

KU LEUVEN

EURADOS School – Annual Meeting 2025

*Metrology in radiation
dosimetry measurements*

Radionuclide Metrology for Nuclear Medicine



prof. dr. Kristof Baete

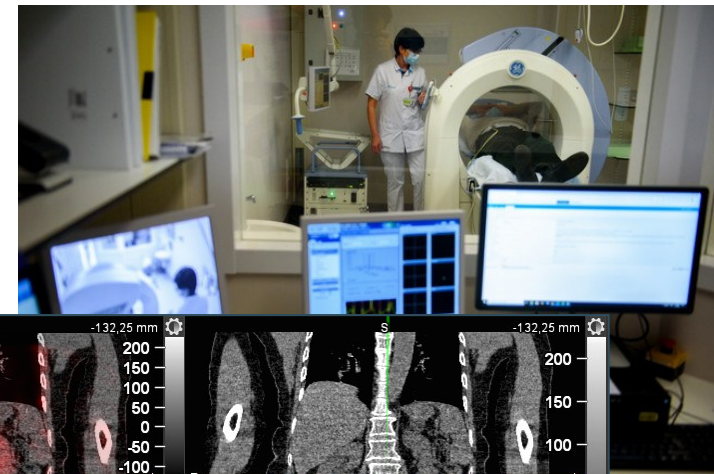
Nuclear medicine & molecular imaging – Medical physics department

KU Leuven & UZ Leuven – Belgium – kristof.baete@uzleuven.be

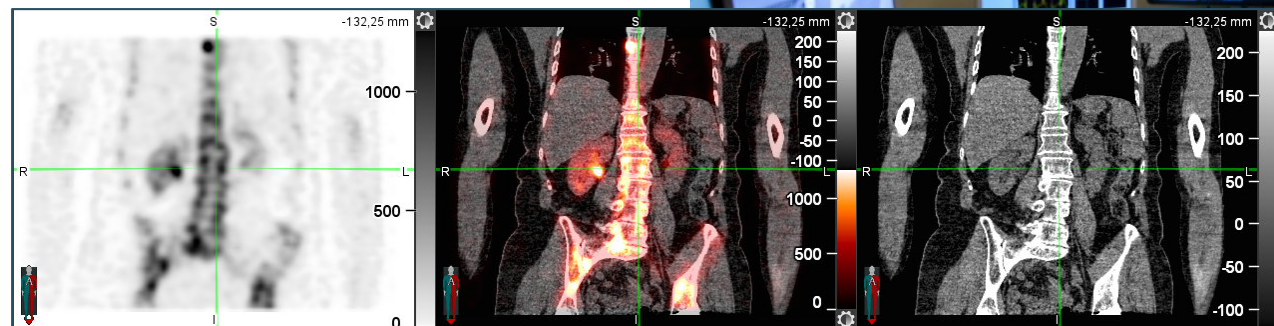


Nuclear Medicine (NM)

- medical specialty that makes use of radiopharmaceuticals for the diagnosis and staging of disease, for monitoring of a disease process, and for radionuclide therapy (RNT)
- used in basic sciences such as biology, drug discovery and in preclinical medicine.

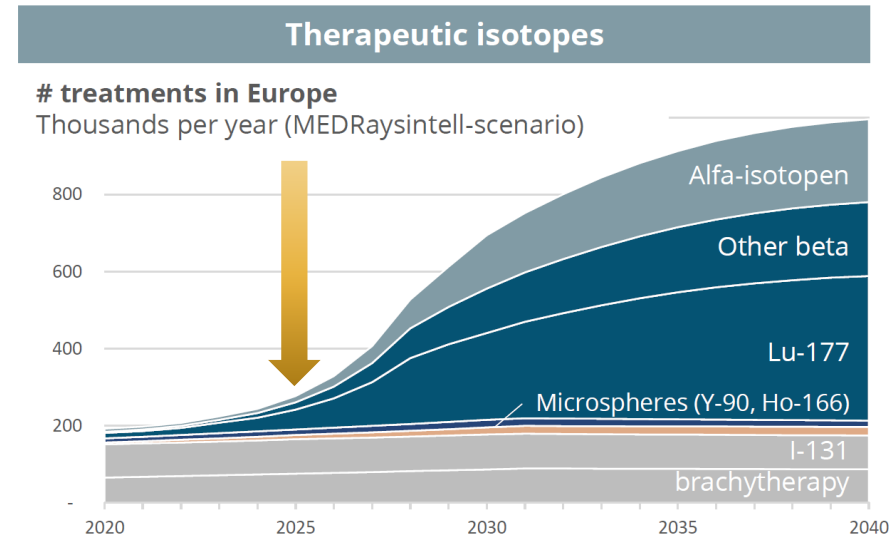
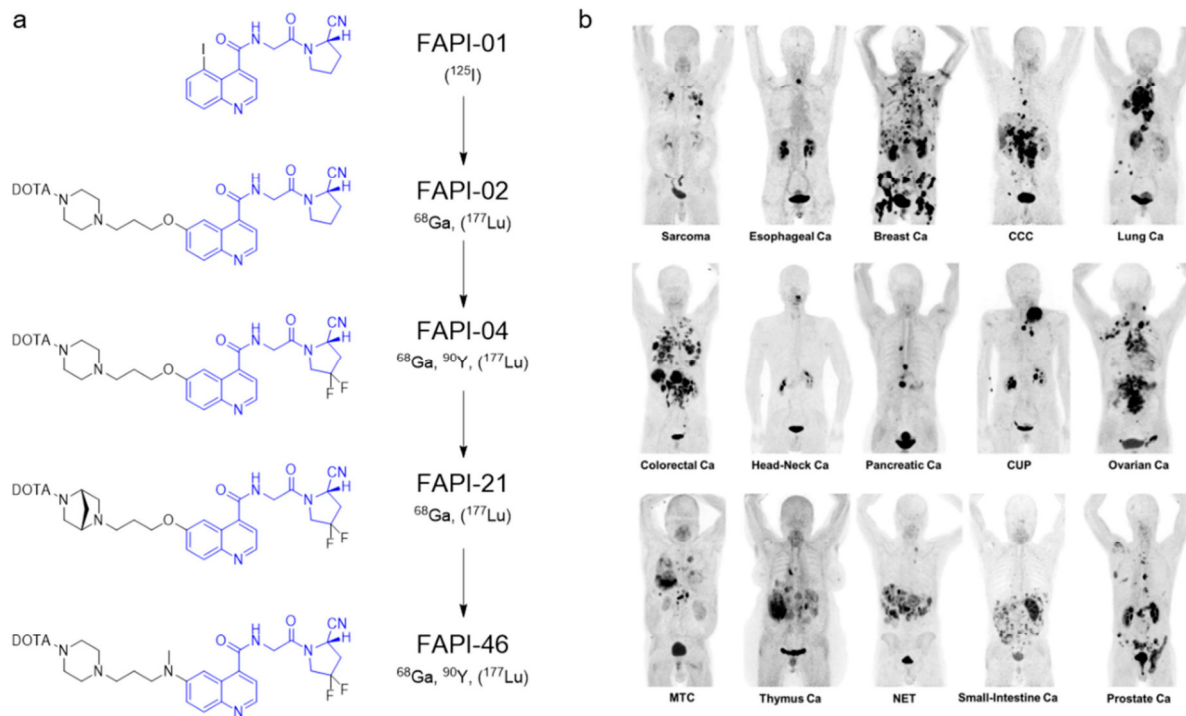


- clinical aspects
- radiopharmaceuticals
- instrumentation



What are the trends in NM

- remarkable radiopharmaceutical market growth
- the NM journey looks like it has only begun and there are a lot ... a lot of challenges ahead



Bron | MEDRaysintell 2021, investor document BC 1.2 (15-dec 2022)



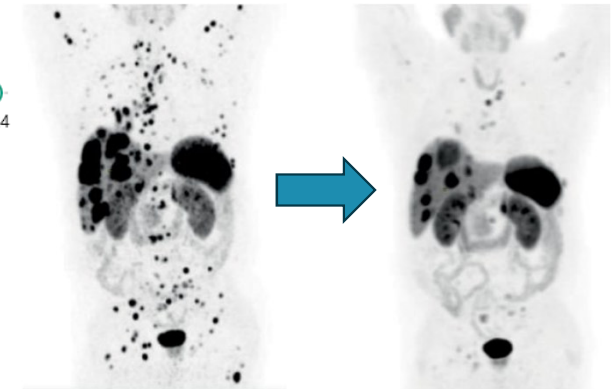


Increased demand for personalized medicine

- “personalized” or “precision” medicine
- tailor-made prevention, diagnosis and treatment
- theranostics – “see what you treat and treat what you see”
- sustainability, cut healthcare costs, avoid unnecessary ...

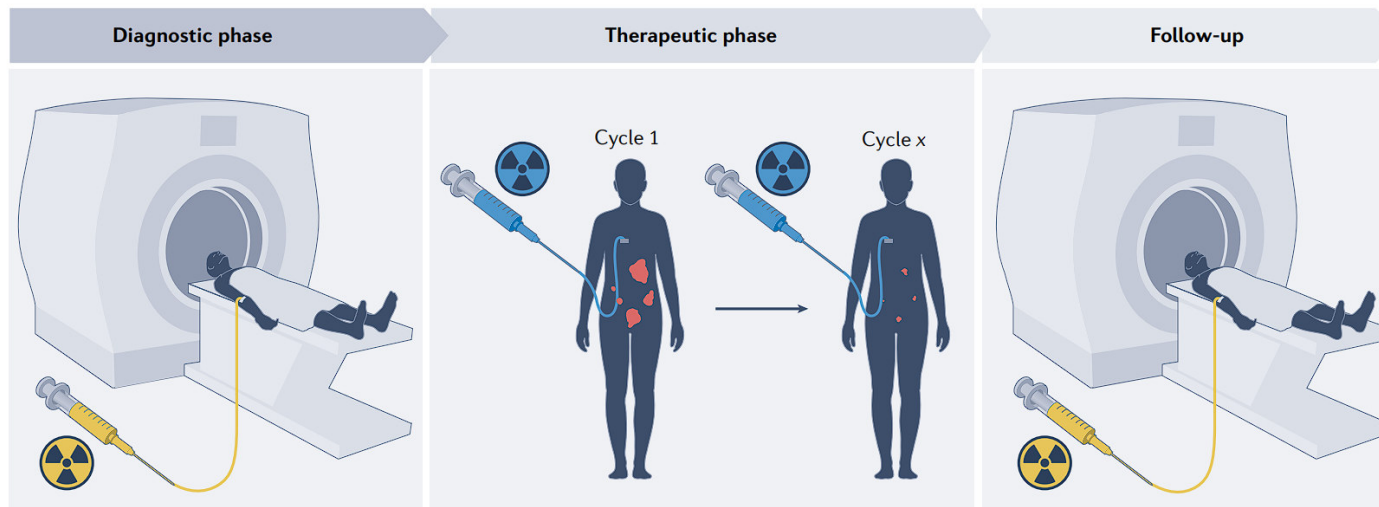


^{68}Ga -DOTATATE



pre/post 4 cycles ^{177}Lu -DOTATATE

Bodei, L., et al. *Nat Rev Clin Oncol* 19, 534–550 (2022).



Personalized or precision nuclear medicine



Official Journal of the European Union



English edition



*A “directive” sets out a goal
that EU countries must achieve*



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, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

Article 56

Optimisation

For all medical exposure of patients for radiotherapeutic purposes, 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.

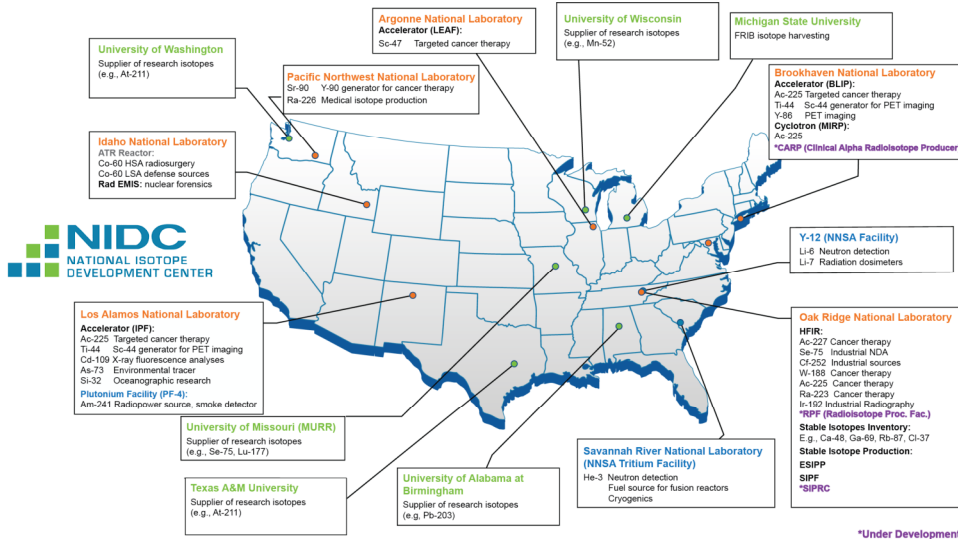
(81) "radiotherapeutic" means pertaining to radiotherapy, including nuclear medicine for therapeutic purposes;

Trends in NM: theranostics & novel radionuclides



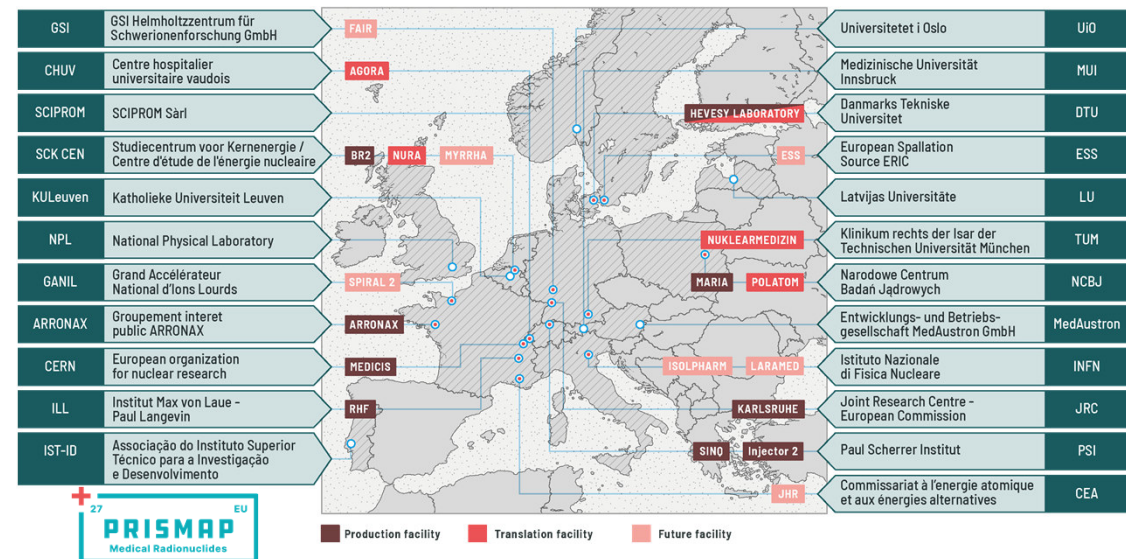
- search for novel radionuclides: theranostic pairs, triplets, quadruplets, ... alpha emitters

www.isotopes.gov



*Under Development

www.prismap.eu

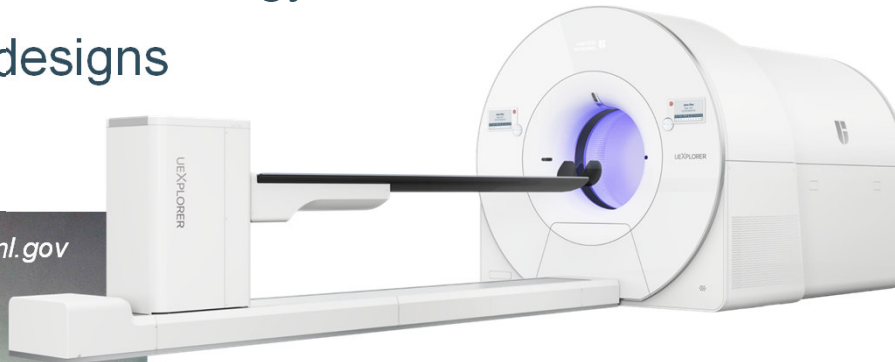


■ Production facility ■ Translation facility ■ Future facility

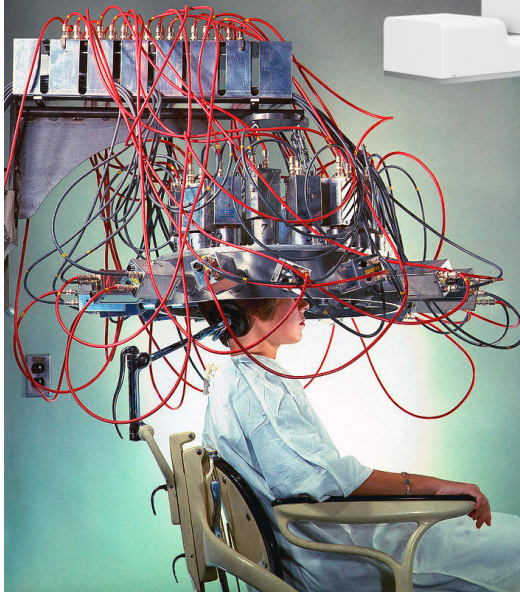
Technological advances in NM

- novel detector technology
- new gantry designs

Total-body PET/CT



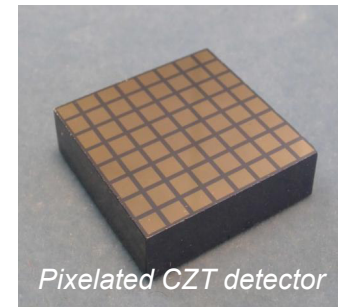
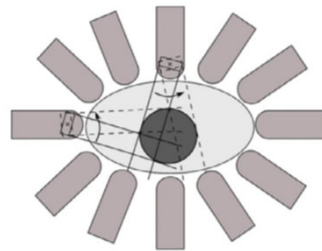
First PET scanner – www.bnl.gov



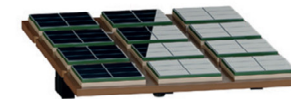
CZT based SPECT/CT



GE HealthCare



Pixelated CZT detector



Quantitative imaging

- targeted molecular imaging – NET
- [^{18}F]-MFBG-**PET** / [^{123}I]-MIBG-**SPECT** comparison
- for that: PET & SPECT quantification $\rightarrow$ Bq/ml

European Journal of Nuclear Medicine and Molecular Imaging
<https://doi.org/10.1007/s00259-020-04830-x>

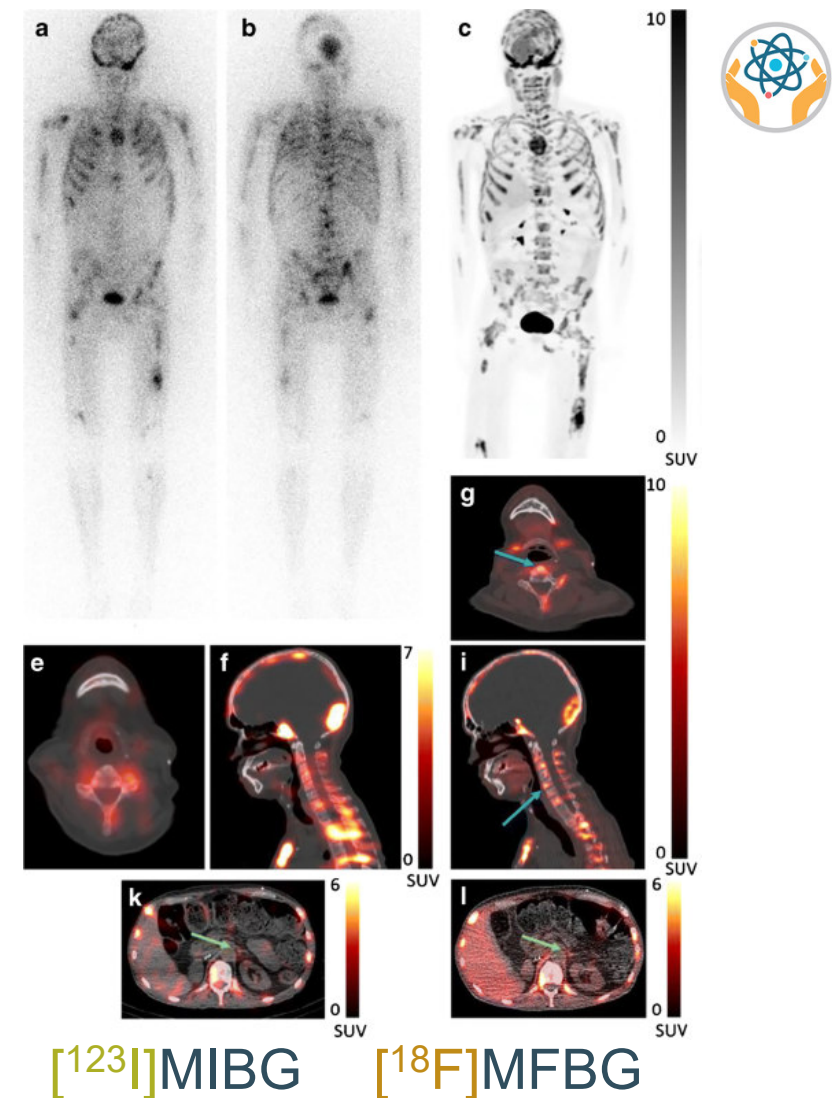
IMAGE OF THE MONTH

Improved resolution and sensitivity of [^{18}F]MFBG PET compared with [^{123}I]MIBG SPECT in a patient with a norepinephrine transporter-expressing tumour

Elin Pauwels^{1,2} • Sofie Celen³ • Mathilde Vandamme³ • William Leysen³ • Kristof Baete^{1,2} • Oliver Bechter⁴ • Marie Bex⁵ • Kim Serdons^{1,2} • Koen Van Laere^{1,2} • Guy Bormans³ • Christophe M. Deroose^{1,2}

Received: 4 March 2020 / Accepted: 14 April 2020

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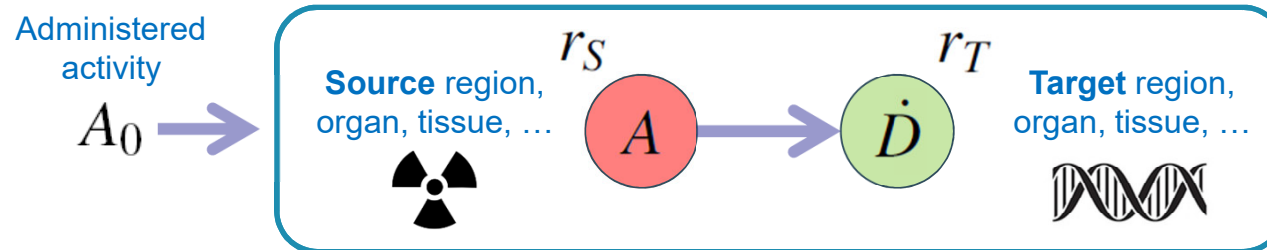


[^{123}I]MIBG

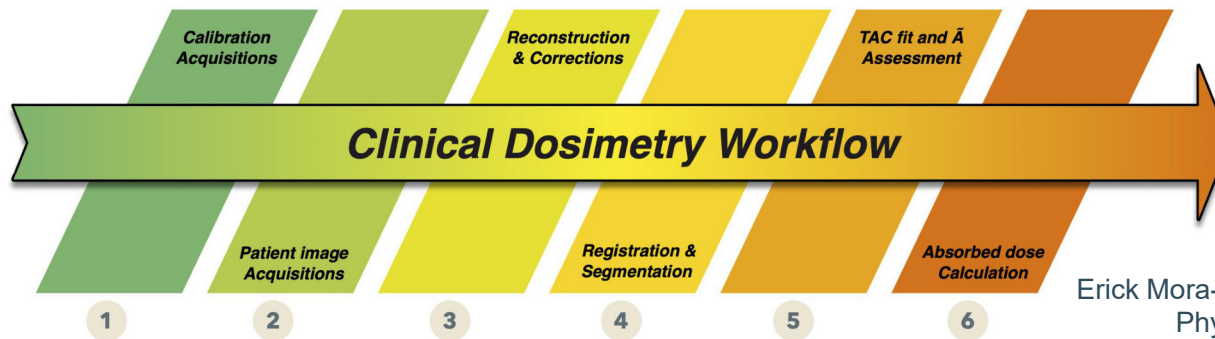
[^{18}F]MFBG

Dosimetry and therapy planning

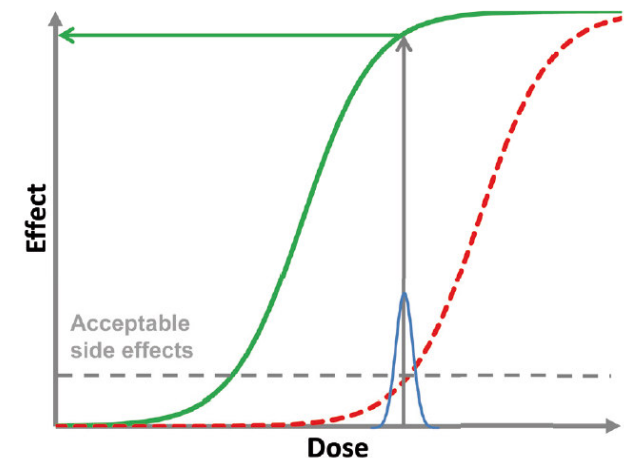
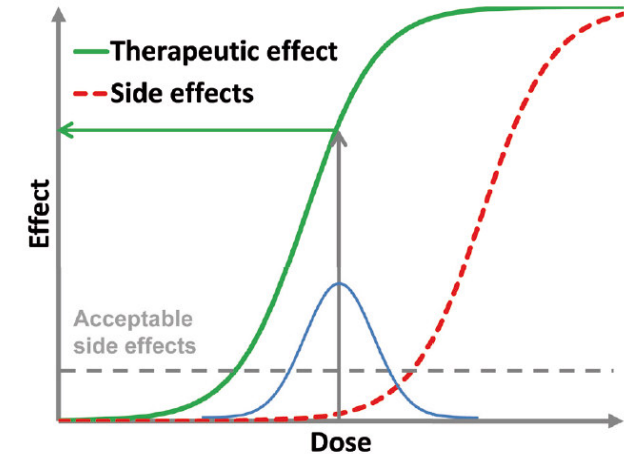
- General aim: the absorbed dose to target region(s)



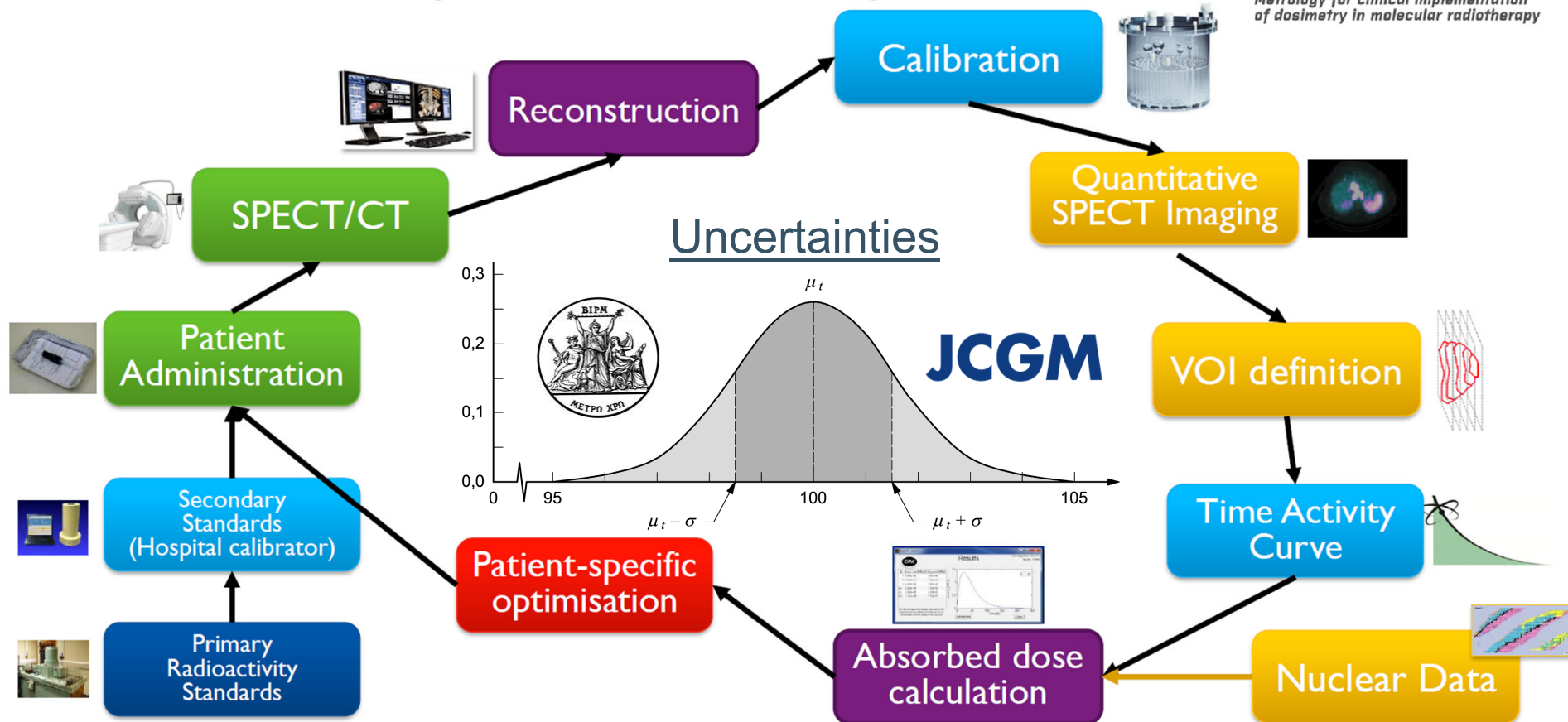
$$\dot{D}(t) \propto A(t) \quad D(r_T) = \int_0^{T_D} \dot{D}(r_T, t) dt$$



Erick Mora-Ramirez *et al.*, Med Phys 47 (9), Sept 2020



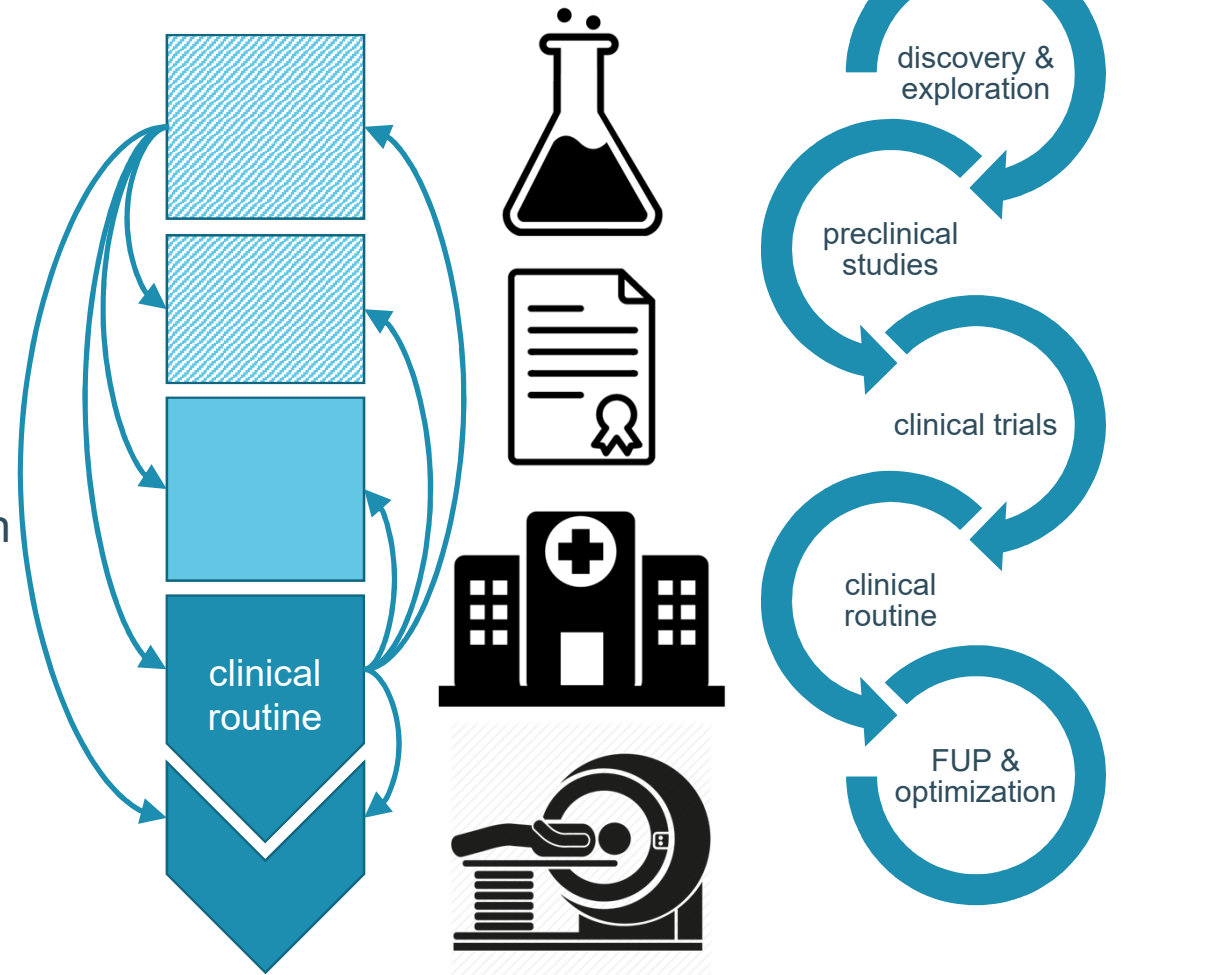
Measurements (and calculations) in MRT



National Physical Laboratory - 20th May 2019

The roadmap to clinical applications in NM

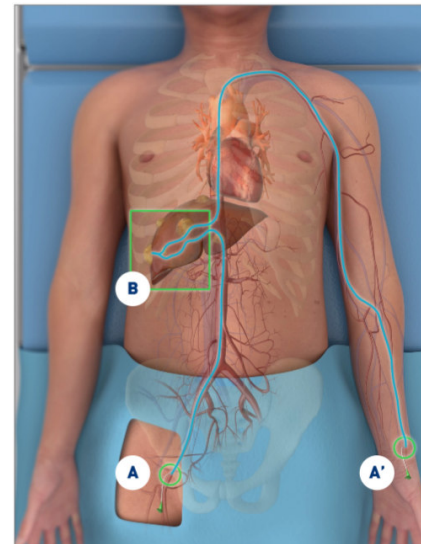
- early discovery and exploration
 - nuclear physics & radiochemistry
 - radiopharmacy & medical physics
- preclinical studies
 - models, safety, translation
- clinical trials
 - safety, efficacy, dosage
 - effectiveness, response & comparison
- clinical routine
 - protocols & procedures
- follow-up and optimization
 - quality assurance & control
 - patient-specific precision medicine



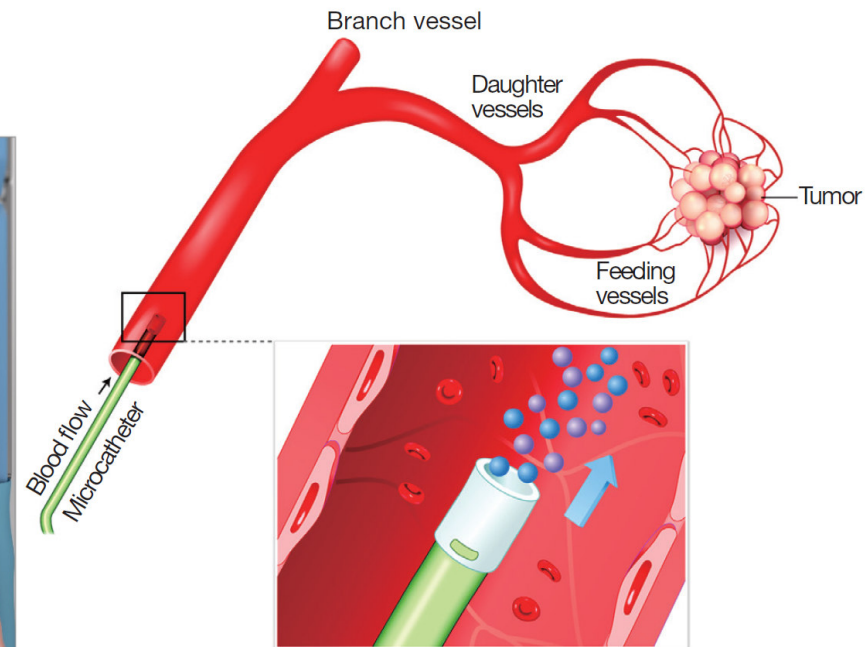
Selective Internal Radiation Therapy (SIRT)



- primary liver tumors: HCC, ICC
- liver predominant metastatic disease: mCRC, breast, NET
- SIRT portfolio @ UZ Leuven
 - ^{90}Y – SIR-Spheres – Sirtex Medical Europe GmbH
 - ^{90}Y – TheraSphere – Boston Scientific Benelux NV
 - ^{166}Ho – QuiremSpheres – Quirem Medical, Terumo
- patient selection & work-up (CBCT, SPECT)
- pre- & post-SIRT procedures & analysis



SIRTeX





*Treatment planning
&
Treatment verification*

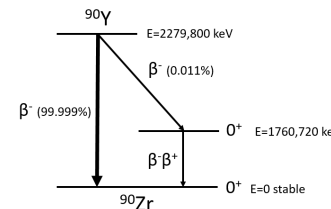
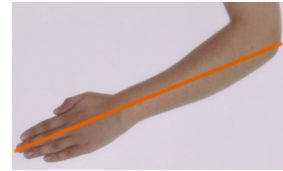
Advanced radio-nuclide-therapy





Challenges: standardization

- the challenge of standardization is not new
 - ell (ulna) – cubit (forearm)
- nuclear data, half-life, e.g. branching ratio for positron emission of ^{90}Y in PET acquisition software
 - device A: 32×10^{-6}
 - device B: 34×10^{-6}
- imaging standards (DICOM, ISO-12052, ...)
 - time references & decay correction
- it looks like ... there's **much more need for standardization**, even before calibration !!!



Branching Ratio
 $\text{Bq} \leftrightarrow \text{e}^+$



In support of the World Metrology Day 2025



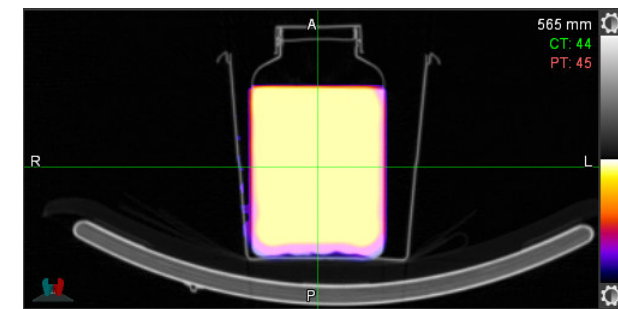
2024 • 2033
International Decade of
Sciences for Sustainable
Development

worldmetrologyday.org



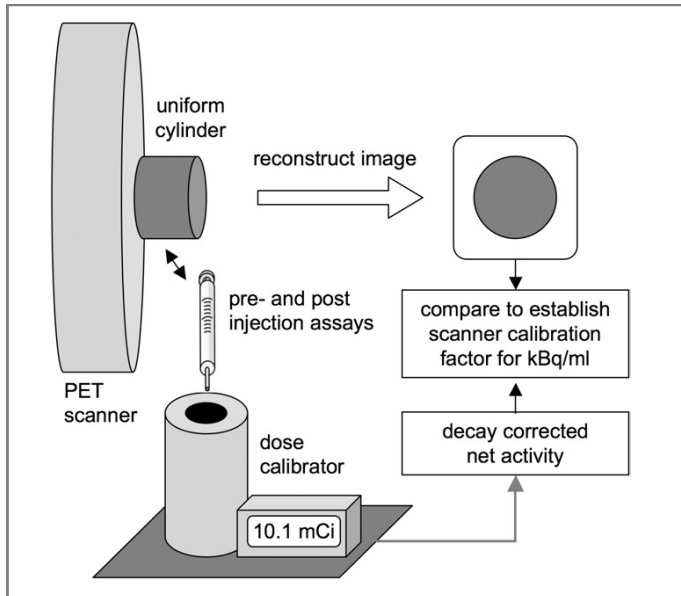
Nuclear Medicine Equipment Standards

- a **quantified and traceable measure** using an NM instrument
 - numerical value – relative or absolute measure
 - physical quantity – (SI) unit of measurement
- nuclear medicine (NM) instruments
 - radionuclide calibrator or activity meter (Bq)
 - gamma counter samples (Bq/ml)
 - SPECT phantom (cps/voxel)
 - quantitative PET/CT or SPECT/CT (Bq/ml)
- a **calibration** step
 - conversion between units
- verification and follow-up
 - QA & advanced QC

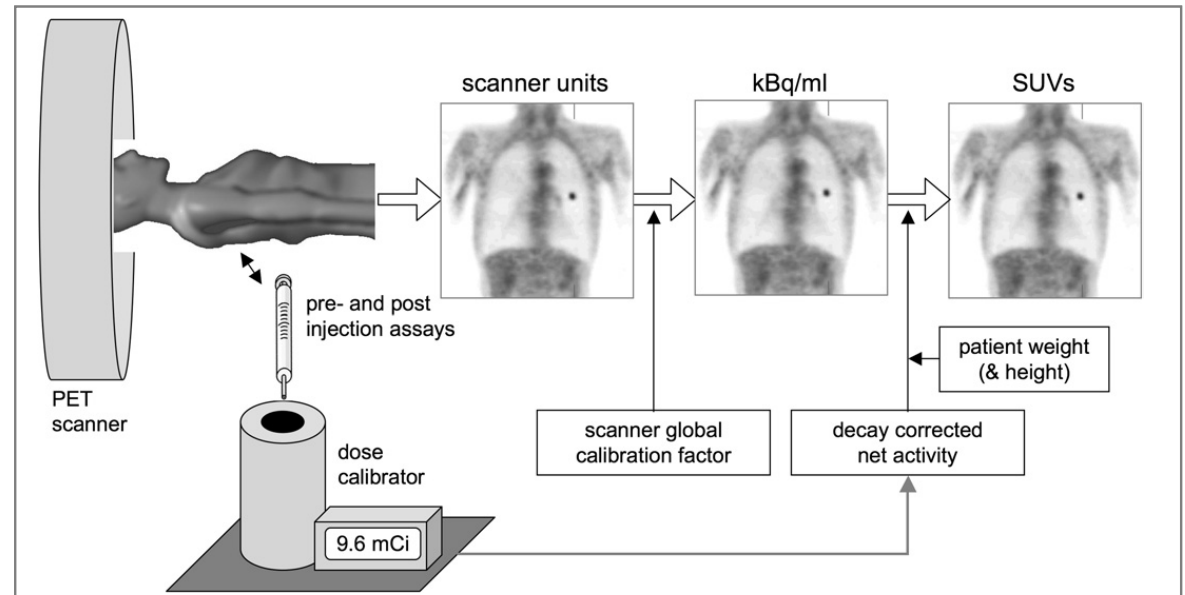




PET activity meter cross-calibration



- uniform cylinder with ^{18}F solution
- radionuclide calibrator (RC) measure (Bq)
- known cylinder volume (ml)
- known Bq/ml $\rightarrow$ measured cpm/voxel
- cross-calibration factor determined



- same RC used for patient administration
- measured cpm/voxel
- converted to Bq/ml, SUV, ...



Additional calibration using gamma counter

- problem for radionuclides with short $T_{1/2}$
 - ^{11}C , ^{13}N , ^{15}O , ^{68}Ga , ...
- positron emitters $\rightarrow$ narrow E window
 - correction factor for positron branching ratio

➤ F-18 eff. (%) = 34.2 cps/positron
➤ Ge-68 eff. (%) = 33.2 cps/positron

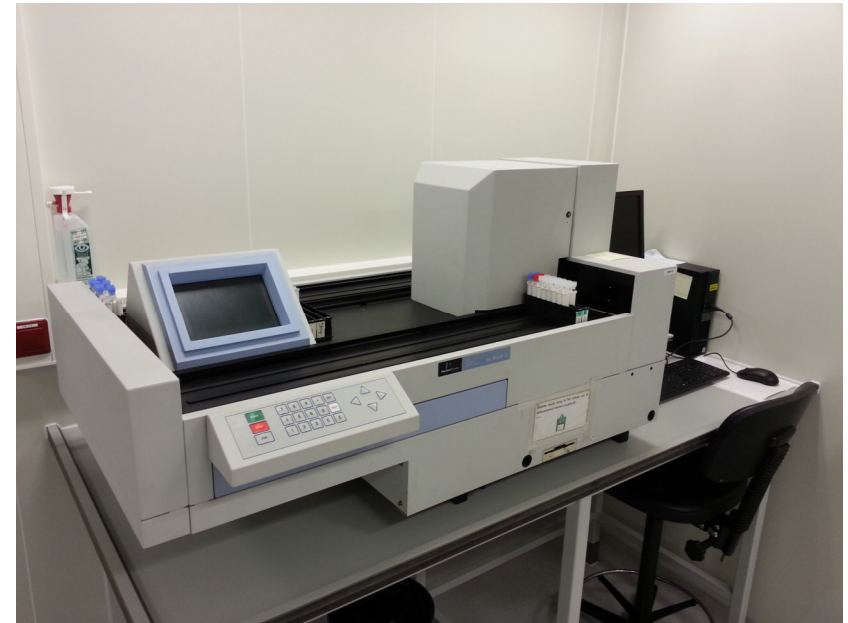
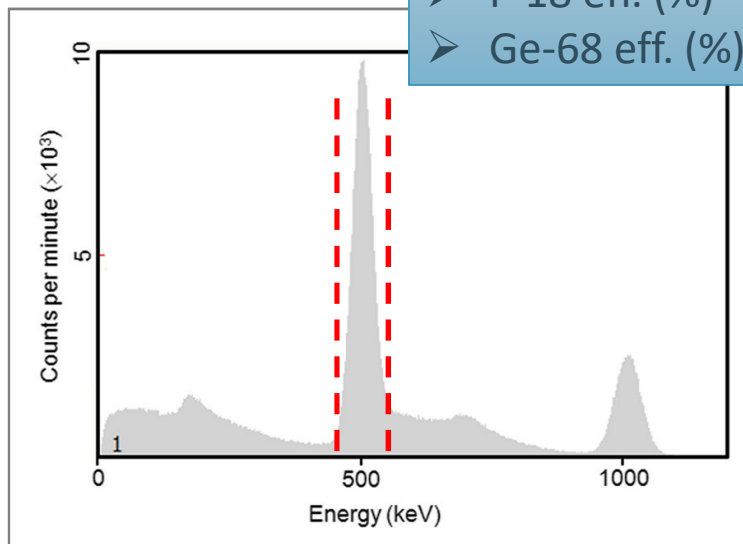


Table 1 Experimental measurements of gamma counter efficiency (mean $\pm$ SD) for ^{18}F and $^{68}\text{Ge}/^{68}\text{Ga}$

Isotope	Efficiency (%)	Positron fraction	Efficiency (%) / positron fraction
^{18}F	34.4 ± 0.18	0.97	35.5 ± 0.18
$^{68}\text{Ge}/^{68}\text{Ga}$	30.1 ± 0.07	0.89	33.8 ± 0.07

Both isotopes were measured using a 409- to 613-keV energy window.



Quality assurance – gamma counter efficiency

- ^{68}Ge reference sources
- mean eff. (%) = 33.5 ± 0.4 cps/pos

 **Eckert & Ziegler**
Isotope Products

CERTIFICATE OF CALIBRATION
GAMMA STANDARD SOURCE

Radionuclide: Ge-68
Half-life: 270.8 ± 0.3 days
Catalog No.: GF-0318-220N
Source No.: 1924-30-2

Customer: IDB HOLLAND BV
P.O. No.: 04040/19JAN
Reference Date: 2017-02-01 12:00 PST
Contained Radioactivity: 225.7 nCi 8351 Bq (Ge-68 only)

Physical Description:
A. Capsule type: T (12 mm diameter x 75 mm length)
B. Nature of active deposit: Dispersed in epoxy matrix
C. Active diameter/volume: Approximately 0.71mL (0.7124 grams; balance filled with inactive epoxy)
D. Backing: Plastic
E. Cover: Plastic

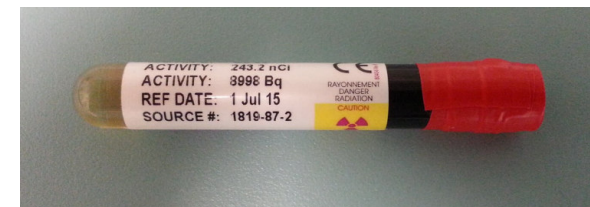
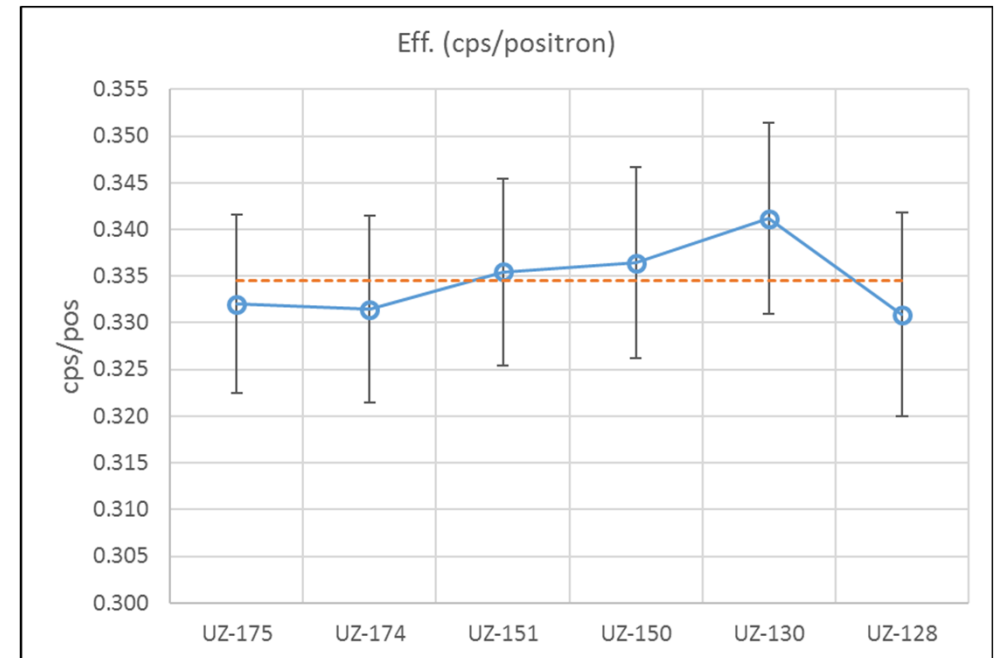
Radioimpurities:
None detected (Ga-68 daughter in equilibrium)

Method of Calibration:
This source was prepared from a weighed aliquot of solution whose activity in $\mu\text{Ci/g}$ was determined using a pressurized well type ionization chamber.

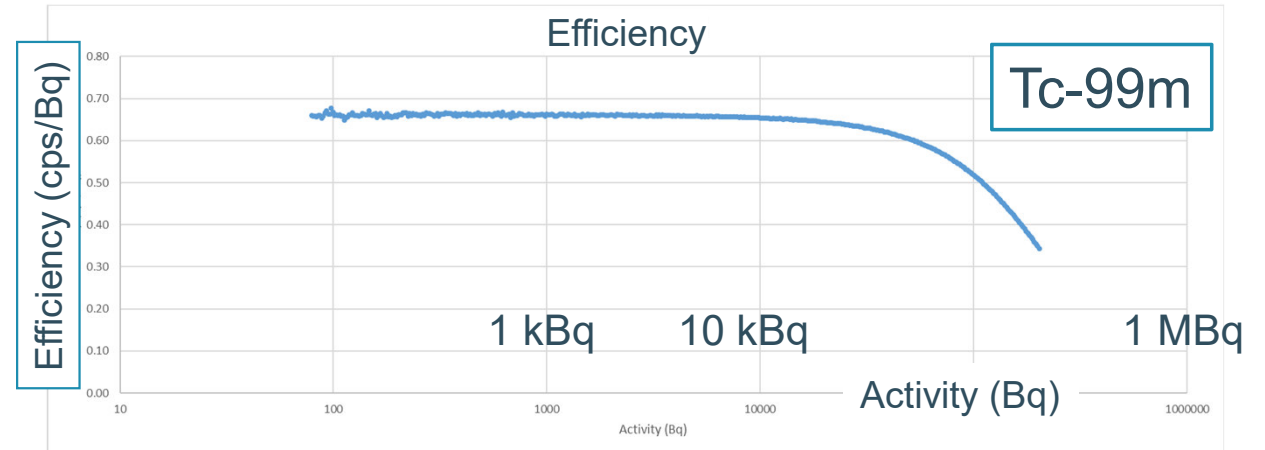
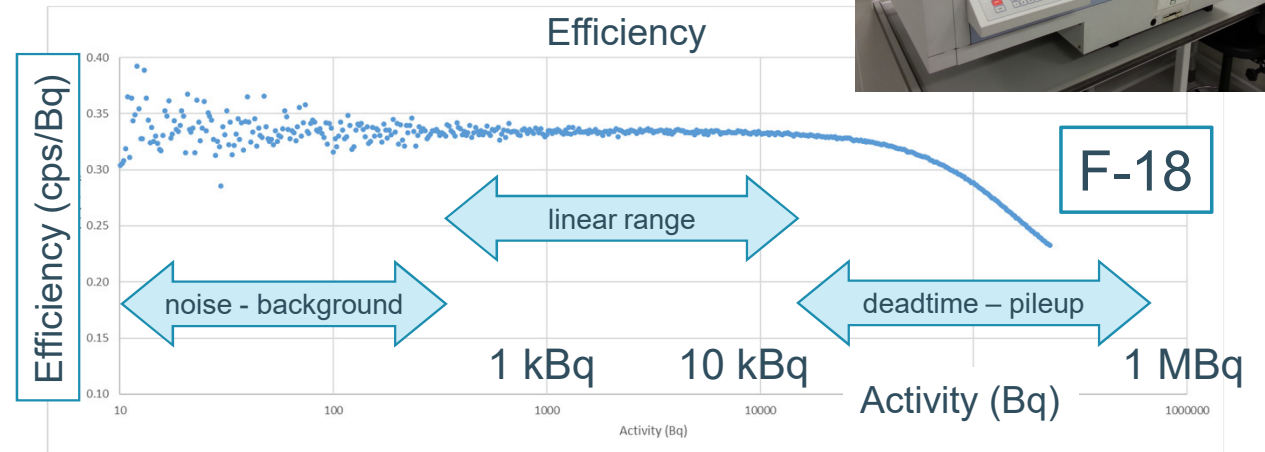
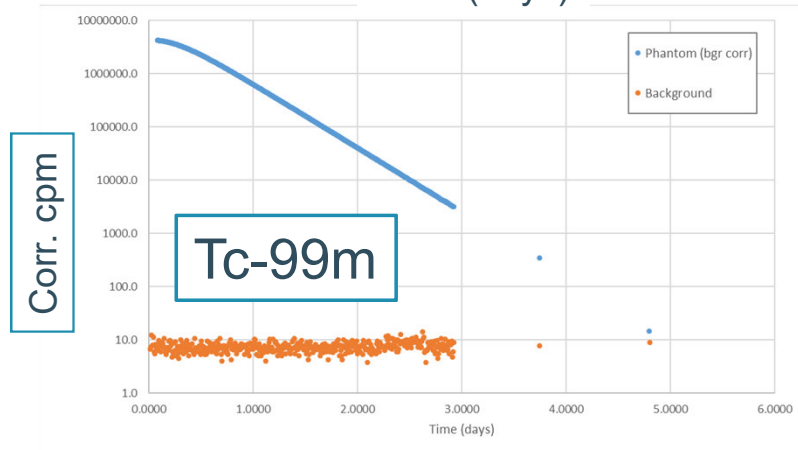
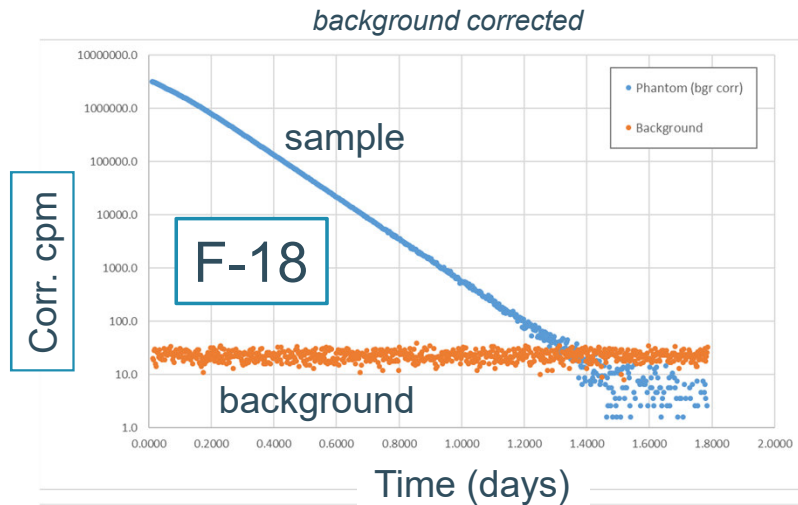
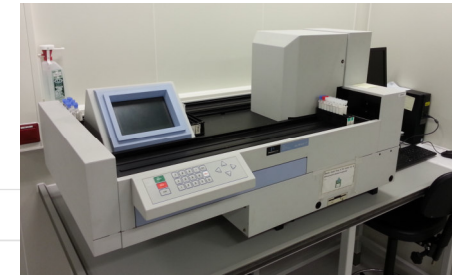
Uncertainty of Measurement:
A. Type A (random) uncertainty: ± 0.0 %
B. Type B (systematic) uncertainty: ± 3.0 %
C. Uncertainty in aliquot weighing: ± 0.0 %
D. Total uncertainty at the 99% confidence level: ± 3.0 %

Notes:
- See reverse side for leak test(s) performed on this source.
- This document uses the date convention YYYY-MM-DD in accordance with ISO 8601.
- EZIP participates in a NIST measurement assurance program to establish and maintain implicit traceability



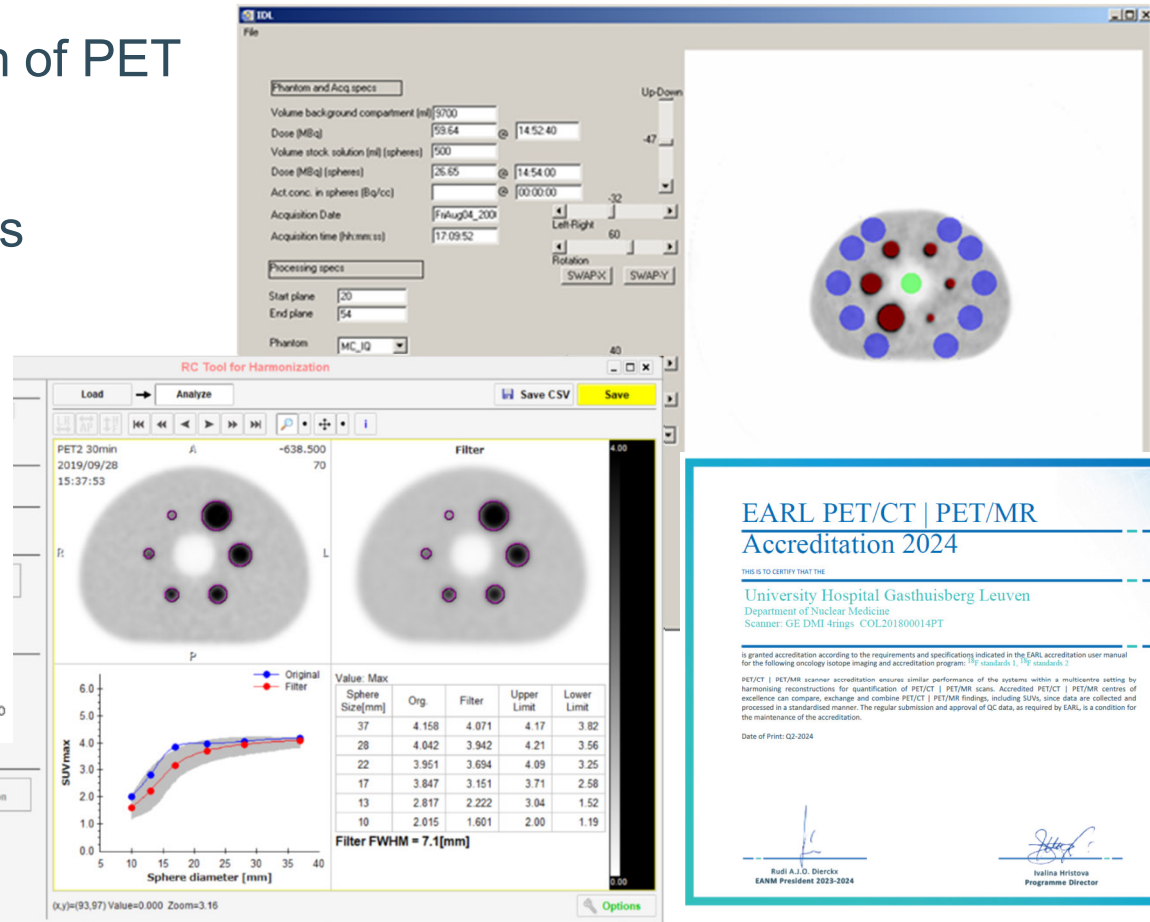


Linearity analysis – gamma counter



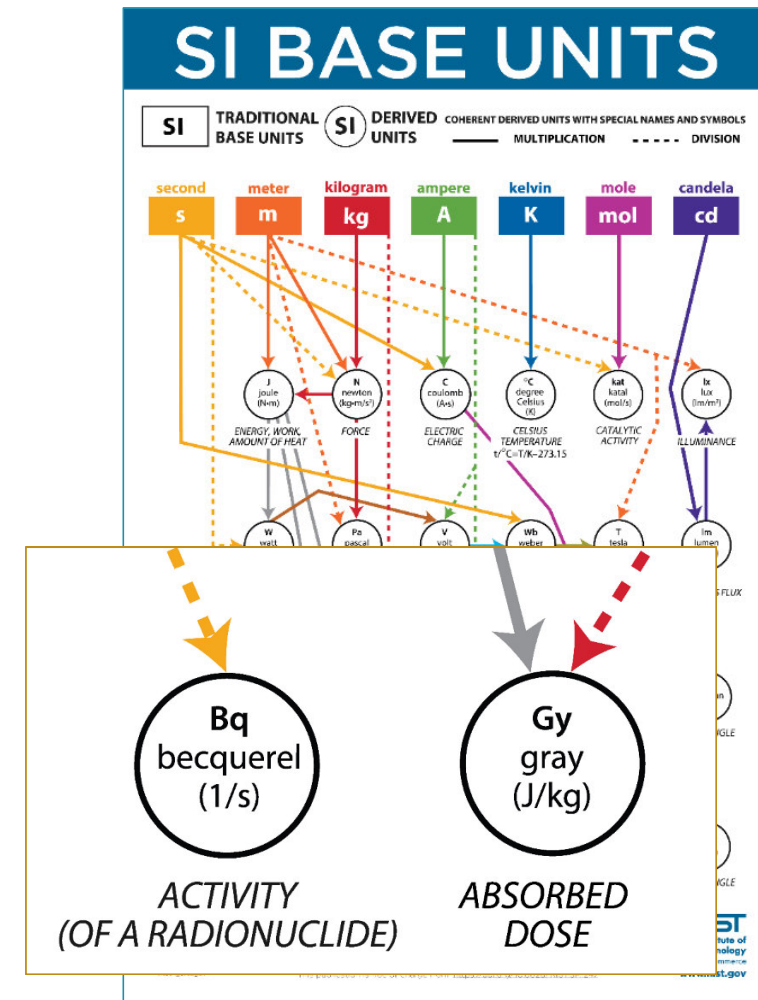
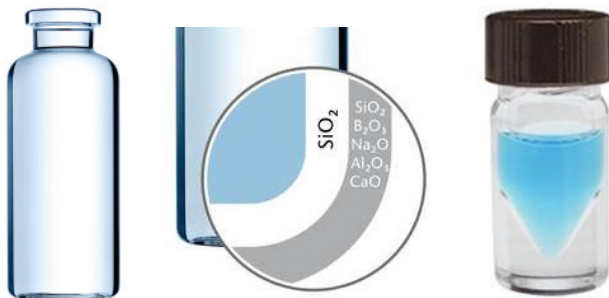


- international effort → accreditation of PET
- SUV & image quality verification
- harmonization for multicenter trials



Standardization challenges in NM

- crossing the valley of death – translational research
 - global : regulatory – radioprotection – medicines agencies
 - local : health physics – radiopharmacy – clinical environment
- close **gaps** between **radiopharmacy** and **medical physics**
 - use of standardised recipients : V-vial, 10R Type 1+ Schott vial, ...
- approach manufacturers
- approach R-pharma suppliers
- approach EMA, FAGG, ...

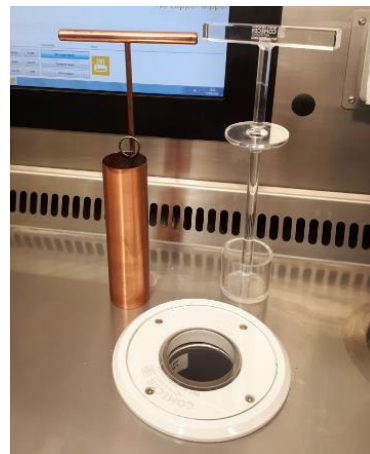
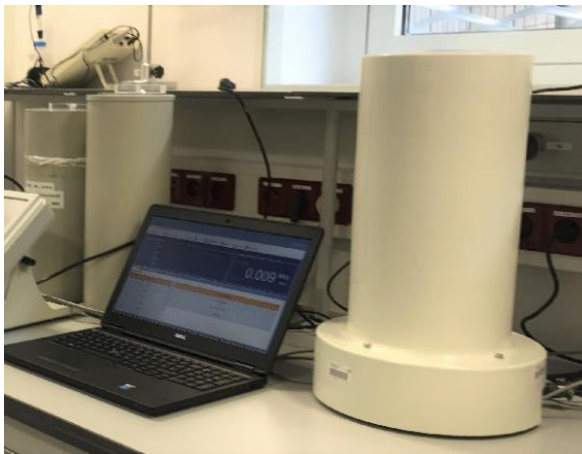


Special Publication (NIST SP) – 1247
<https://doi.org/10.6028/NIST.SP.1247>

NIST
 National Institute of
 Standards and Technology

Calibration challenges in NM

- the “calibration” problem is typically **not** intercepted by **standard quality assurance** measures in nuclear medicine (unfortunately)
- this can lead to **significant inaccuracies** with the determination of the activity [Bq] of a radiopharmaceutical
- more **advanced quality control** measures are therefore urgently required → medical physics experts & metrology experts
- theranostics: **quantitative** imaging for radionuclide **therapy** and **personalized dosimetry** are based on this



TRS-374 – Calibration of Dosimeters Used in Radiotherapy (IAEA, 1994)

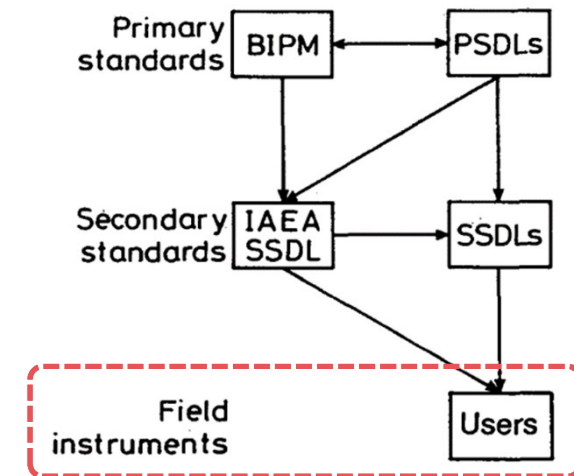
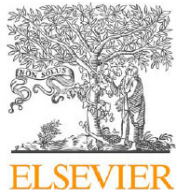


FIG. 1. The international measurement system.

Traceability of radionuclide calibrators

Physica Medica 45 (2018) 134–142



Contents lists available at ScienceDirect

Physica Medica

journal homepage: www.elsevier.com/locate/ejmp



Original paper

Intercomparison of ^{99m}Tc , ^{18}F and ^{111}In activity measurements with radionuclide calibrators in Belgian hospitals

Clarita Saldarriaga Vargas^{a,*}, Sunay Rodríguez Pérez^a, Kristof Baete^{b,c}, Stefaan Pommé^d, Jan Paepen^d, Raf Van Ammel^d, Lara Struelens^a

^a Belgian Nuclear Research Centre (SCK-CEN), Boeretang 200, 2400 Mol, Belgium

^b UZ Leuven, Department of Nuclear Medicine, Herestraat 49, 3000 Leuven, Belgium

^c KU Leuven, Department of Imaging and Pathology, Herestraat 49, 3000 Leuven, Belgium

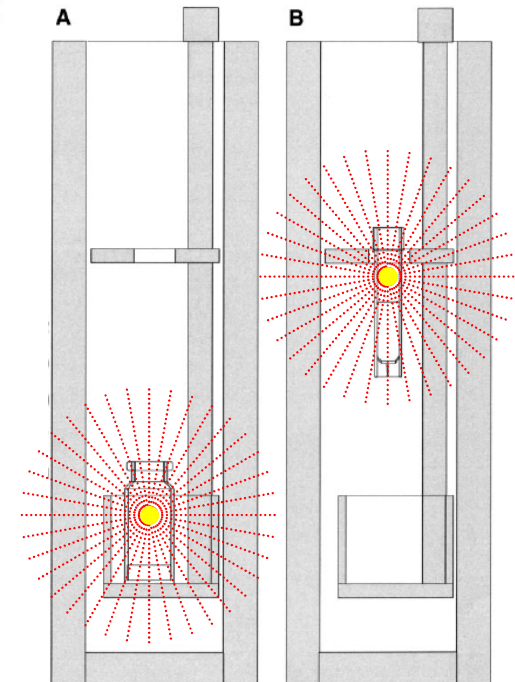
^d European Commission, Joint Research Centre (JRC), Directorate for Nuclear Safety and Security, Retieseweg 111, 2440 Geel, Belgium



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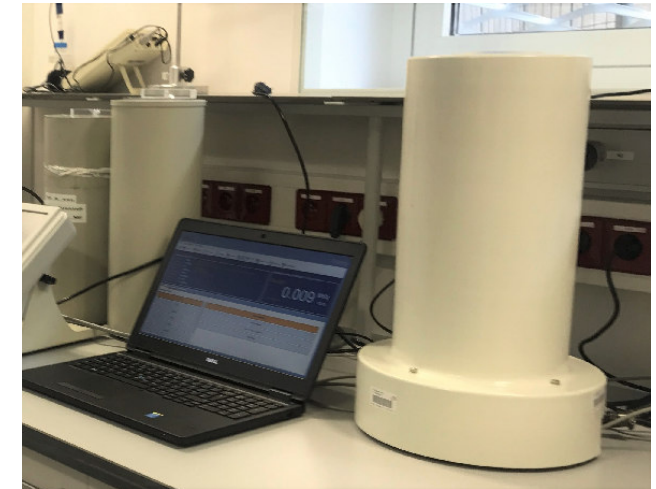
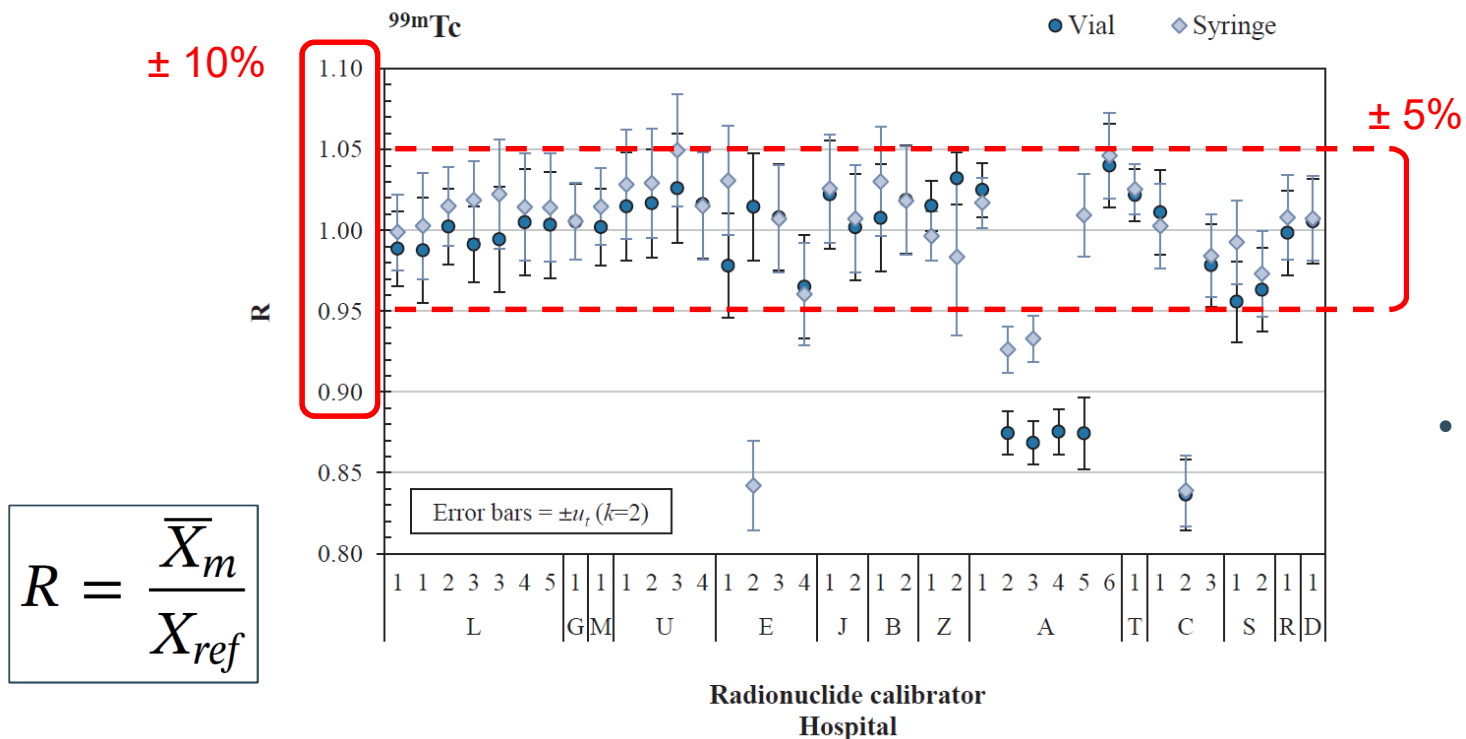


irm
Institute for Reference
Materials and Measurements



Traceability of radionuclide calibrators

- results for Tc-99m
- use of Fidelis – secondary standard radionuclide calibrator



- a **suspension level** for accuracy deviation > 5% for > 100 keV (RP-162, EC 2012 & NPL 2006)



Traceability of radionuclide calibrators

- results for In-111 – “The Good, the Bad and the Ugly”

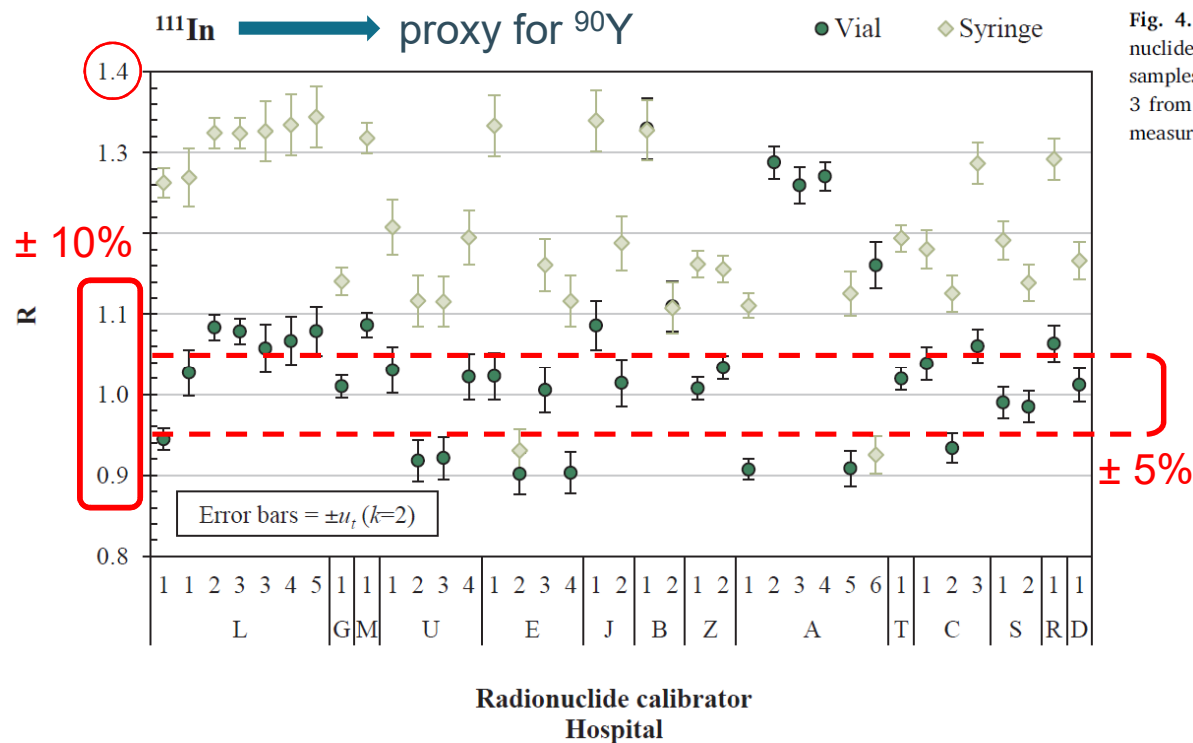


Fig. 4. Ratio of the mass activity obtained from radionuclide calibrator measurements and the reference value for samples of ^{111}In in a vial and a syringe container. RCs 1 and 3 from hospital L were measured twice (first and second measurement campaigns).

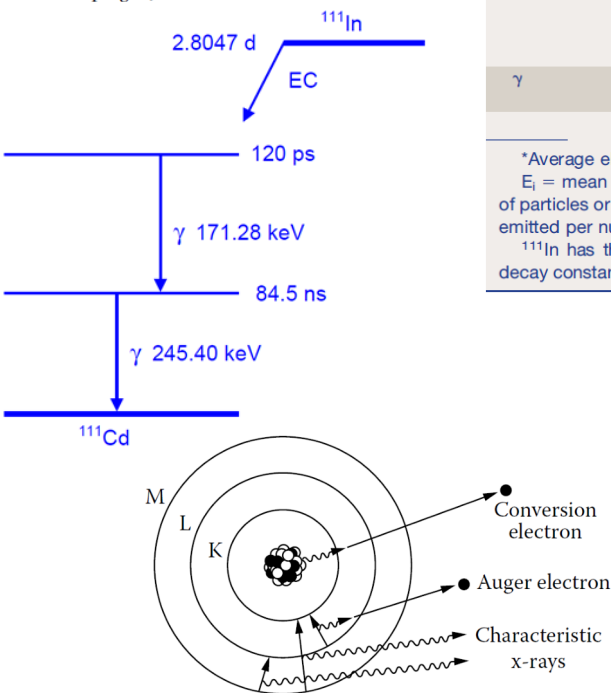
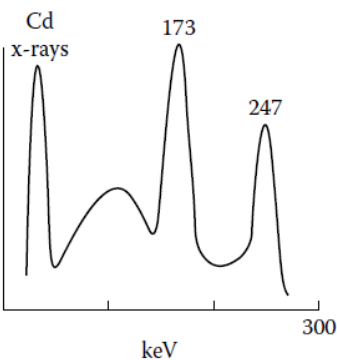


TABLE 3. Nuclear Data for ^{111}In				
Principal radiation	E_i (keV)*	n_i	Equilibrium dose constant, Δ_i	
			(rad g $\mu\text{Ci}^{-1} \text{h}^{-1}$)	(Gy kg $\text{Bq}^{-1} \text{s}^{-1}$)
Auger electron	2.7	0.98	5.68E-03	4.27E-16
	19.3	0.156	6.41E-03	4.82E-16
	144.6	0.078	2.40E-02	1.80E-15
Conversion electron	167.3	0.0106	3.78E-03	2.84E-16
	170.5	0.00203	7.37E-04	5.54E-17
	171.2	0.000424	1.55E-04	1.16E-17
	218.7	0.0493	2.30E-02	1.73E-15
	241.4	0.00785	4.04E-03	3.03E-16
	244.6	0.00151	7.87E-04	5.91E-17
x-ray	245.3	0.000301	1.57E-04	1.18E-17
	3.1	0.069	4.60E-04	3.46E-17
	23	0.235	1.15E-02	8.64E-16
	23.2	0.443	2.19E-02	1.64E-15
	26.1	0.145	8.06E-03	6.06E-16
	171.3	0.902	3.29E-01	2.47E-14
γ	245.4	0.94	4.91E-01	3.69E-14

*Average electron energies.
 E_i = mean energy per particle or photon; n_i = mean number of particles or photons per nuclear transition; Δ_i = mean energy emitted per nuclear transition.
 ^{111}In has the following properties: physical half-life, 67.3 h; decay constant, 0.0103 h^{-1} ; and decay mode, electron capture.



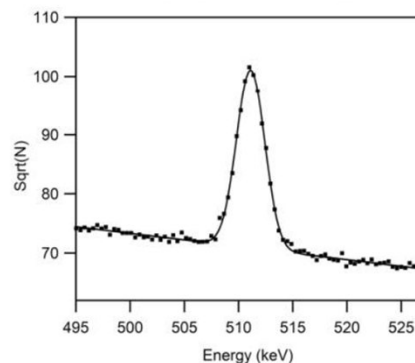
Accuracy of activity for ^{90}Y -SIRT

- SIRT = selective internal radiation therapy of liver cancer
- gamma spectrometry reveals that the ^{90}Y primary SIR-Spheres® activity calibration appears to be a **significant underestimate** of true activity: 1.233 ± 0.030



SIR-Spheres® activity measurements reveal s

High-purity Germanium
 ^{90}Y 511 keV γ -spectrometry

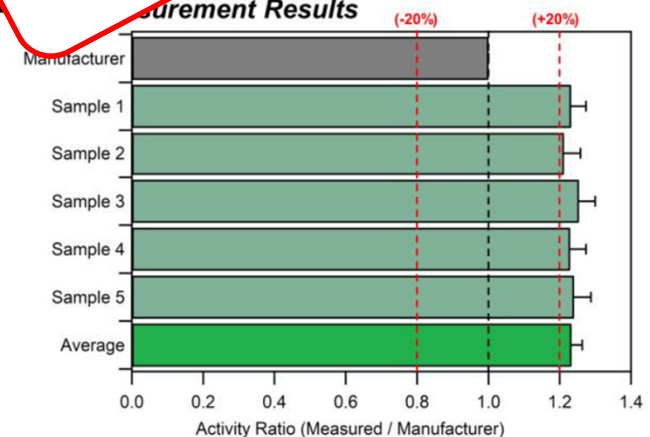


Redundant NIST-
Traceable Efficiency
Calibration



January 2022

Measurement Results



Stephen A Graves, *et al.*
JNM, Jan 2022,

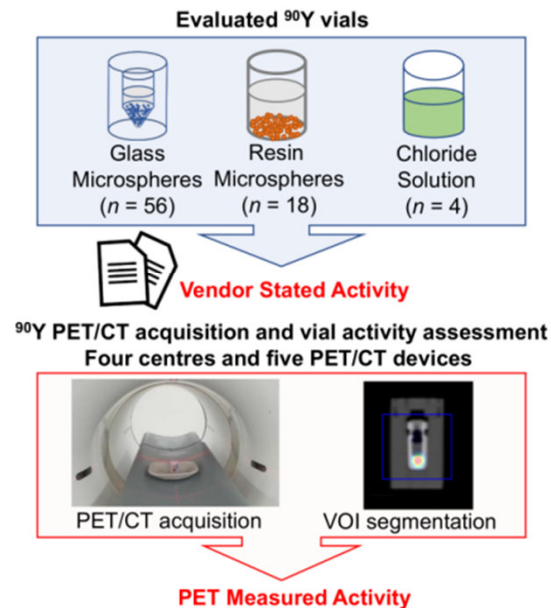
DOI: 10.2967/jnumed.121.262650

Accuracy of activity for ^{90}Y -SIRT

Silvano Gnesin, et al.
JNM, Nov 2022,
DOI: 10.2967/jnumed.122.264455

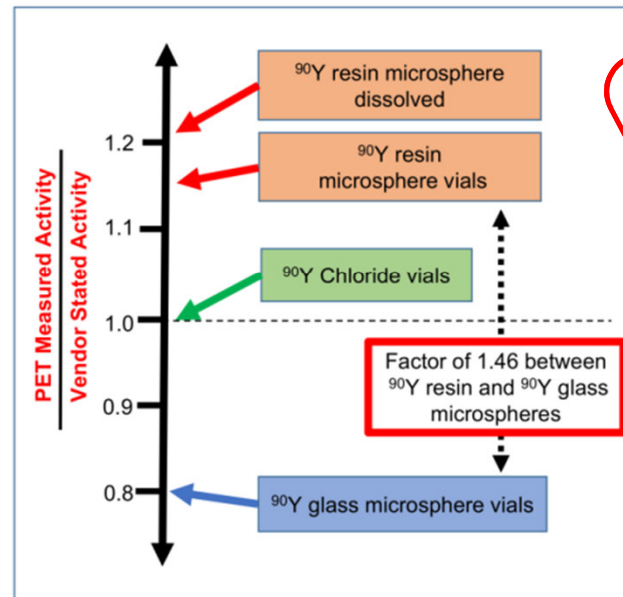
- confirmation of previous study and observations

Graphical Abstract



Title: A multicenter study on observed discrepancies between vendor-stated and ^{90}Y activities for both glass and resin microsphere devices

Authors: Silvano Gnesin*, Justin K. Mikell*, Maurizio Conti*,
Thiago V. M. Lima, Yuni K. Dewaraja.



November 2022

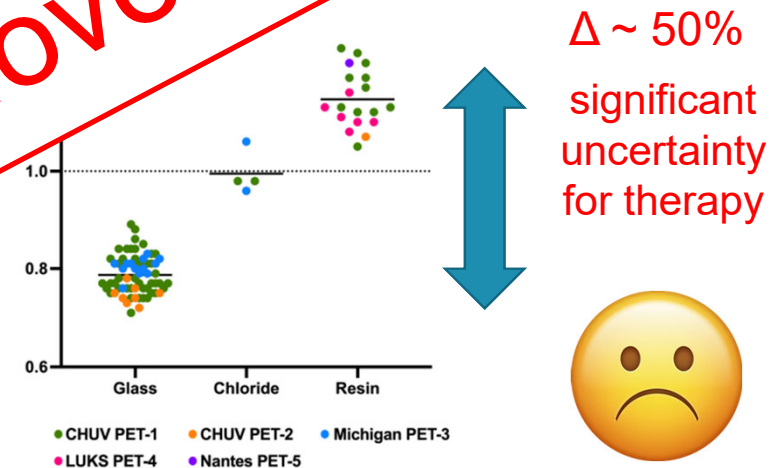


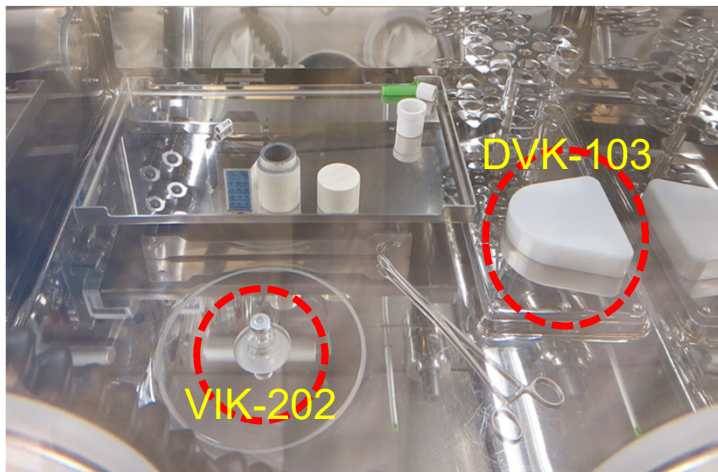
Figure 1. Distribution of $A_{\text{PET}}/A_{\text{M}}$ ratios for the four vial products tested in this study (i.e. ^{90}Y -labeled glass microspheres, ^{90}Y -Chloride solution, ^{90}Y -labeled resin microspheres and ^{90}Y -labeled liquefied resin).

Synthesis and dispensing shielded isolator for cGMP



- 2 activity meters, both 14 bar Argon, internal elevators
 - VIK-202: well-type, for preparation & synthesis vial
 - DVK-103: pass-through, for dispensed vials
- DVK-103 is most important for the end-user
 - measurement of vial containing radiopharmaceutical for administration to patients or equipment calibration

Phaedra Combo (Comecer, Italy)



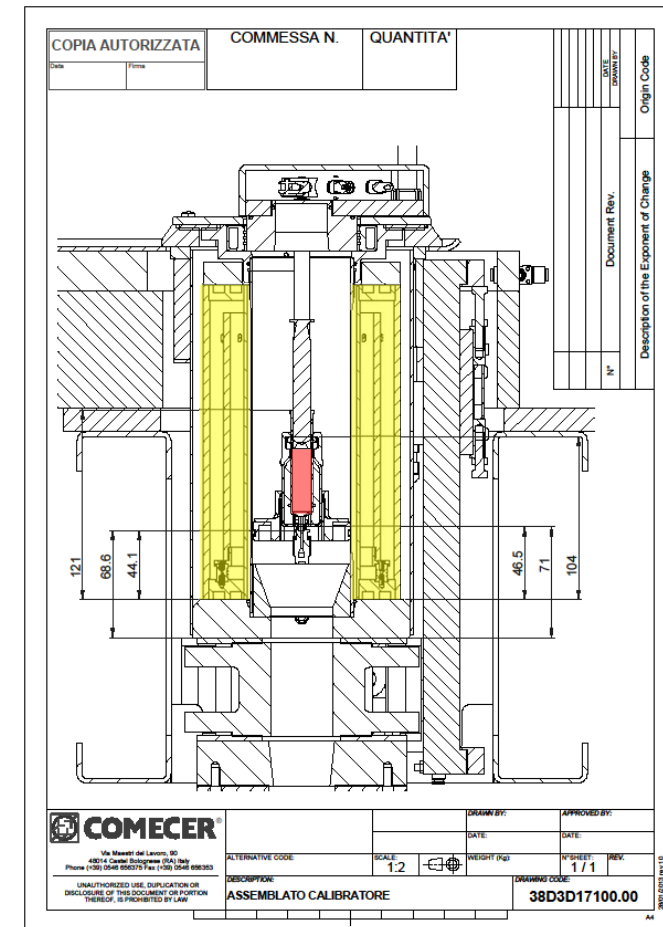
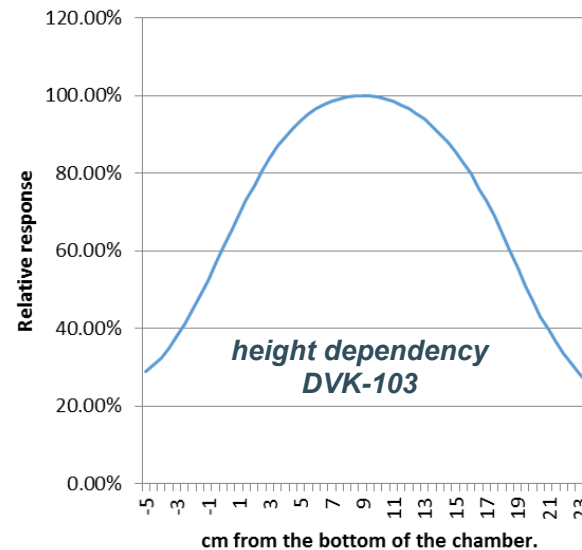
 **COMECER**
an  company



Problems encountered during acceptance testing

- DVK pass-through chamber
- SAT by Comecer using ^{137}Cs
 - accuracy deviation: 3%
- MPE acceptance using ^{57}Co
 - accuracy deviation: 18%

- limited number of calibration factors
- suspected influence of the elevator
- no traceability

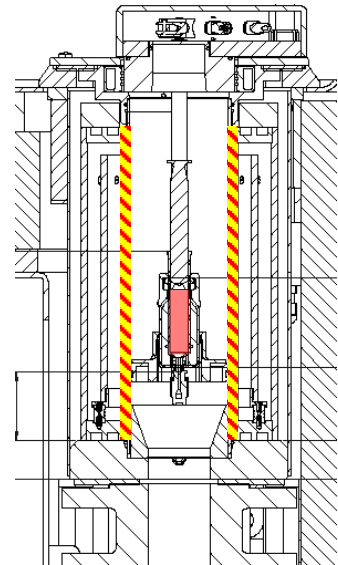
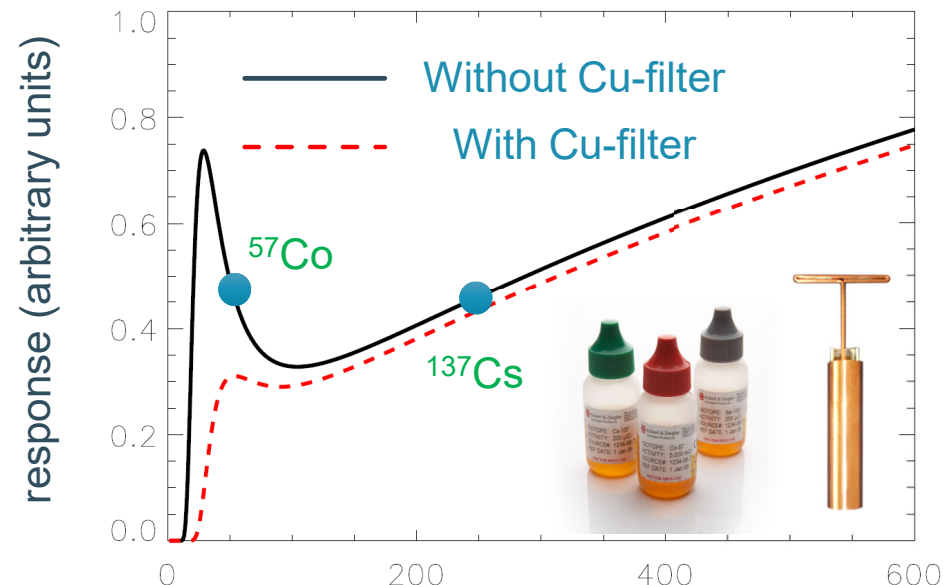
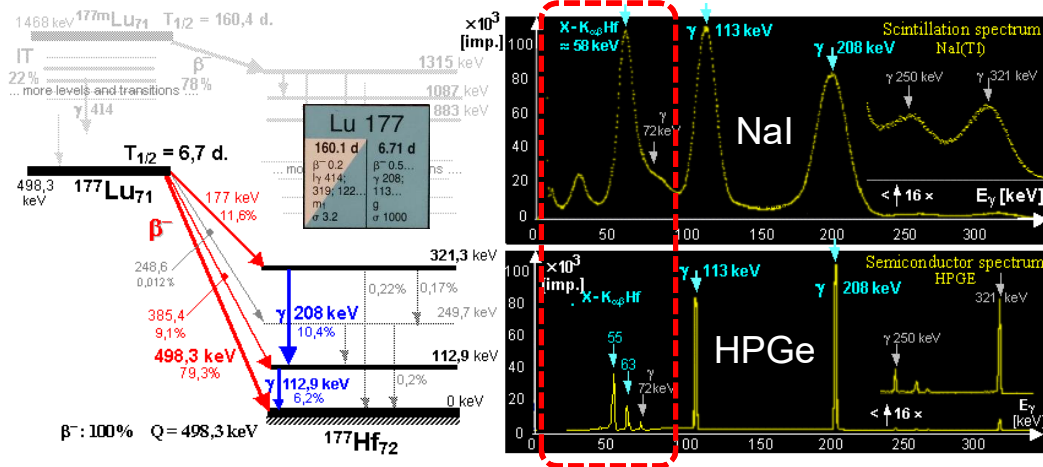
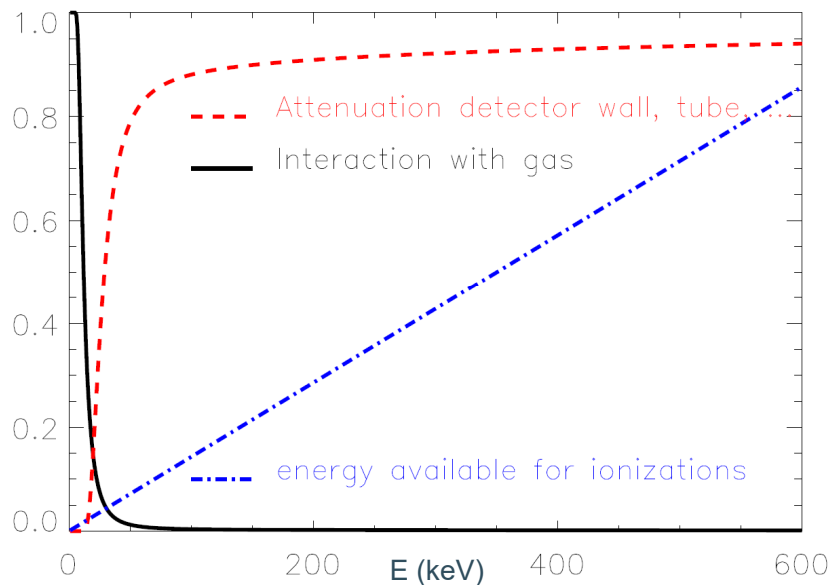


Energy response

- influence of the wall, elevator, recipient holder

$$R(E) \propto E \cdot \left(1 - e^{-\mu(E)}\right) \cdot \left(e^{-\mu(E)}\right)$$

ionizations attenuation interaction gas



Performing on-site traceable calibration

- Comecer adjusted the gain of the DVK-103 for ^{57}Co and ^{137}Cs ref. sources
 - deviation of the accuracy for ^{57}Co changed from 18% to 0.1% → recalibration !!!
- involvement of the SCK Fidelis secondary standard radionuclide calibrator
 - calibrated at a national metrological institute, traceable to primary standards
 - reference geometry: 10R Schott type 1+ vial
- on-site calibration for ^{89}Zr , ^{177}Lu and ^{68}Ga
 - master solution with a fixed activity concentration (Bq/ml)
 - mass derived reference and secondary geometries

Zr 89	
4.16 m	78.4 h
ϵ 588	ϵ 0.9
β^+ 0.9;	β^+ 0.9
2.4	γ (1713...)
γ 1507; g	m

Lu 177	
160.1 d	6.71 d
β^- 0.2	β^- 0.5...
γ 414;	γ 208;
319; 122...	113...
m	g
σ 3.2	σ 1000

Ga 68	
67.63 m	
β^+ 1.9...	
γ 1077; (1833...)	



SV25A



master solution



10R Schott type 1+



reference geometries



Phaedra Combo
VIK-202 & DVK-103

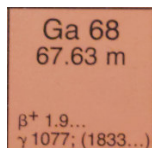
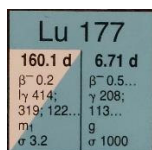
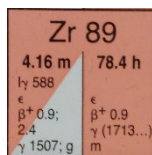


stand-alone
VIK-202



stand-alone
CRC-55tR

- 





Suppliers' Certificate of Calibration
 (SCK-CEN Form 01-2020)
 Issued on 20.03.2021
 Issued by: SCK-CEN, Belgium
 Issued for: XXXXXXXXXXXXXXXXXXXX
info@sck-cen.be
www.sck-cen.be

(Name of the customer)
 (Address)
 (City)
 (Country)
 (Postal code)
 (Telephone)
 (Fax)
 (E-mail)
 (Website)

Calibration certificate

Certificate number: FIDELITY-2024-0008
Issue date: 2025-01-27
Item: Commencement VIK-2021 (inside Phasmat) in: 22.501.05 515
Customer: IZD Boven
Customer's address: Herestraat 49
 8-2000 Leuven
Contact person: Dr. Kristof Baete
E-mail: kristof.baete@izdbelgium.be
Customer's reference: Calibrations June 2024
Calibration method: Calibration of radionuclide calibrators according to SCK-CEN / LNK
 validation file 187-SUP-M714
Radionuclides: Ge-68 (+Ge-68), Zr-89, Lu-177
Calibration date: 2024-06-17
Number of pages: 2

Traceability:

The calibration is done with reference standards and calibration devices for which the traceability to national and international standards is assured.
 When the calibration is covered by the ISO 17025:2017 accreditation scope of LNK, unless explicitly stated.

Performed by:

Digitally signed by **IRIS AARTIS**
 Date: 2025.01.27
 14:09:57 +01'00'

Reviewed by:


LNW-Cristian Mihalescu
 2025.01.27
 16:10:24 +01'00'

This certificate may be re-used without prior written approval of the Issuing Body. The Issuing authority only is the Issued authority and not liable for any liability regarding the legal validity of the equipment or the effect of its operation. The document is based on accounts and the certificate is not transferable to other calibration facilities. The Issuing authority is not responsible for the use of the certificate for purposes other than those intended by the Issuing authority.

Exploring
 a better tomorrow

FIDELITY-2024-0008_FK2021 Phasmat
 printed on: 2025-01-27 13:51

content 4 g solution	Factory IF / SF	New IF / SF	Diff (%)
CRC-55tR	499 × 1 (§)	462 × 1	-6.3%
VIK-202 (stand-alone)	786 × 1	770 × 1	-6.9%
VIK-202 (Phaedra)		773 × 1	
DVK-103 (Phaedra)		692 × 1	
CRC-55tR	456 × 10 (§)	449 × 10	-1.3%
VIK-202 (stand-alone)	751 × 10	763 × 10	+5.2%
VIK-202 (Phaedra)		758 × 10	
DVK-103 (Phaedra)		597 × 10	
CRC-55tR	416 × 1	430 × 1	+2.7%
VIK-202 (stand-alone)	749 × 1	755 × 1	+2.4%
VIK-202 (Phaedra)		758 × 1	
DVK-103 (Phaedra)		669 × 1	

IF = isotope factor / SF = scale factor / § = clinical trials

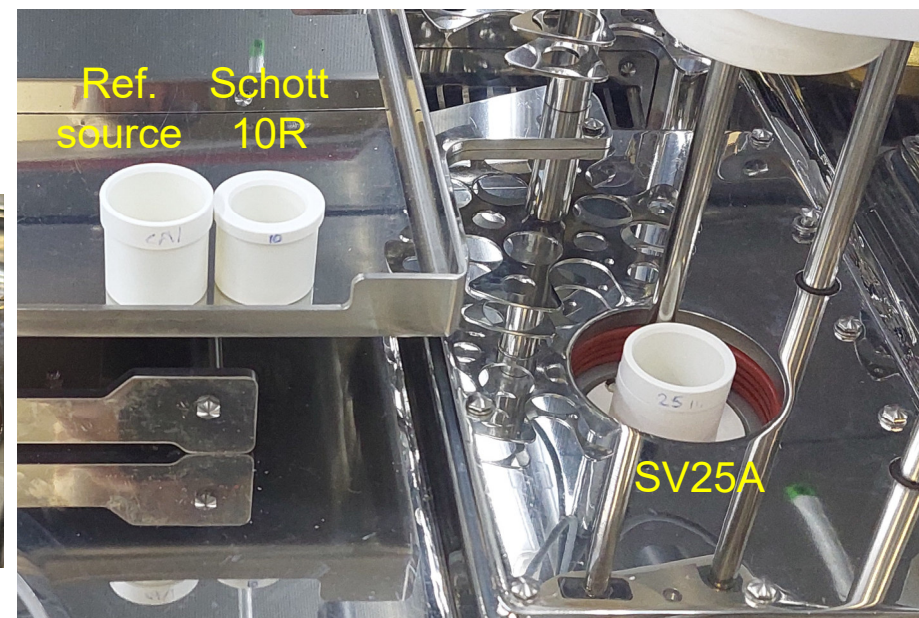
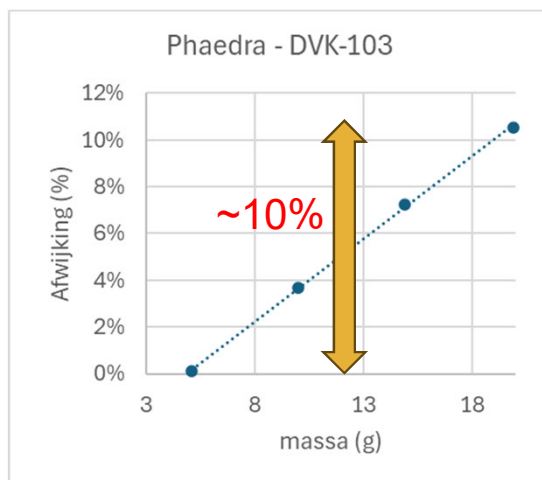
Results DVK-103



- calibration factors for
- an operational geometry
- SV25A vial (25 ml)
- performed for ^{177}Lu
- influence content SV25A ~ 10% (~5 → ~20 g)

Lu 177	
160.1 d	6.71 d
$\beta^- 0.2$	$\beta^- 0.5...$
$\gamma 414$	$\gamma 208$
319; 122...	113...
ml	g
$\sigma 3.2$	$\sigma 1000$

DVK-103 (Phaedra)		IF / SF	Re-calib	Diff (%)
Schott 10R	4 g	597 × 10	566 × 10	-7.5%
SV25-A	~5 g	597 × 10	566 × 10	-7.5%
SV25-A	~10 g	597 × 10	582 × 10	-3.7%
SV25-A	~15 g	597 × 10	596 × 10	+0.2%
SV25-A	~20 g	597 × 10	608 × 10	+2.7%



Value of metrology

- European Union: 2013/59/EURATOM
 - art. 56 – Optimisation: “...verification of administered activities ...”
- Belgium: Medical Exposure Decree (2020)
 - art. 9 – Optimisation: “... verification of administered activities ...”
 - art. 60 – Reporting: “... deviation of **>10% of the intended activity**”
- recipients often do not meet the calibration requirements
- Unknown calibration uncertainties on certificate of analysis
- lack of knowledge about the **unbroken chain of traceability** or calibration path for **radioactivity prescription** by a physician
- how to compare that to the concept of **maximum permitted tolerance** on “content” in the EU (76/211/EEC) 🤔 ???



Traceability pyramid



CSIR-National Physical Laboratory, New Delhi, India

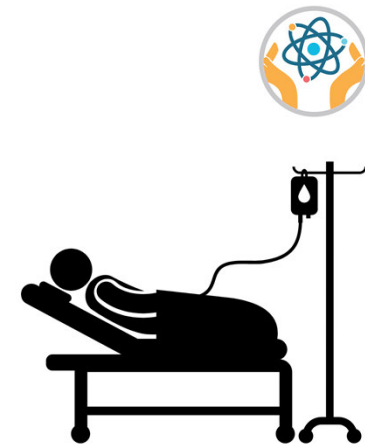


Status of traceability in NM

- production and supply chain of radiopharmaceuticals
 - single or multi-dose vial
 - on-site radiopharmaceutical preparation



- involvement of national metrology institute (NMI)
- clinical practice
 - manufacturer settings of radionuclide calibrators
- clinical trials
 - calibration of equipment towards the “trial standard”
- no control over the traceability of the manufacturer or the supplier

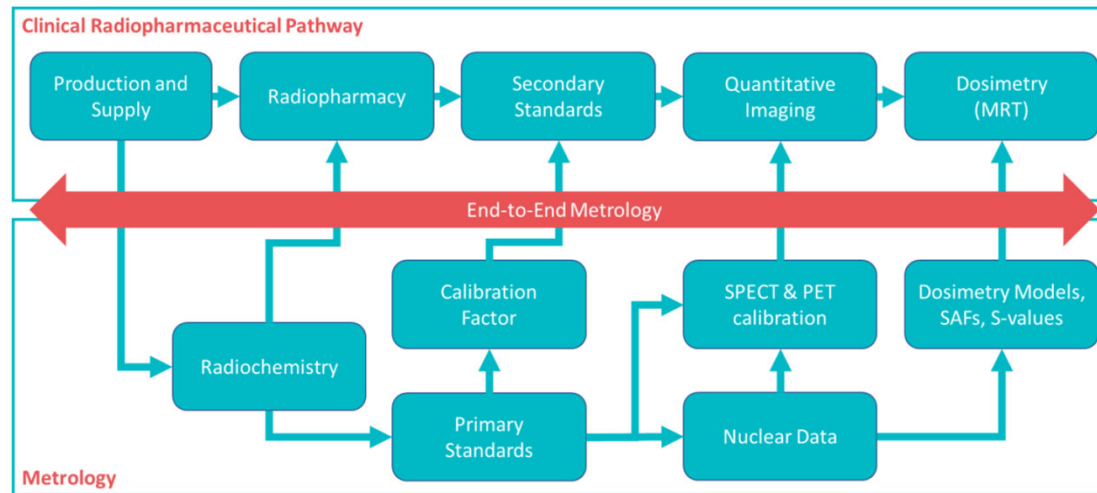




Standards for clinical translation

- PRISMAP recommends the implementation of
 - an **end-to-end metrology** methodology, and
 - the **involvement of medical physics experts (MPE)**

for the standardization and harmonization of novel radiopharmaceuticals for **imaging and therapy**



Deliverable D4.1
Standards for clinical translation

www.prismap.eu



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**UZ
LEUVEN**

*Thank
You!*

KU LEUVEN



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EU

PRISMAP

Medical Radionuclides

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