



# PRISMAP NEWS

PRISMAP in Nantes

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PRISMAP CM7 – Nantes – 18 Sept 2024

# PRISMAP on track

- 32 projects from 4 calls
  - Find out what they are all about on our website!  
<https://www.prismap.eu/access/user-projects/>
- >60 deliveries of 15 different radionuclides for 28 projects
- 5 projects completed
- 2 projects published already
  - Holzleitner, N. *et al.*; Preclinical Evaluation of Gastrin-Releasing Peptide Receptor Antagonists Labeled with  $^{161}\text{Tb}$  and  $^{177}\text{Lu}$ : A Comparative Study; *Journal of Nuclear Medicine* jnumed.123.266233 (2023). doi: [10.2967/jnumed.123.266233](https://doi.org/10.2967/jnumed.123.266233)
  - Sevenois, M. B. *et al.*; Optimised solid-phase extraction of  $^{211}\text{At}$ : Activity balance of  $^{211}\text{At}$ ,  $^{210}\text{At}$  and  $^{210}\text{Po}$  after wet chemistry target dissolution; *Radiation Physics and Chemistry* **225**, 112146 (2024). doi: [10.1016/j.radphyschem.2024.112146](https://doi.org/10.1016/j.radphyschem.2024.112146)



# PRISMAP behind the scene

- Besides the supply of radionuclides or the access to our biomedical research facilities, PRISMAP keeps developing our infrastructures and building knowledge to support the community.
- All our outcomes can be found on our website: <https://www.prismap.eu/about/outcomes/> and much information is shared through our newsletter: sign up to the PRISMAP Community to stay tuned! <https://www.prismap.eu/radionuclides/user-forum/>

# NCBJ has received its new Cyclone 30XP





# Radiolanthanides workshop at PSI

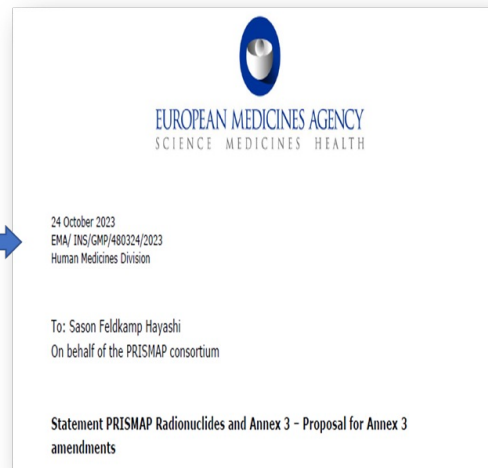


# WP-4 Regulatory Activities with EMA and regulatory bodies

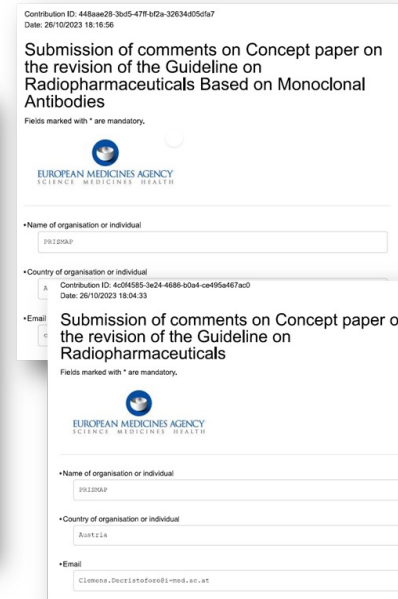
## EMA Innovation Task Force Briefing meeting



## Inspectors Working Group, EMA Reply to PRISMAP's questions



## Reply to EMA's Concept papers to revise guidelines



# Proposals for Revision of EU Pharma regulation

## Comments on EU-Commission proposal for revision of pharmaceutical legislation released in April 2023



*Proposal to revise definitions and regulatory  
texts on „radionuclide precursors“  
Emails sent to MP's, alignment with EANM*



## IAEA Participation in TM Meeting on Radiopharmaceutical Regulations March 2023

## Position paper in EJNMMI RPC in Jan. 2024



European Commission legislative proposal	European Parliament draft negotiating position	EANM suggested amendment	Rationale/justification
<p><b>Recital 19</b></p> <p>This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom, including with regard to the justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation. In the case of radiopharmaceuticals, the use of such substances should be subject to specific rules governing their production, distribution, use, and disposal, taking into account the specific characteristics of such substances and the need to ensure the safety of patients and the public.</p>	<p><b>Amendment 5 - Recital 19</b></p> <p>This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom.</p>	<p><b>Any rules governing radiopharmaceuticals must take into account the provisions of COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (2) and subsequent directives, the objective of which is to prevent the exposure of the general public, workers, volunteers or patients to excessive or unnecessarily high levels of ionising radiation, and in particular Article 28 (a) and (c) thereof, which subjects the use of radioactive sources to regulatory control of such medicinal products and Article 56 requiring for all medical exposure of patients for radiotherapeutic purposes, that exposures of target volumes shall be individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.</b></p>	<p>The introduction of Directive 2013/59/Euratom (BSS Directive) requires to update the reference regarding specific authorisation of the use of radioactivity in the context of medical applications (and with it radiopharmaceuticals), as rightly indicated by Article 41 of the Directive 2003/85/EC, i.e., community rules on medicinal products should not contradict the BSS Directive.</p> <p>Additionally the BSS Directive has introduced the requirement to individually plan treatment involving ionising radiation, which includes therapy with radiopharmaceuticals. The missing alignment of the current Directive 2003/85/EC with this requirement in the BSS Directive has caused an unclear situation in Member States and should be clarified.</p> <p>It is acknowledged that in Recital 19 of the proposed legislation reference is made to the Basic Safety Standards Directive (Council Directive 2013/59/Euratom) which needs to be taken into consideration for Radiopharmaceuticals. However, neither the positioning (as a Recital) nor the verbatim quote of the Euratom Directive (which in the spirit of the European Commission's own pledge for regulatory harmonisation through SAMIRA Action Plan should be avoided) are expected to help in establishing a clear and feasible approach for radiopharmaceuticals which takes into account the major innovations in the field and regulatory provisions of BSSD and pharmacovigilance.</p>
<p><b>(4)</b> In cases where, taking into account all its characteristics, a product falls within the</p>	<p><b>5</b></p>	<p><b>4.</b> In cases where, taking into account all its characteristics, a product falls within the definition of a medicinal</p>	<p>See the rationale for Recital 19.</p>

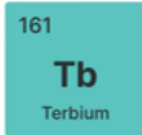




# WP4-Standardisation, exemplified by Tb-161

## ■ Tb-161:

Drafting a **Monograph** (SCK CEN, PSI, NCBJ) and developed standardised analytical methods to provide harmonised specifications across different producers.



**sck cen**  
Belgian Nuclear Research Centre



Narodowe Centrum Badań Jądrowych  
National Centre for Nuclear Research  
SWIERK  
JRC collaboration partner

N.C.A.-TERBIUM<sup>161</sup>TB)-CHLORIDE-SOLUTION-FOR-RADIOLABELLING¶

N.c.a.-Terbium-(<sup>161</sup>Tb)-chloridi-solutio-ad-radio-signandum¶

¶

<sup>161</sup>Tb<sup>3+</sup>¶

DEFINITION¶

Solution-containing<sup>161</sup>Terbium-161-in-the-form-of<sup>161</sup>Terbium(III)-ion-in-dilute-hydrochloric-acid.¶

M,<sup>161</sup>¶

Tb 161  
6.95 d  
β<sup>-</sup> 0.5, 0.6...  
γ 26, 49, 75...  
e<sup>-</sup>

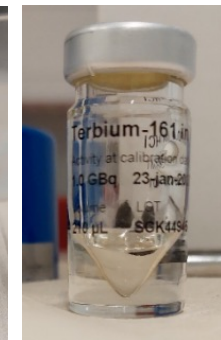
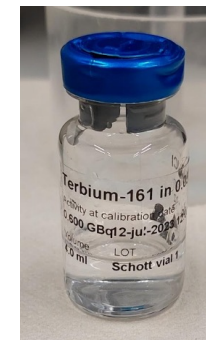


## ■ Tb-161 – Nuclear Medicine Equipment study (NMES)

- Measurement Tb-161 in different geometries traceable to NPL standards
- Comparison of multiple dose calibrators
- Exploration of a calibration workflow for quantitative SPECT

**KU LEUVEN**

**NPL**  
National Physical Laboratory



# From a dream to recommendations for the future

- The European Economic and Social Committee issued an opinion in Spring 2024 about Europe's Beating Cancer Plan, the SAMIRA Action Plan, and in particular the European Radioisotope Valley Initiative (ERVI)
- The Council of the European Union has taken up that opinion to recommend the ERVI programme and the consolidation of PRISMAP to **PRISMAP+**.

<https://www.consilium.europa.eu/en/press/press-releases/2024/06/17/radioisotopes-for-medical-use-council-approves-conclusions/>





# PRISMAP Information Portal

<https://www.prismap.eu/radionuclides/information-portal/>

**PRISMAP Information Portal**

This portal gathers documents providing information on specifications, standard practices and regulations relevant for the following major fields and topics addressed by PRISMAP:

- Nuclear decay data
- Production of radionuclides
- Development and Preparation of Radiopharmaceuticals
- Specifications and Quality Control/Metrology
- Radioprotection/Transport Issues

The uploaded information relies on knowledge acquired or produced within the PRISMAP network, but links to entities with relevant information not available in PRISMAP documents are also provided. It is in tune with the PRISMAP's goal to standardize and harmonize research and development activities with novel radionuclides within and outside PRISMAP network, while providing guidance for their clinical translation, namely to pharmaceutical authorities and policy makers at the European and national levels.

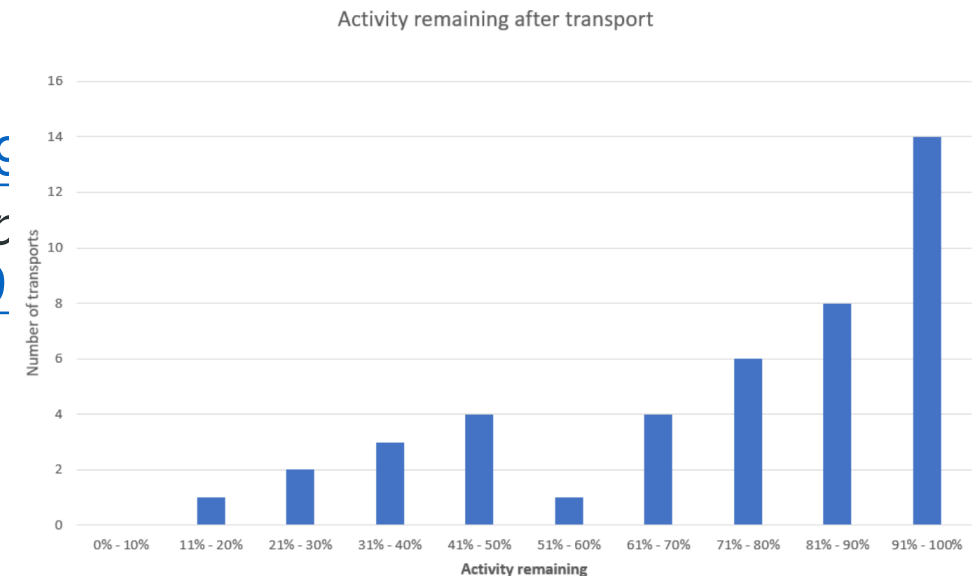
Q Keyword... Search

Nuclear decay data    Production of radionuclides    Development and preparation of radiopharmaceuticals    Specifications and quality control/metrology    Radioprotection/transport issues

- PRISMAP has opened its information portal, a new feature on our website.
- It collates together all the data and information that are relevant for our many communities under 5 main themes:
  - Nuclear decay data
  - Production of radionuclides
  - Radiopharmaceuticals
  - QC & metrology
  - RP & transport
- It provides links to databases and guidelines, but also to publications and deliverables with new data and information generated by PRISMAP.

# PRISMAP shipping & logistics

- Transport of radionuclides remains a challenge for PRISMAP and our entire community.
- With >60 deliveries for project + internal deliveries for development, we are gaining a lot of experience with shipping.
- Our findings are summarised in a series of 3 deliverables, available online:
  - D9.1: *First public report from the PRISMAP work package 9 (WP9, transport and logistics)*.  
<https://zenodo.org/record/6606494>
  - D9.2: *Compliant and efficient transportation*.  
<https://zenodo.org/doi/10.5281/zenodo.10069>
  - D9.3: *Database of packages, documents, app*  
<https://zenodo.org/doi/10.5281/zenodo.11109>



# PRISMAP Community

- Formerly known as the PRISMAP User Forum, the PRISMAP Community is meant to be more inclusive, and a place where all stakeholders and interested parties can feel they belong, not just the users.
- <https://www.prismap.eu/radionuclides/user-forum/>
- Kristoff Muylle (VU Brussel) and Stijn De Schepper (UZ Antwerpen) have agreed to lead the PRISMAP Community and shape its activities through working groups.
- More information to be expected shortly after the EANM symposium in Hamburg.



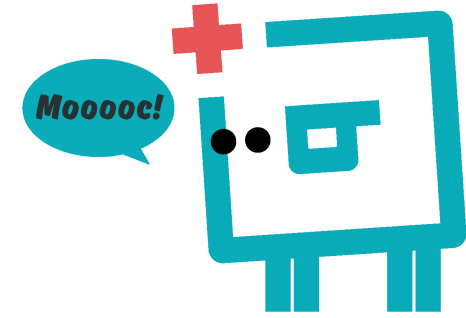
# PRISMAP Call 5



- <https://www.prismap.eu/access/project-application/>
- **Deadline 15 Oct 2024**  
Selection through the autumn and start early 2025
- Same portfolio as before (no new radionuclide at this stage) and full access to our biomedical facilities
- Limited time to completion: all deliveries and activities should happen before 30 Sept 2025! Make sure to scope your project accordingly.
  - Limited number of deliveries
  - Emphasis towards SME and to prepare clinical trials in the near future
- **Reach out to the PRISMAP Helpdesk for advice in preparing your proposal**  
<https://www.prismap.eu/access/helpdesk/>
- Extra info and guidelines on our portal  
<https://www.prismap.eu/access/application-guidelines/>



# Training news & opportunities



- **MOOC** “At the heart of European medical radioactivity”
  - Has already attracted 28 participants
  - Perfect introduction to anyone new in the field, or for anyone who would like to broaden their interest in another discipline.
  - Continuous expansion of the content, especially thanks to lecturers at our training events.
  - <https://www.prismap.eu/radionuclides/educational/>
- School on **medical imaging**, Riga (Latvia), 18-21 Feb 2025





KEEP POSTED ON OUR UPDATES THROUGH THE  
PRISMAP COMMUNITY

<https://www.prismap.eu/radionuclides/user-forum/>



WWW.PRISMAP.EU



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PRISMAP PROJECT



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