Current work and challenges on innovative medical radioisotopes supply

International Workshop on Medical Radioisotopes Supply
OECD-NEA
30-31 October 2023

Margarida Goulart
Joint Research Centre
Head of Unit, Euratom coordination

Content

1. The Joint Research Centre of the European Commission
2. Innovative cancer treatments using medical radioisotopes
3. Why is this a policy challenge?
4. Expert & Stakeholder consultation workshops

European Commission

1. The Joint Research Centre

- Mission :
  - As the **science and knowledge service of the European Commission** our mission is to support EU policies with independent evidence throughout the whole policy cycle.
- JRC sites:
  - Headquarters in Brussels
  - Research facilities located in 5 EU Member States
  - 4 sites with nuclear activities/infrastructures

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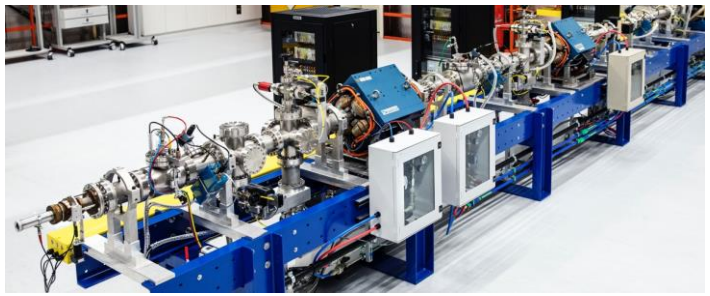
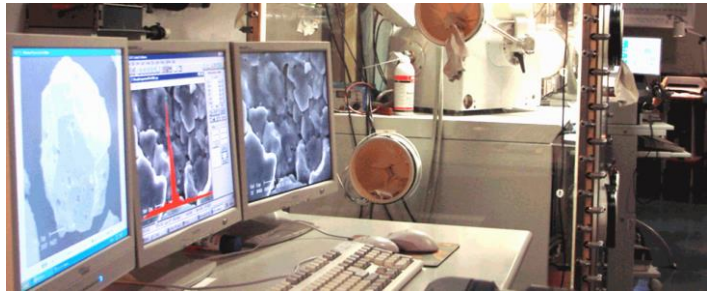
JRC nuclear facilities – some examples

Virtual tour at *https://visitors-centre.jrc.ec.europa.eu/en/media?type=8*

Accelerator
Neutron beams to explore the femtoscale (MONNET)



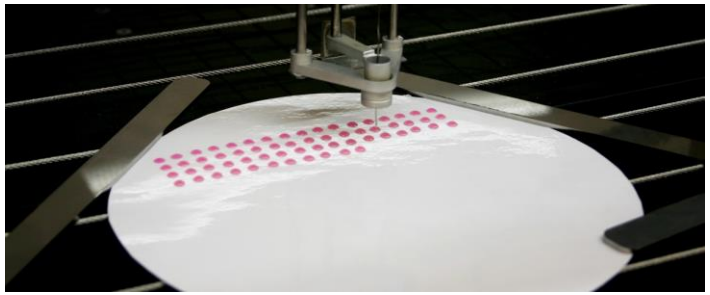


Laboratory
Nuclear Forensics

Underground lab
JRC ultra low-background gamma-ray spectrometry (HADES)

Accelerator
JRC neutron time-of-flight facility (GELINA)

Laboratory
Radionuclide metrology (RADMET)



OPEN ACCES PROGRAMME

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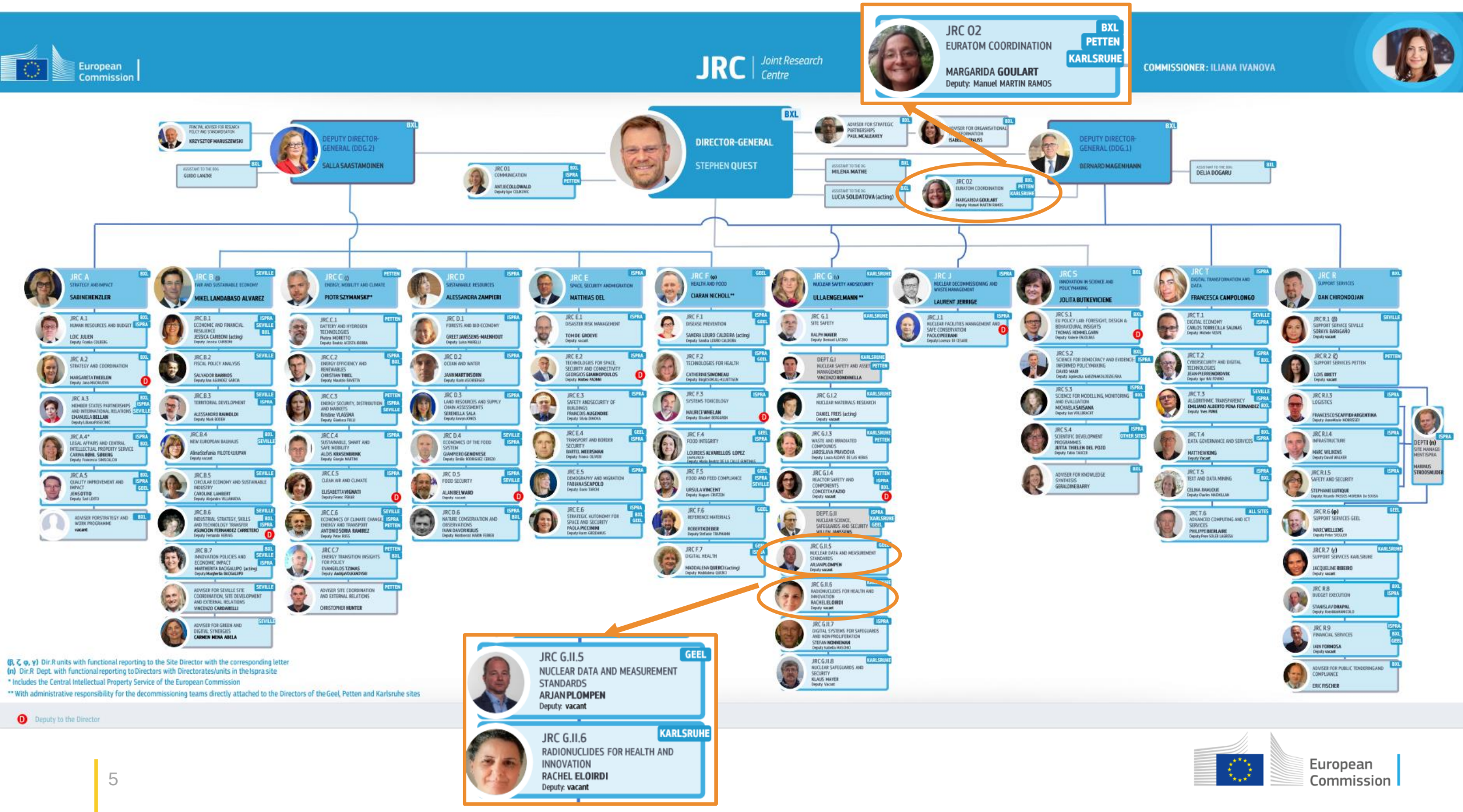
JRC 02
EURATOM COORDINATION
MARGARIDA GOULART
Deputy: Manuel MARTIN RAMOS
BXL
PETTEN
KARLSRUHE
COMMISSIONER: ILIANA IVANOVA
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DEPUTY DIRECTOR-GENERAL (DDG.2)
SALLA SAASTAMOINEN
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JRC E
MATTHIAS DEL
JRC F
CIARAN NICHOLL**
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LAURENT JERRIGE
JRC 5
JOLITA BUTKEVICIENE
JRC T
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DAN CHIRONDOJAN
JRC G.II.5
NUCLEAR DATA AND MEASUREMENT STANDARDS
ARJAN PLOMPEN
Deputy: vacant
GEEL
JRC G.II.6
RADIONUCLIDES FOR HEALTH AND INNOVATION
RACHEL ELOIRDI
Deputy: vacant
KARLSRUHE
(β, ζ, φ, γ) Dir.R units with functional reporting to the Site Director with the corresponding letter
(η) Dir.R Dept. with functional reporting to Directors with Directorates/units in the Ispra site
* Includes the Central Intellectual Property Service of the European Commission
** With administrative responsibility for the decommissioning teams directly attached to the Directors of the Geel, Petten and Karlsruhe sites
D Deputy to the Director

Nuclear Safety and Security @ JRC

Implementing the EURATOM Research & Training Programme

Radioactive Waste Management

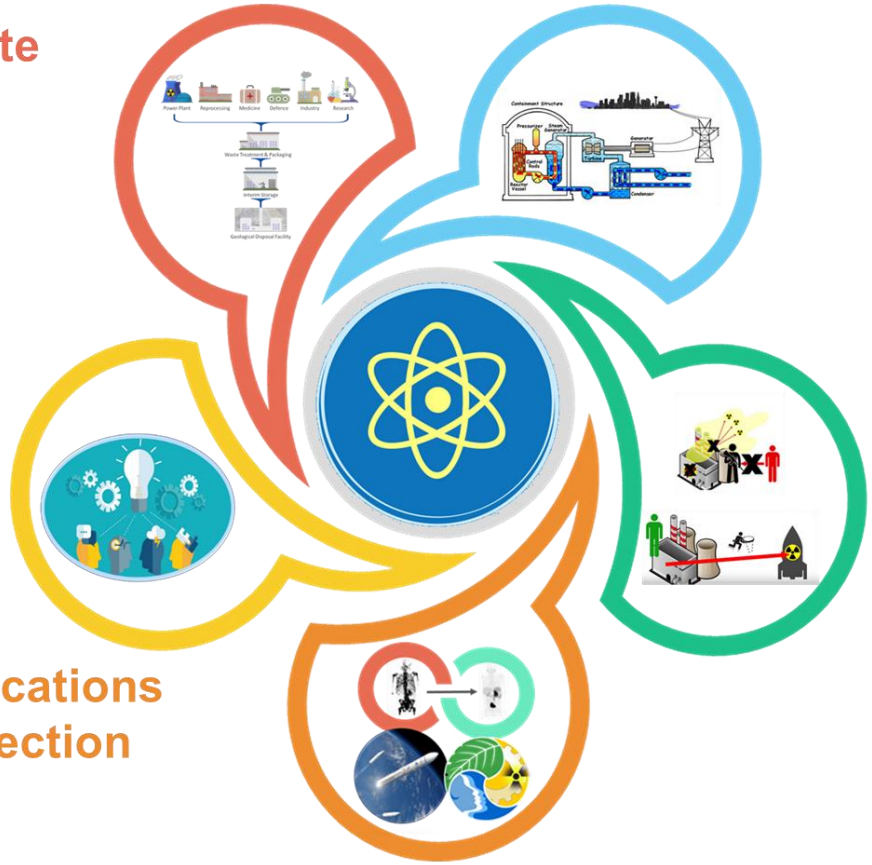
Deep Geological Disposal
Extended Interim Storage
New Waste Forms (ATF, SMR)
Regulatory framework
E&T, KM, Open Access

Nuclear Knowledge & Competence

Maintain Competence (E&T)
Human Resources Observatory
Support JRC Open Access
Reference Data & Standardization
Innovation & Technology
from Research to Industry

Non-power Applications & Radiation Protection

Medicine, Environment, Space
EU beating Cancer
Standardization
Accelerators
Open access, E&T



Nuclear Safety of Nuclear Power Plants

Nuclear reactor safety
Update of safety regulations
LTO, SMR, Gen-IV
Innovative materials
Fuel development and testing
Infrastructures: JHR, HFR and Open Access
Emergency Preparedness

Nuclear Safeguards and Security

EU Safeguards obligations
EU nuclear non-proliferation
Synergies with Security Union & Defense
International Partnership
E&T, KM

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Legal basis

Council Regulation (Euratom) 2021/765 of 10 May 2021 establishing the Research and Training Programme of the European Atomic Energy Community for the period 2021-2025

"The newly adopted Euratom Programme will complement Horizon Europe. It will support research and innovation in areas such as cancer treatment and diagnostics, nuclear safety and fusion. Thanks to Euratom, Europe will maintain world leadership in fusion, nuclear safety, radiation protection, waste management and decommissioning, safeguards and security with the highest level of standards."

Mariya Gabriel *Commissioner for Innovation, Research, Culture, Education and Youth*

2. Innovative cancer treatments using medical radioisotopes

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Nuclear Medical Applications under the EU programmes

- Euratom Research and Training programme
- SAMIRA initiative
- Europe’s beating cancer plan
- Cancer Mission
- EU4Health

- EU Observatory on the Supply of Medical Radioisotopes

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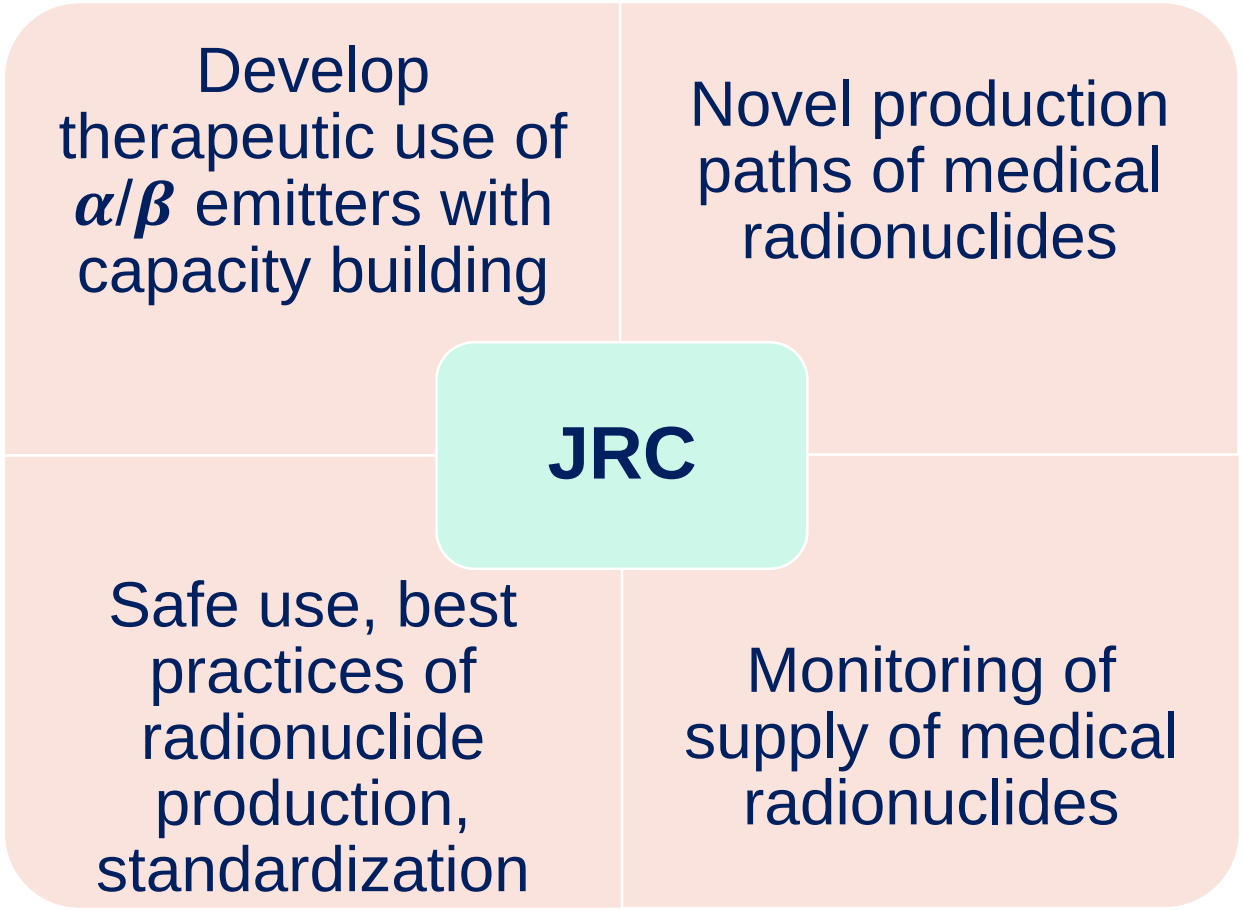
Nuclear Medical applications: a JRC priority



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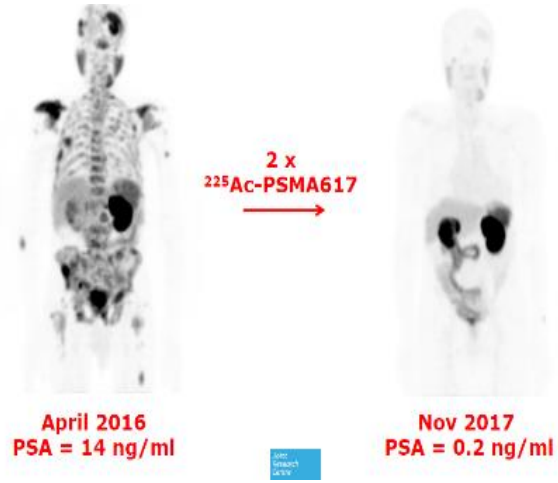
TAT project: Targeted alpha therapy

- **Early research on use of Bi-215 and Ac-225 for TAT in the early 90's**
- **Successful advances for the treatment of advanced prostate cancer**:
  - Compound Actinium225-PSMA617.
  - First characterized at **JRC Karlsruhe**
  - Clinical testing in collaboration with hospitals in Germany (Heidelberg and South Africa).
  - 1st patient treated in 2014.
- To date, more than **1000 patients** have been treated worldwide **in partnerships.**
- **Marie Curie Award 2017 of the European Association of Nuclear Medicine.**
- Several studies to **develop drugs for other cancers**



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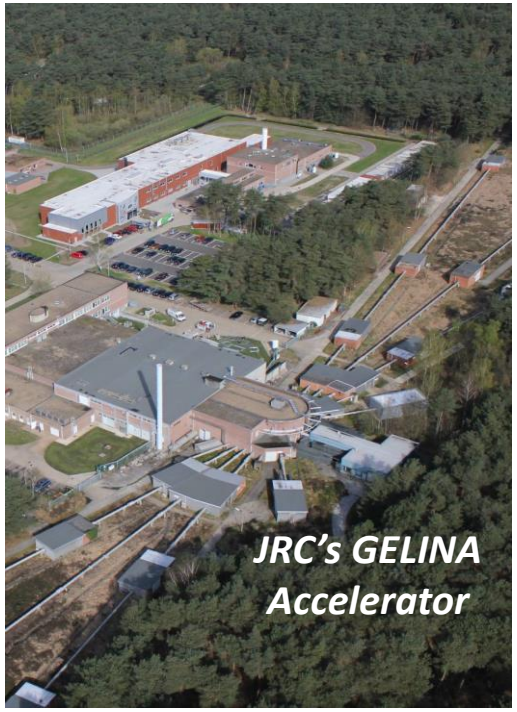
Research on methods of production

- **RADIOMED project (Radionuclides for medicine):**
  - **Radiopharmaceuticals** for diagnosis and treatment : investigating radionuclide properties and their possible medical use.
  - **New production methods** to ensure a safe, sustainable and economically viable supply of the relevant radionuclides (includes study of accelerator-based production methods and production of nuclear data).
    - Ra-226 route for Ac-225
    - Nanoparticle-based irradiations



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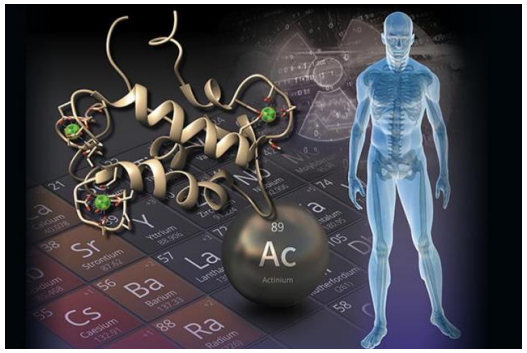
JRC Portfolio on cancer and NCD

Cancer guidelines for
- Prevention
- Screening
- Diagnosis
- Treatment
- Post-treatment & care

Data on Tackling inequalities, to integrate, plan and anticipate

Strengthen innovation and security of supply of medical radionuclides



Identify & dismantle illicit trade of products harmful to health

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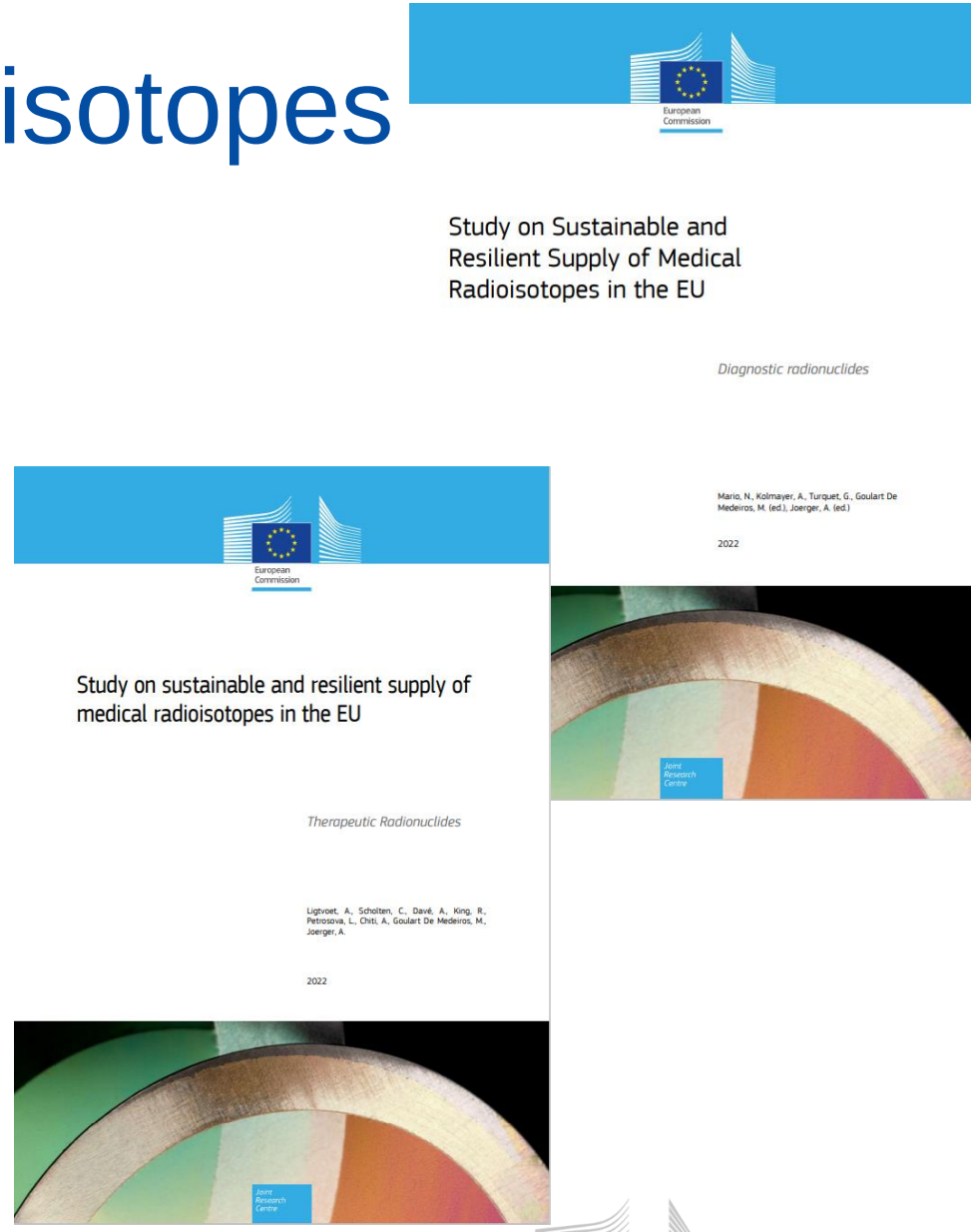
Intercomparison of radionuclide calibrators in Belgian hospitals

Lara Struelens, Clarita Saldarriaga Vargas, Sunay Rodriguez Perez – SCK•CEN
Stefaan Pommé, Jan Paepen, Raf Van Ammel – EC-JRC-IRMM
Kristof Baete – UZ Leuven/KU Leuven

^{99m}Tc, ^{18}F and ^{111}In

EU market of Medical Radioisotopes

- **2 studies on Sustainable and Resilient Supply of Medical Radioisotopes** (SMER reports)
  - SMER 1 on diagnostic radionuclides 2019
  - SMR 2 on therapeutic radionuclides 2021
- **Support to the European Observatory on the supply of Medical radioisotopes**
  - Next meeting : 21 November 2023, JRC Karlsruhe



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International Cooperation

IAEA

- **Practical Arrangement on Human Health**, Soil sciences; Agriculture; Emergency preparedness; Earth observation; Food safety and control; Animal health; Ocean science; Environment and climate monitoring; Sustainable water management; Reference materials and nuclear data for science and technology. More than **60 joint actions.**

- In this framework, the JRC participates in the **IAEA CRP (Coordinated Research Project) "Production & Quality Control of Ac-225 Radiopharmaceuticals"**

OECD-NEA

- Contribution to the international High Level Group on Medical Radioisotopes

Visit to Seibersdorf and Steering Committee, IAEA (October 2023)

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3. Why is this a policy challenge?

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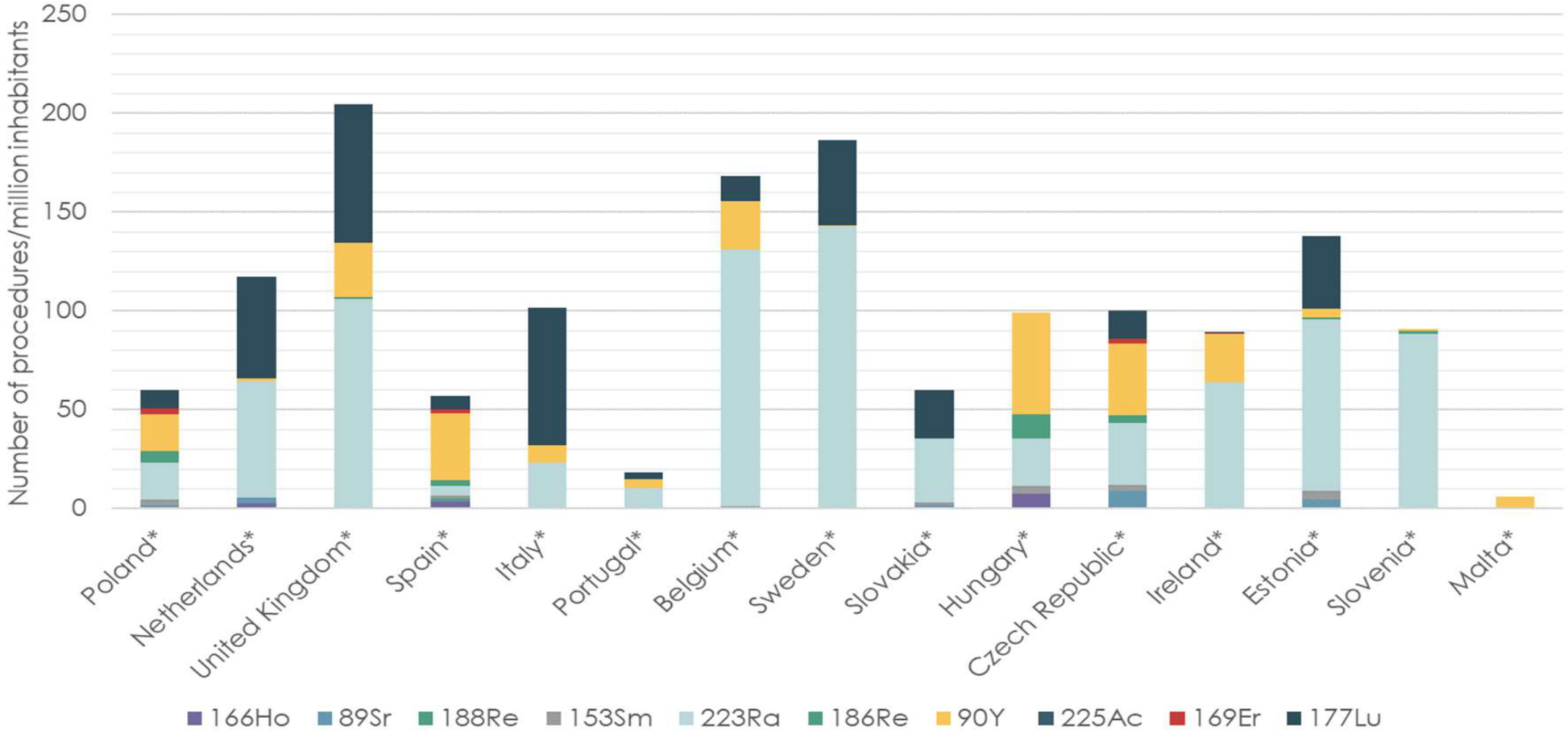
Radionuclide therapy procedures in the EU, 2021



- https://publications.jrc.ec.europa.eu/repository/handle/JRC124565

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Lu-177 treatment hospital stay, 2023

^{177}Lu-PSMA-617 (Pluvicto)

	Inpatient	Outpatient	Duration of hospital stay
US		✓	1-4 h
CA		✓	1-4 h
AU		✓	2-3 h
UK	✓ ~20%	✓ ~80%	~ 3-6 h
DE	✓		≥ 48 h
IT	✓		≥ 48 h
JP	✓		3-4 days

^{177}Lu-DOTATATE (Lutathera)

	Inpatient	Outpatient	Duration of hospital stay
DE	✓		≥ 48 h
I	✓		≥ 48 h
UK	~25%	~75%	~ 7-8 h
FR		✓	6 h
US		✓	1-4 h

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~+10 000 new nuclear experts/year needed to keep up with energy developments in the EU

Aiming for 150GWe in 2050

today ~100GWe, ~100 units, ~37 years(avg)

Highlights

- 30-45 new large (1GWe) reactors + LTO + SMR
- Research, development, innovation
- Supply chains: **talent** and equipment

(Nuclear Alliance) signed on **May 16, 2023**, in Paris (France) by energy ministers of 15 (out of 27) member countries all nuclear - 1 (Spain), + 4 non nuclear (Italia, Croatia, Poland, Estonia)

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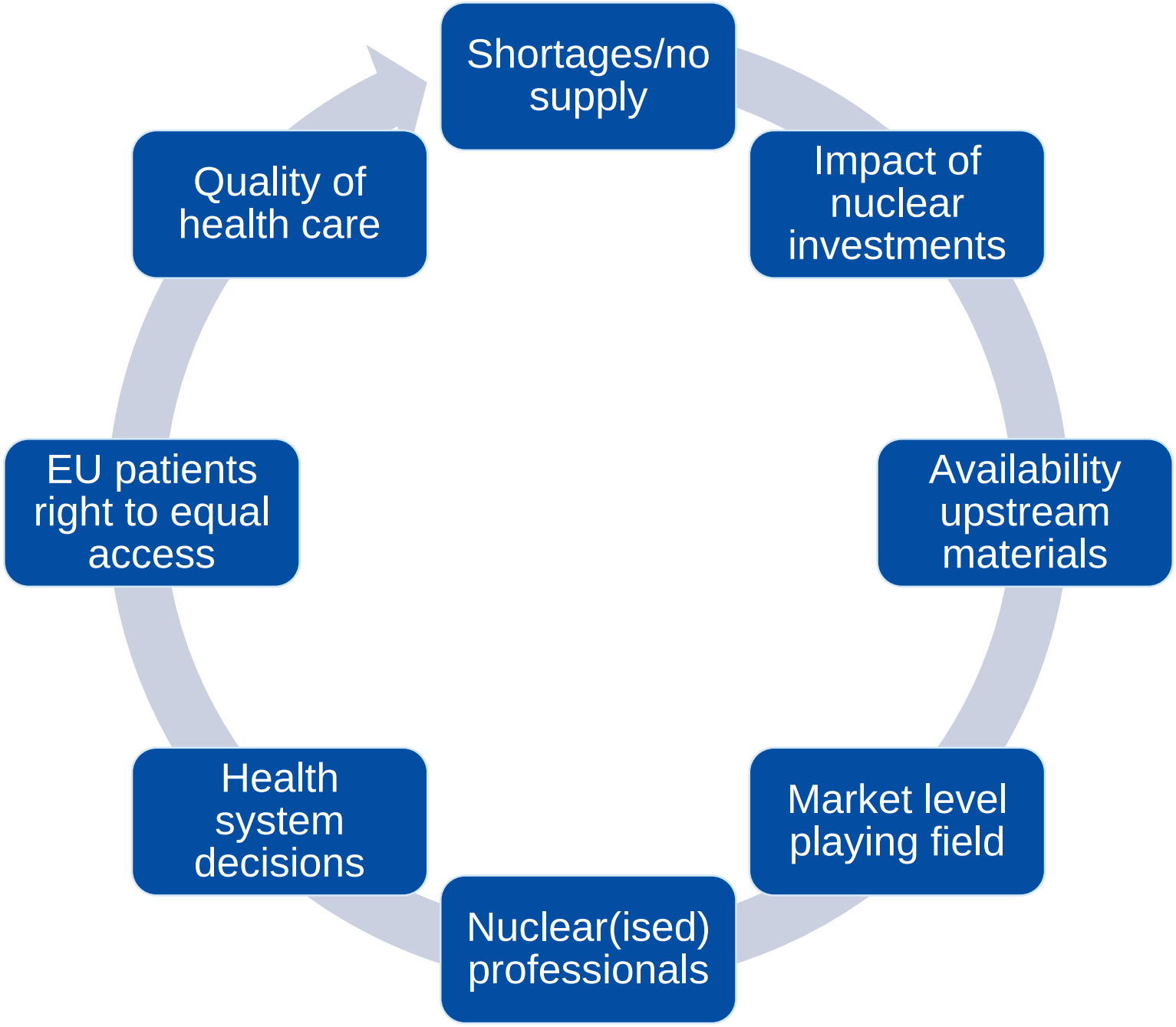

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4. Expert and stakeholder consultations

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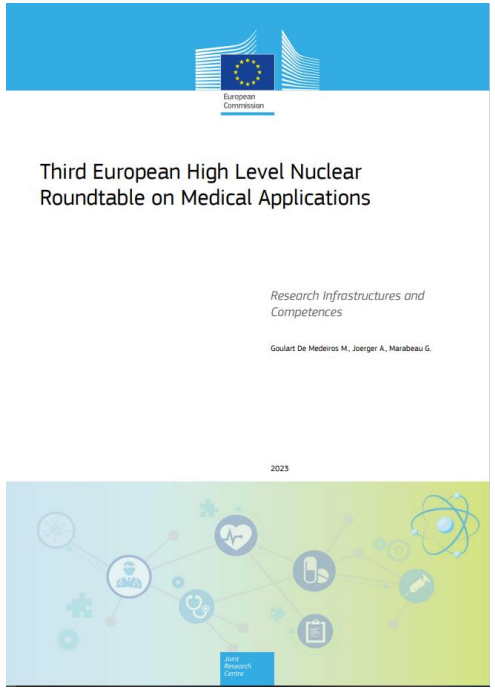
European High Level Nuclear Roundtable on medical applications : 13 February 2023

- Chaired by EU Commissioner Mariya Gabriel
- Objectives: explore main challenges faced by NMA to reach patients
- Critical areas: patient access to **nuclear technologies**, ensuring **competences** and **security of supply**



Report available on the JRC Publications Repository:

[JRC Publications Repository - Third European High Level Nuclear Roundtable on Medical Applications (europa.eu)]

Workshop “Translating radiotheranostic cancer research into clinical practice in Europe”

- JRC Ispra, 27 April 2023
- Stakeholders: various areas clinicians, academia, industry, research, patients

- Main objective:
  - Discuss new advances in combining imaging and treatment targets as well as new radiopharmaceutical uses in cancer therapy and help improve their accessibility for patients.

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Workshop “Competences for medical applications”

- JRC Petten, 24 October 2023
- Stakeholders from EU MS and international (OECD-NEA): clinicians, medical associations, academia, research, industry
- Main objective:
  - Discuss development of competences and skills for medical applications of nuclear science

European Commission

Workshop “Research & innovation for the security of supply of medical radioisotopes”

- JRC Karlsruhe, 22 November 2023 (hybrid)
- Key stakeholders from academia, industry, research, and health policy makers
- Main objective:
  - Discuss the forefront of research and innovation for ensuring secure supply and expediting the process from R&D to clinical trials.

Registration:
https://web.jrc.ec.europa.eu/remjrc/screen/meeting/14416/registration-form/76808

5. Challenges…… and opportunities

- Broad and specific competences needed at all levels of the process: R&D, supply, clinical use, regulators, policy makers.
- Health technology and cost-effectiveness assessments of radiopharmaceuticals to support reimbursement decisions.
- Assessment and harmonization of radiation protection guidelines.
- Monitoring of the radionuclide supply sustainability factors.
- Joining forces on education and training for all audiences, including health care but also government decision makers
- Renewed interest in nuclear industry provides opportunity to attract new talent
- Coordinated approach between actors and programmes (including Euratom, Horizon Europe, EU4Health, etc)

Thank you

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