I
 - Jean Bonnet, Head of Strategy, Sales and Marketing, IRE (Confirmed)
- 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*)

Sponsor showcase –Curium (11:10-11:20 am)

Coffee break (11:20-11:35 am)



Session 2: The Current Situation and Challenges on Supply of ¹⁷⁷Lu (11:35 am-12:25 pm)

Demand for 177Lu is expected to grow rapidly over the next few years as patients have very 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 ⁹⁹Mo and ¹³¹I, ¹⁷⁷Lu also faces the challenge of ageing irradiation reactors, and efficient production methods are still in the process of technological development. Session 2 will provide insights from key producers of ¹⁷⁷Lu on the current supply and demand situation and future projections, and discuss issues that stakeholders should address in the future.

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

- Overview of current situation of supply of ¹⁷⁷Lu by chair
 - Ira Goldman, Vice President, Global Public Policy and Government Relations, Lantheus (Confirmed)
- Current situation and challenges of supply of ¹⁷⁷Lu
 - Robin Gommers, Novartis (Switzerland) (Confirmed)
 - Eli Shalom, CEO, ISOTOPIA (Israel) (Confirmed)
 - Harrie Buurlage, Chief Commercial Officer of Isotopes, SHINE (U.S.) (Confirmed)

Lunch Break (12:25 -1:25 pm)

Sponsor showcase –Canadian Nuclear Isotope Council (1:25-1:35 pm)

Session 3: Current developments on new production (1:35-3:20 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 over 60 years of age—to produce the majority of the world's supply of ⁹⁹Mo. 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 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 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 ⁹⁹Mo production process

-Harrie Buurlage, Chief Commercial Officer of Isotopes, SHINE (U.S.) *(Confirmed)* -Jonathan Cirtain, CEO, BWX Technologies, Inc. (Canada) *(Confirmed)*



- Plans for new radioisotope production reactors
 - -Ronald Schram, Director Strategic Alliances, NRG|PALLAS (Netherlands) *(Confirmed)* -Marion Libessart, Business Development Manager, JHR PROJECT Client and Consortium Directorate, CEA (France) *(Confirmed)*
 - Natalia Stankevicius, Manager of Radioisotopes Production, National Atomic Energy Commission (Argentina) (Confirmed)

Coffee break (3:20-3:35 pm)

Session 4: Progress of Full Cost Recovery (FCR) Programmes and sustainable financing models (3:25-5:15 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 4 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 Economic Advisor at the NEA (Confirmed)

- Introduction to the discussion on the realisation of the FCR
 - Jan Horst Keppler, Senior Economic Advisor 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)

Closing Remarks by Diane Cameron, Head of Division, Division of Nuclear Technology Development and Economics, the NEA (5:15-5:20 pm)

Cocktail Reception (6:00 -7:30 pm)



Day 2: October 31, 2023

Arrival and check-in (8:00-8:30 am)

Session 1: Innovative Medical Radioisotopes and Radiopharmaceuticals (1) (8:30-10:00 am)

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*)
 - Richard Paul Baum, Curanosticum Wiesbaden-Frankfurt, Center for Advanced Radiomolecular Precision Oncology (*Confirmed*)
- 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)*
 - Margarida Goulart, Head of Unit at the European Commission Joint Research Centre (Confirmed)

Coffee break (10:00-10:15 am)

Session 2: Innovative Medical Radioisotopes and Radiopharmaceuticals (2) (10:15 am-12:05 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 (⁶⁸Ge) and its daughter nuclide gallium-68 (⁶⁸Ga), which is used in theranostics in combination with ¹⁷⁷Lu, will be examined. Secondly, α -emitting ²²⁵Ac and ²¹¹At, which have attracted attention for their high cancer therapeutic potential and are being actively researched, will be highlighted. The focus of discussion on ²²⁵Ac and ²¹¹At 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 ⁶⁸Ge and ⁶⁸Ga for diagnostics
 - Roy Brown, Vice President, Government Affairs & Strategic Alliances, Curium (Confirmed)
 - Erich Kollegger, CEO, IRE (Belgium) (Confirmed)
- Production of ²²⁵Ac for treatment
 - Cathy Cutler, Director, Medical Isotope Research & Production, Collider Accelerator Department, Brookhaven National Laboratory (Confirmed)
 - Cornelia Hoehr, Deputy Associate Laboratory Directorm TRIUMF (Canada) (Confirmed)
 - Rachel Eloirdi, Head of Unit at the European Commission Joint Research Centre (Germany) (Confirmed)
 - Shigetaka Maeda, Principal Research Engineer, Department of Experimental Fast Reactor, Oarai Research and Development Institute, JAEA (Japan) (Confirmed)
 - Sven Van den Berghe, CEO of Pantera (Belgium) (Confirmed)
- Development of R&D Networks and Production of ²¹¹At radioisotopes for treatment

-Jean-Francois Gestin, Director of Research, INSERM (France) (Confirmed) -Kohshin Washiyama, Associate Professor, Fukushima Medical University (Japan) (Confirmed)

Lunch Break (12:05 -1:20 pm)

Session 3: Pharmaceutical regulatory considerations for medical radioisotopes and radiopharmaceuticals (1:20 -2:20 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, guality control, manufacturing processes, and labeling requirements
 - Aruna Korde, Radiopharmaceutical Scientist, Radioisotope Products and Radiation Technology Section, Division of Physical and Chemical Sciences, IAEA(Confirmed)
 - Ravindra Kasliwal, Office of New Drug Products DNDP-3, Branch-6 Office of Pharmaceutical Quality, FDA (Confirmed)
 - Rolf Hesselmann, Scientific Advisor, the Swiss Federal Office of Public Health (Confirmed)
- Key current challenges of pharmaceutical companies

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

Coffee break (2:20-2:35 pm)



Session 4: Stakeholders Panel Discussion (2:35-5:25 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 of Radioisotope Products and Radiation Technology *(Confirmed)*

- 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)*
- Margarida Goulart, Head of Unit at the European Commission Joint Research Centre (Confirmed)
- Adriana Serquis, President, National Atomic Energy Commission (Argentina) (Confirmed)
- Kathleen Prosser, Advisor for radioisotopes, the Uranium and Radioactive Waste Division, Natural Resources (Canada) (Confirmed)
- Specialists in medical field and private sector panel discussion

Chair: Guy Turquet de Beauregard, Honorary President, NMEU(Confirmed)

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

Closing Remarks by Nick Sherman, Deputy Head of Division and Lead Technologist, Division of Nuclear Technology Development and Economics, the NEA (5:25-5:35 pm)