

M. Marengo

**Radiation Protection of Patients in Nuclear Medicine:
Diagnostic Reference Levels and Accuracy of
Activity Meters**

*Medical Physicist
University of Bologna, Italy*

mario.marengo@unibo.it



Outline

- An introduction to DRLs in Nuclear Medicine
 - Who is establishing DRLs ?
 - Which physical quantities ?
 - Examples and practical aspects
- Radionuclide activity calibrators
 - A recall on principles of operation and general characteristics
 - Why they matter for radiation protection of patient
 - Calibration issues and traceability to standards



An introduction to DRLs in Nuclear medicine



Reference documents

IAEA. Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. IAEA Safety Standards Series No GSR Part 3. IAEA, Vienna, 2014. Available online at:

<https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards>

European Commission. Diagnostic Reference Levels in Thirty-six European Countries. Radiation Protection Series No. 180, part 2, 2014. Available online at: https://ec.europa.eu/energy/topics/nuclear-energy/radiation-protection/scientific-seminars-and-publications/radiation-protection-publications_en

ICRP. Diagnostic Reference Levels in Medical Imaging. ICRP Publication 135, Ann. ICRP 46(1), 2017. Available at:

<https://www.icrp.org/publication.asp?id=icrp%20publication%20135>

IAEA. Radiation protection and safety in medical uses of ionizing radiation. IAEA Safety Standards Series No. SSG-46. IAEA, Vienna, 2018.

Available online at:

<https://www.iaea.org/publications/11102/radiation-protection-and-safety-in-medical-uses-of-ionizing-radiation>



What do the BSS say ?

Is not saying “shall establish” !

3.148 - The government ***shall ensure***... that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, ***a set of diagnostic reference levels is established*** for medical exposures incurred in medical imaging, including image guided interventional procedures. In setting such diagnostic reference levels, account shall be taken of the need for adequate image quality... . Such diagnostic reference levels shall be based, as far as possible, on wide scale surveys or on published values that are appropriate for the local circumstances.



What do the BSS say ?

3.169. Registrants and licensees shall ensure that:

Local assessments ... are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established.

A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:

- (i) Typical doses or activities exceed the relevant diagnostic reference level; or
- (ii) Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.



Who is establishing DRLs ?

This is much different
from “shall be” !

- DRLs **may be** established by authorised bodies.
- The numerical values of DRLs **are advisory**.
- An authorised body **may require implementation of the DRL concept**.
- Organisations responsible for different components of the tasks of collating data on DRL quantities and setting national DRLs should be identified in each country or region.
- **DRL values shall not be used for individual patients** or as trigger (alert or alarm) levels for individual patients or individual examinations.

*The Government or the Regulatory body
cannot know exactly which type of collimator
you have for the gamma camera,
or which version of reconstruction software is installed ...*

Which quantities should be used?

- Quantities used for DRLs should assess the amount of ionising radiation applied to perform a medical imaging task.
- ***Should be easily measured or determined.***
- DRL quantities assess the amount of ionising radiation used for a medical imaging procedure, not absorbed dose to a patient or organ (one exception is mammography, for which D_G may be used).
- ***DRL quantities should be appropriate to the imaging modality being evaluated***, to the specific study being performed, and to the specific size of the patient.
- The ICRP stresses that the radiation protection quantity ‘effective dose’ (used for other purposes in the ICRP radiological protection system) should not be used as a DRL quantity. It introduces extraneous factors that are neither necessary nor pertinent for the purpose of a DRL.



Which quantities should be used?

- ***For Nuclear Medicine, the suggested DRL quantity is administered activity/body weight*** of a specific radionuclide for a specific clinical task and, if relevant, the radiopharmaceutical used.
- The ICRP recommends that ***weight based administered activities should be used for children, adolescents, and low-weight patients, and considered for other groups.***
- Setting a fixed maximum administered activity for very obese patients may also be considered. It is recognised that, in many countries, a standard activity is used in clinical practice for adult patients.
- Weight-based administered activities may not be appropriate for examinations where the radiopharmaceutical is concentrated predominantly in a single organ (e.g. thyroid scans, lung perfusion scans).



Multi-modality systems

As DRL values for nuclear medicine procedures and CT procedures apply to radiation from very different modalities, and use different DRL quantities, for hybrid imaging procedures (SPECT-CT, PET-CT),

It is appropriate to set and present DRL values for each modality independently.

Which quantities should be used?

- *The recommended DRL quantities for CT are:*
 - **$CTDI_{vol}$** ;
 - **DLP**.
- The recommended $CTDI_{vol}$ value to be used is the $CTDI_{vol}$ for each sequence.
- The recommended DLP value is the cumulative DLP for the entire examination. DLP values for individual scan sequences can also be useful, and may be used in addition to the cumulative DLP.



Local / National DRLs

- ***The ICRP recommends setting local and national DRL values based on DRL quantities for imaging examinations and procedures performed on patients.***
- The use of phantoms is not sufficient in most cases. When phantoms are used, the effects of operator performance, the selected imaging protocol, and patient variability are not taken into account.
- The use of phantoms is important in the investigation of x-ray equipment performance, and is important in evaluating the performance of fluoroscopy and CT equipment with respect to the amount of radiation used during the optimisation of protection.
- ***Data on DRL quantities may be collected using surveys, registries, or other automated data collection methods.***



Relevance of Information Systems

- Hospital Information Systems (HIS) and Radiological Information Systems (RIS) can provide data for large numbers of patients (but may not include patient weight, relevant in some NM studies).
- As with all DRL surveys, the results rely on the accuracy of data entry.
- RIS and associated software (e.g. sw for QA and traceability in Radiopharmacy) may permit data on DRL quantities to be obtained in an automated fashion, either locally or through a national registry.
- Software for scanning DICOM headers or Radiation Dose management systems can be used to collect information for the studies stored in a PACS system. See recommendations on: Loose et al. European Radiology (2021) 31:2106–2114 . DOI: <https://doi.org/10.1007/s00330-020-07290-x>
- When automated processes are used, the data for all cases of a specific procedure should be obtained and used for optimisation.



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ImageJ plugin for scanning the header of DICOM files

The download of the zip archive with the software and the instructions for installing and using it can be done [here](#).

This plugin displays the DICOM header tags about all the images in a folder and its subfolders. The images must be in DICOM format. The plugin does not display information about DICOMDIR.

Use "Select folder" to specify the images main directory and "Select TXT" to specify the tags to display (e.g. see the file "Example.txt") or write the tag's code in the mask. Use "Start" to begin the scanning process. The output displays in the first row the selected tags and in the second row the relative description.

Hint: use the "DICOM_Dictionary.txt" contribution by Johannes Hermen and Christian Mol to upgrade the imageJ dictionary: copy it to the ImageJ folder and ImageJ will use it instead of the built in 680 tag dictionary.

If you download the plugin and publish data achieved with this software, please credit this website: www.medphys.it

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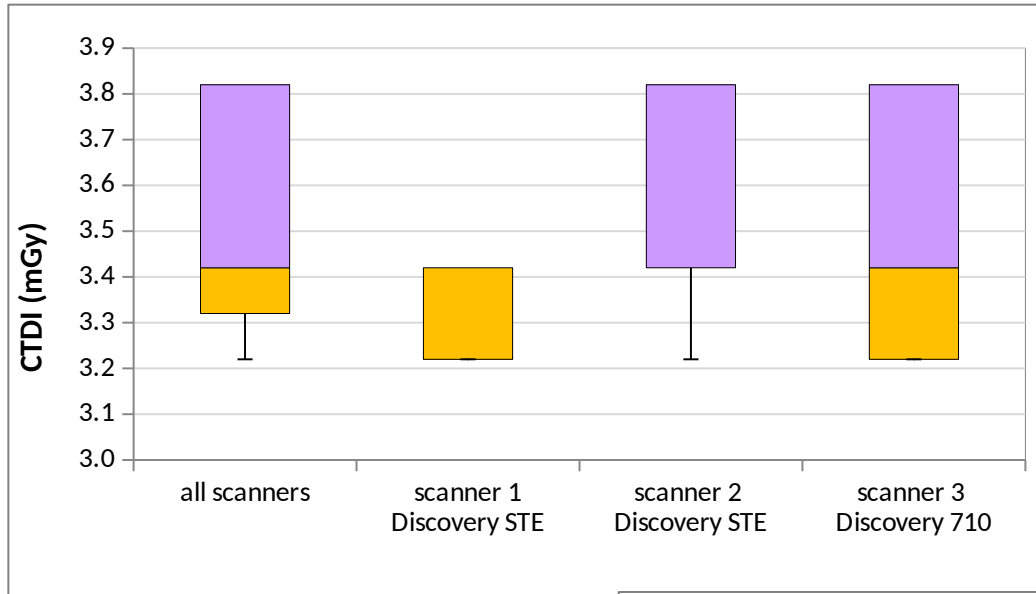
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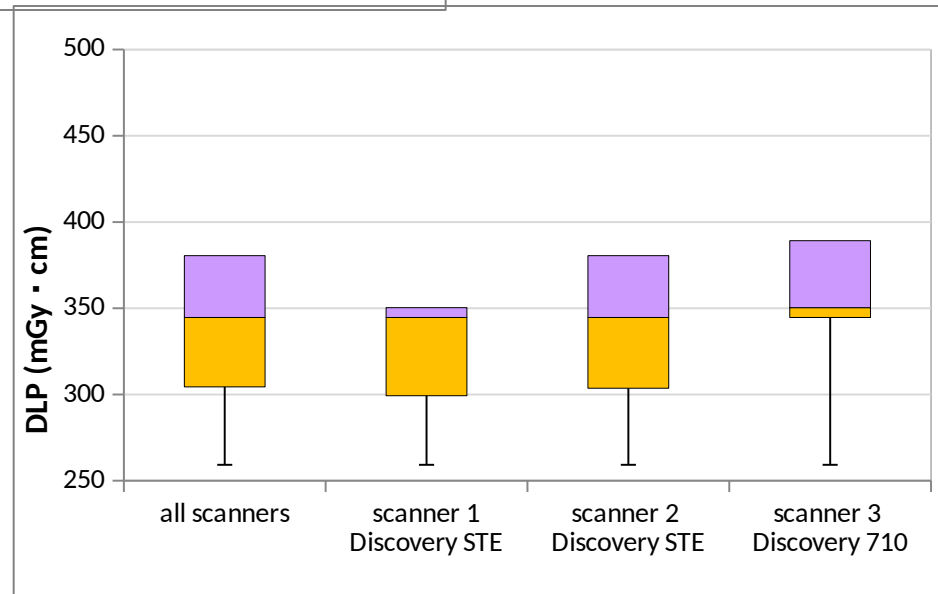
Example: assesement of local DRL for ^{68}Ga -DOTA PET-CT

CT DRL: DRL were assessed as the 75th percentile of the distribution of the values of CTDI and DLP.



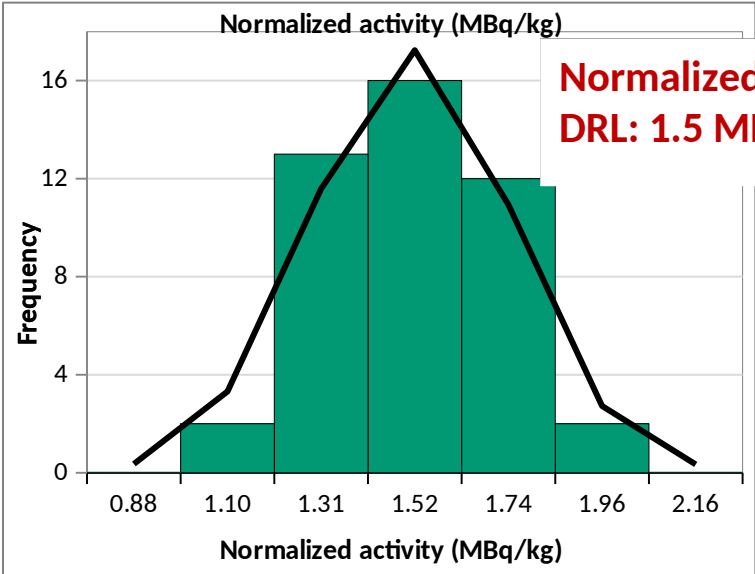
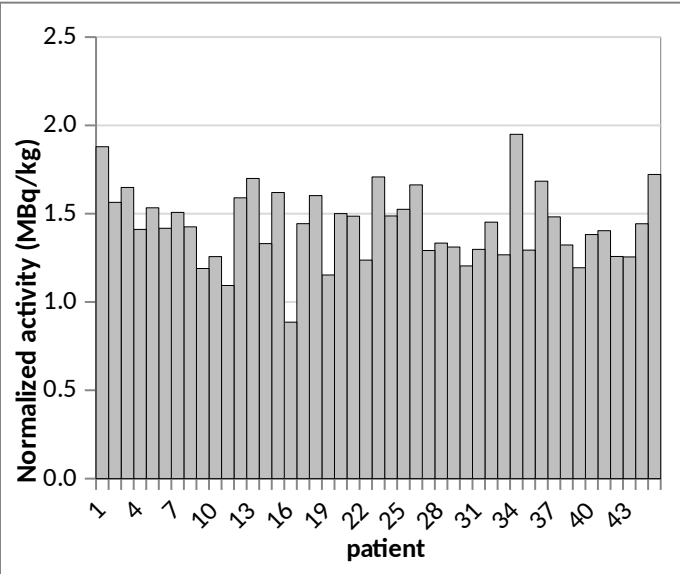
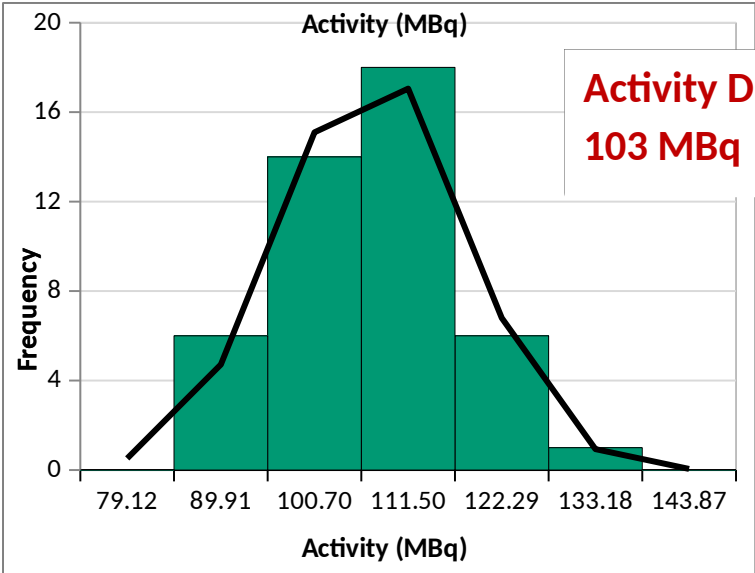
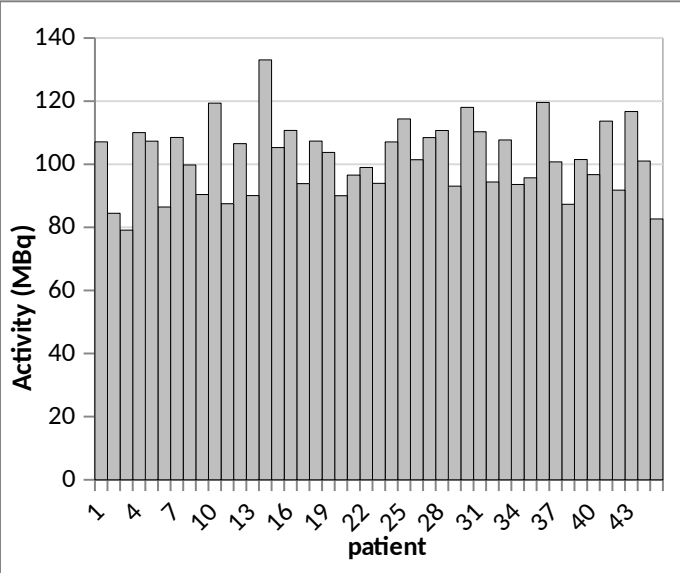
**75^o percentile CTDI:
3.82 mGy**

**75^o percentile DLP:
381 mGy·cm**

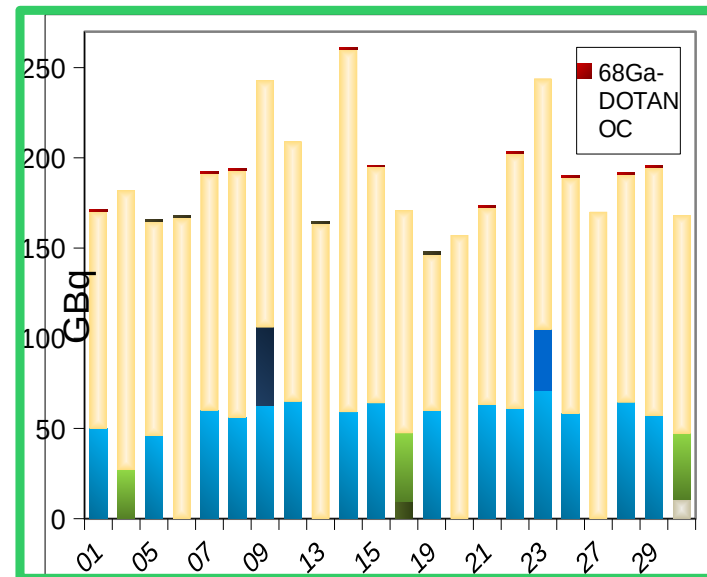
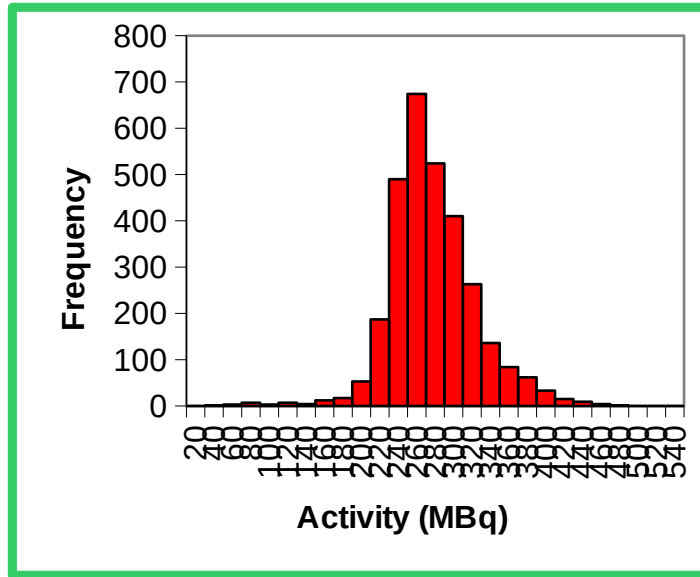


Example: assessment of local DRL for ⁶⁸Ga-DOTA PET-CT

PET DRL: DRL for administered activity were set as the mean activity in the patients' sample, obtained from the **normal distribution** fitted to observed activity values.



Software to support traceability in Radiopharmacy



- Specific softwares to support traceability are nowadays available
- Allow to trace all the process, from radionuclide production, to synthesis, QC and release of radiopharmaceuticals batches, patient's administration, image acquisition etc.
- An additional benefit that traceability software bring, is in the ease of obtaining statistics, for example, data useful for assessing the Diagnostic Reference Levels

Practical issues on setting DRLs

- DRL values are dependent on the state of practice and the available technology (including post-processing software) at a particular point in time.
- In general, median values (not mean values) of the distributions of data collected from a representative sample of patients within an agreed weight range should be used for comparison with DRL values. The mean can be affected substantially by a few high or low values.
- National DRL values should be set as the 75th percentile of median values obtained in a sample of representative centres.
- In the past in Nuclear Medicine, the mean value was used. Given the close connection with the weight of the patients, which has a normal distribution, the difference between mean and median is modest.
- If regional (multi-national) DRL values are created, they should be set as the median value of the national DRL values (each of which is set at the 75th percentile) for the countries in the region. If the sample of available data is small, other approaches may be used by agreement among the involved countries.
- The process to set and to update DRL values should be both flexible and dynamic. Flexibility is necessary for procedures where few data are available (e.g. interventional procedures in paediatric patients), or from only one or a few centres. A dynamic process is necessary to allow initial DRL values to be derived from these data while waiting for a wider survey to be conducted.



From the EU Radiation Protection Series No. 180 (2014)

Table 3.2a Summary of the DRLs for NM procedures.

Procedure	Radiopharmaceutical	Most common value, MBq	Countries with DRL equal to, or lower than, the most common value	Countries with DRL higher than the most common value	Countries with DRL when no common value was identified	Range	Max/min	Comments
Bone imaging	Tc-99m phosphates & phosphonates	600	HR, IE, LT, LV, MD, SE, UK	BG, CZ, DE, EL, ES, FI, FR, IT, LU, NO, PL, RO	-	500-1110	2,2	no SPECT or no details
Myocardial Perfusion	Tl-201 chloride	110	AT, CZ, DE, EL, FR, IT, UK	ES, LU	-	75-150	2,0	1rst injection or SPECT or no details
Myocardial Perfusion	Tc-99m tetrofosmin	1200	CH, DE, ES, FI, FR, IE, LT, LV, NO, SE, UK	IT, LU	-	300-1500	5,0	same day or no details
Myocardial Perfusion	Tc-99m MIBI	1200	AT, BG, CH, DE, ES, IE, LT, RO, SE, UK	FR, IT, LU	-	300-1480	4,9	same day or no details
Tumour imaging (PET)	F-18 FDG	-	-	-	AT, DE, FI, FR, IE, SE, UK	200-400	2,0	2D: 350-400
Thyroid metastases (after ablation, uptake 0%)	I-131 iodide	400	BG, EL, FI, IE, IT, LT, LV, PL, UK	-	-	90-400	4,4	-
Thyroid imaging	Tc-99m pertechnetate	80	CH, DE, FR, LU, PL, RO, UK	AT, BG, CZ, EL, ES, IE, IT, LT, LV, MD, NO, SE	-	75-222	3,0	-
Thyroid imaging	I-123 iodide	20	AT, CH, FR, IS, IT, LV, PL, RO, SK, UK	ES, LU	-	10-37	3,7	-
MUGA, cardiac bloodpool, cardiac blood flow	Tc-99m erythrocytes	750	-	-	AT, BG, DE, EL, FI, FR, IT, LV, RO, UK	600-1000	1,7	pyrophos. & HAS as erythrocytes

Pediatric DRLs

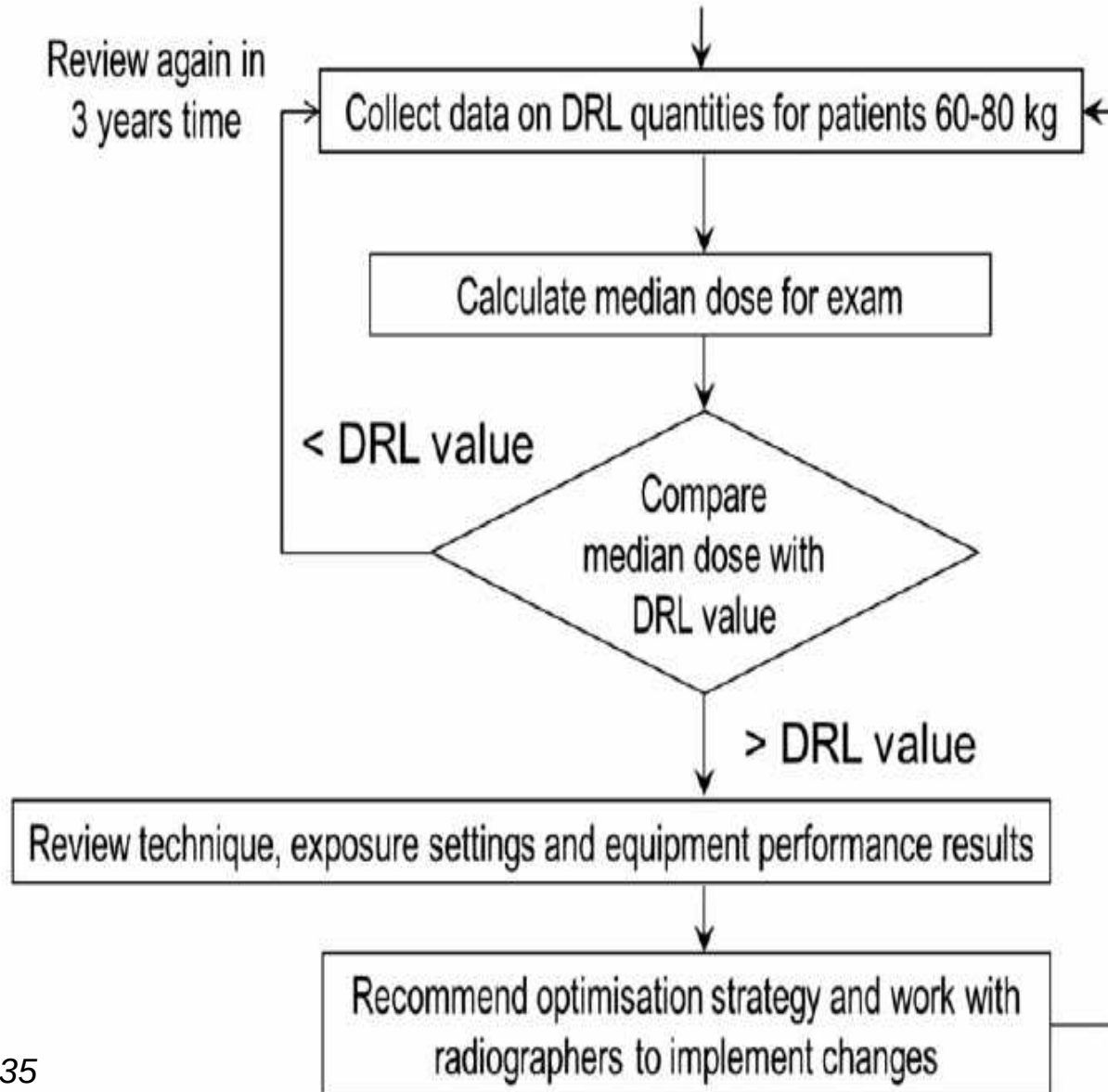
- The amount of radiation used for examinations of children can vary tremendously due to the great variation in patient size and weight, from neonates to adult-sized adolescents.
- A single 'representative patient' should not be used to define DRLs for pediatric imaging, as weight in children can vary by a factor of more than 100 from a premature infant to an obese adolescent.
- Weight bands are recommended for establishing pediatric DRL values for examinations of the trunk and should be promoted for paediatrics. Age bands can be used if age is the only available measure.
- For nuclear medicine imaging, consideration should be given to adjusting administered activities based on agreed factors linked to weight. Adjustments should be made for paediatric examinations. See the EANM/SNM dosage card.

<https://www.eanm.org/projects/dosage-calculator/>

- Modern CT scanners permit determination of effective diameter or patient equivalent thickness. This should be considered as an additional refinement for setting pediatric DRLs.



Patient dose survey and optimisation



From ICRP 135
(2017)



IAEA QUANUM 3.0

3.5	Is there an SOP establishing local Diagnostic Reference Levels for administered activity, cross referring to national or international regulations or guidelines?
3.6	In case of multimodality imaging: Is there an SOP establishing local Diagnostic Reference Levels for X-ray dose, cross referring to national or international regulations or guidelines?

BSS, 2014 Edition

3.154. Registrants and licensees shall ensure that:

- (a) The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients during the planning and delivery of the medical exposure, including the justification of the procedure ... and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiation technologist ...
- (e) For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment ... are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks;

Calibration

3.167. ... the medical physicist **shall** ensure that:

- (a) All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;



RADIONUCLIDE ACTIVITY CALIBRATORS



The “dipper”, to position samples



Detector, surrounded by its shielding

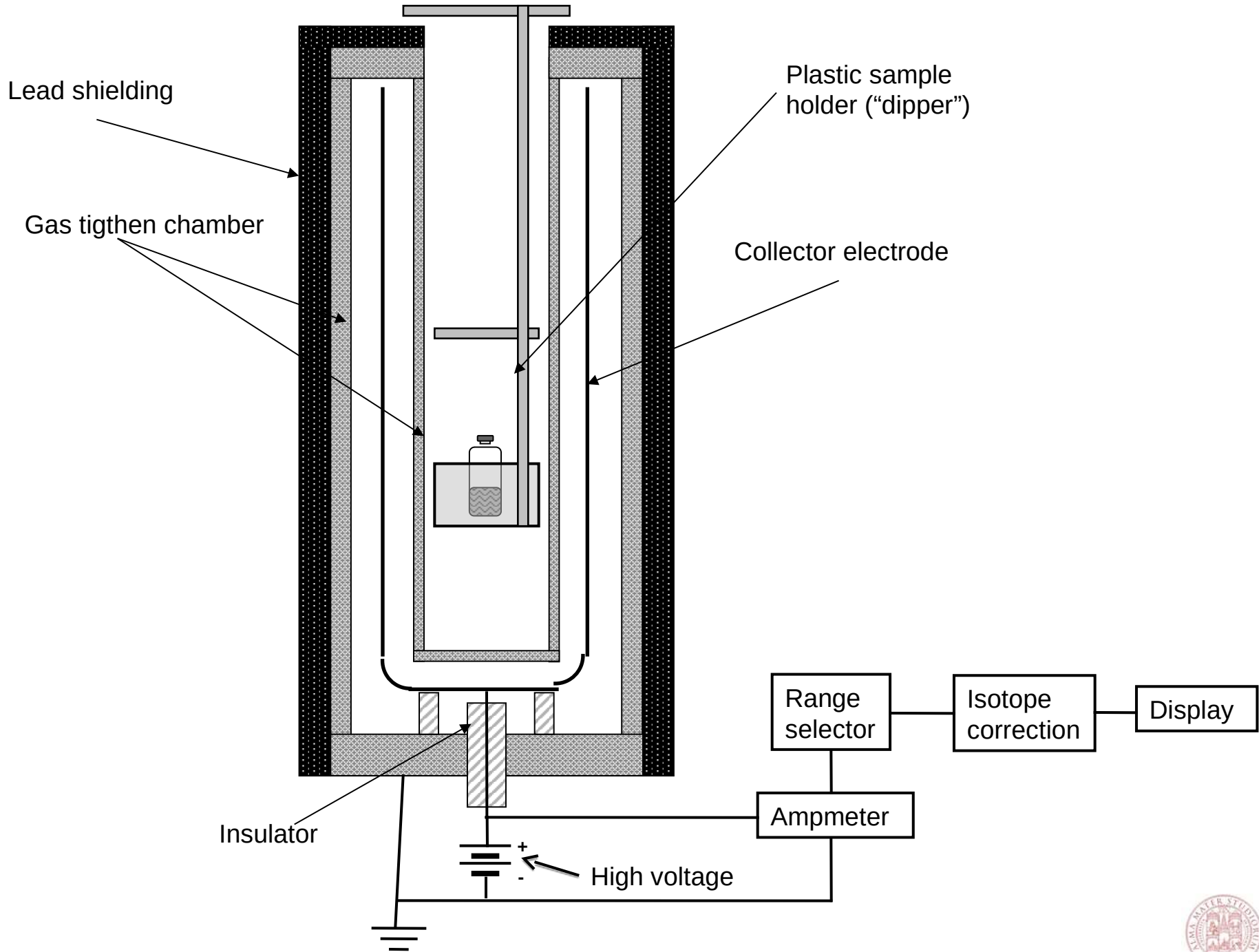


Control unit and display

General characteristics

- Designed to allow measurement of the activity in samples of radiopharmaceuticals
- It is sensitive essentially to X and γ radiation
- Can accurately measure activity in the range 1 MBq – 100 GBq
- Short time for stable response, typically (2 -10) seconds
- Calibrated to measure single radionuclide samples
- Position and shape of the sample may require correction factors



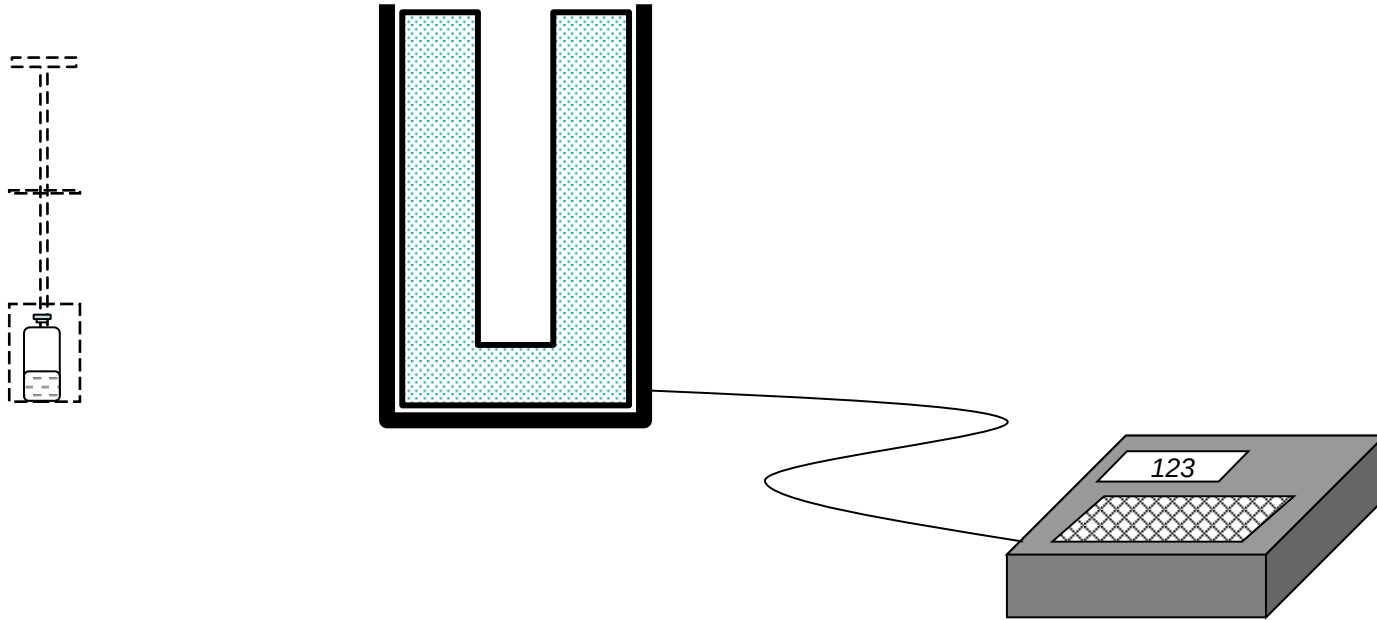


Typical dimensions and data

- Biasing voltage change with manufacturer and model (~ 150 V for Capintec, ~ 450 V for Atomlab)
- In most instruments the DC bias is supplied by a rechargeable battery; for optimal performance, they should normally left ON at all time.
- The cylindrical chamber has a diameter of ~ 16 - 20 cm, and an height of ~ 40 - 50 cm
- The internal well has a diameter of ~ 6 cm and depth of ~ 25 cm.
- The internal walls of the well are lined with a removable thin layer of Polymethylmethacrylate, in order to allow for easy decontamination
- A PMMA sample holder allows for reproducible positioning of different types of samples (vials, syringes, ...)
- The chamber is shielded with Lead, typically 3 - 10 mm, to reduce interference from external radiation
- The chamber is typically in Aluminum
- The filling gas is pure Argon, at a pressure of several bar, depending on the field of use (e.g. 10 – 12 bar for SPECT calibrators, 5 – 6 bar for PET calibrators)

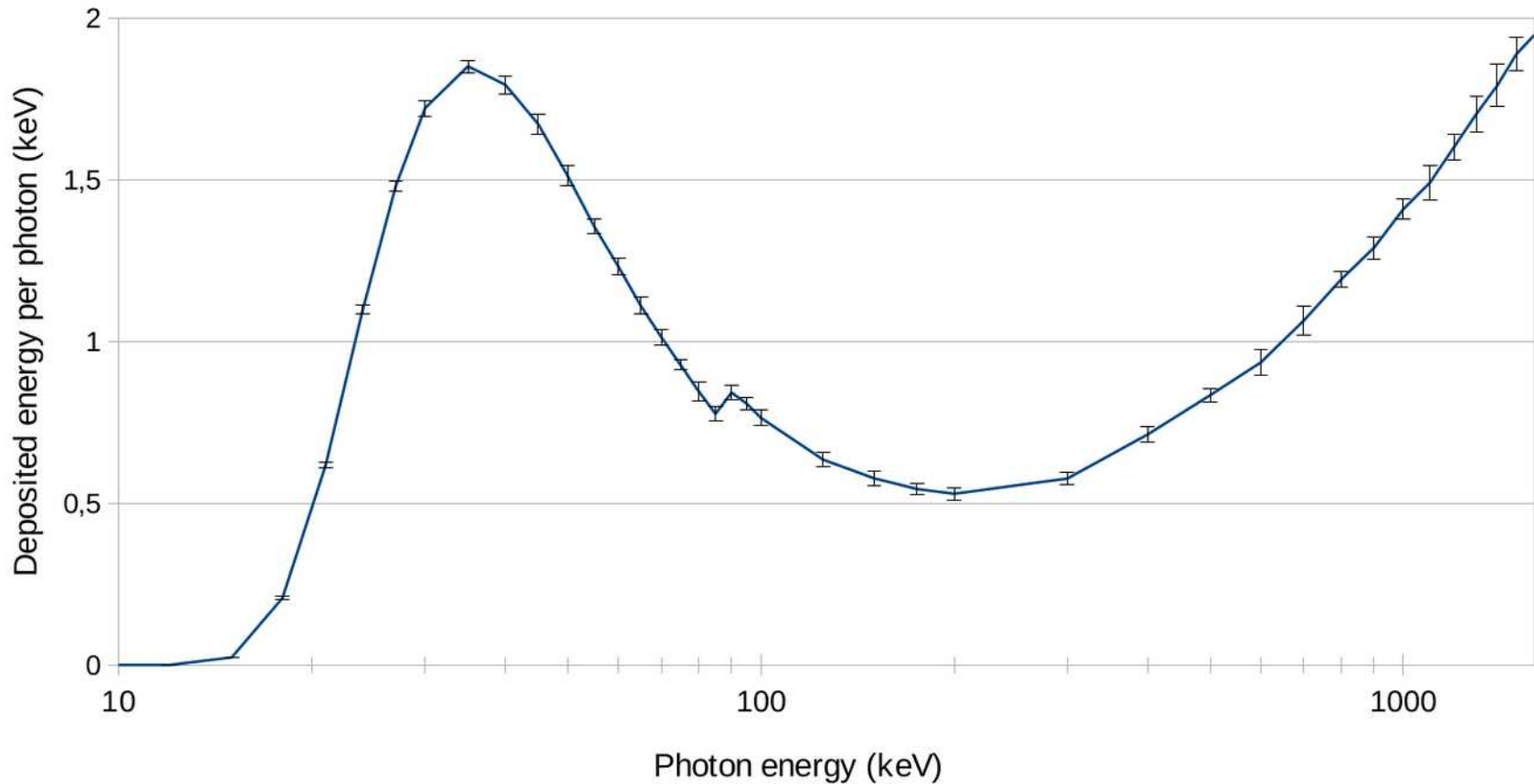


Measurement of activity with a radionuclide meter



- Operation of a radionuclide activity meter is so easy that the principle of operation is not always properly considered !
- The activity meters is not a “discriminator” instrument; when selecting a radionuclide, the operator is not “peaking” on specific gamma ray emission of the radionuclide of interest.
- Rather, activity meter gives a reading that is proportional to the total charge produced by all radiation in the decay scheme of a radionuclide

Response as a function of gamma ray energy



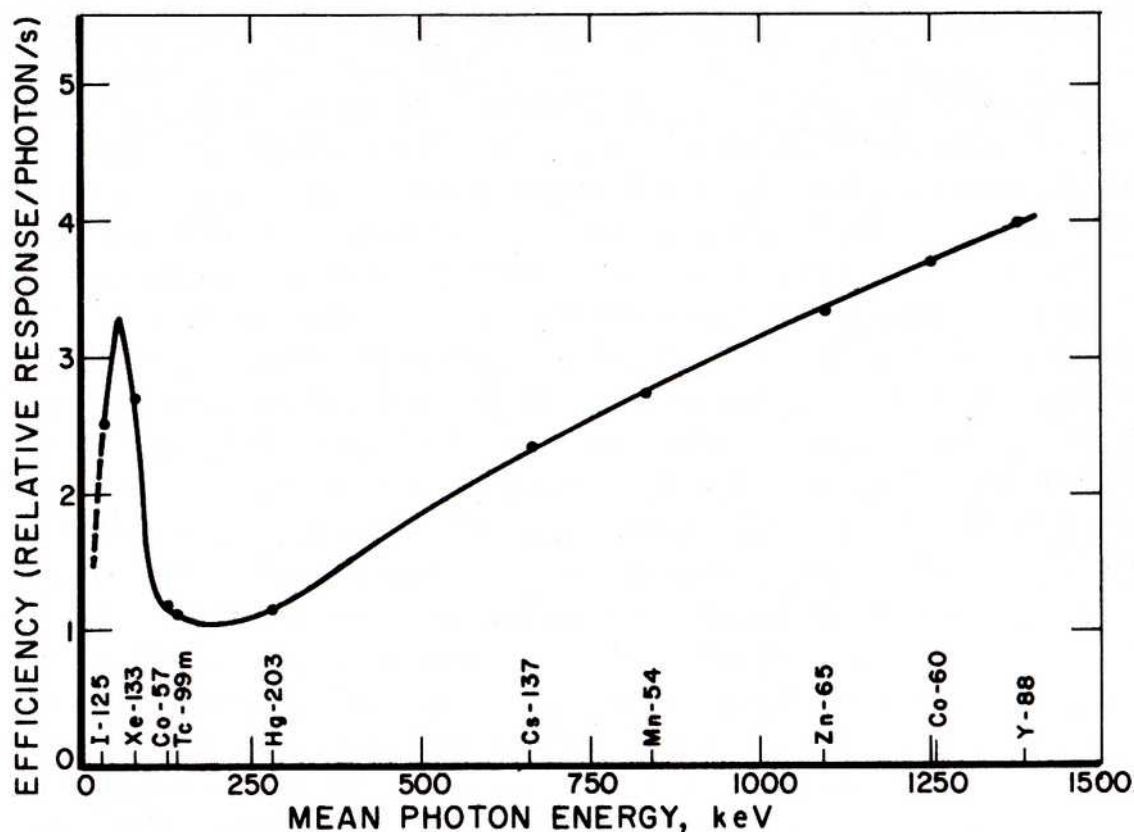
Zagni F., et al.: "Monte Carlo modeling provides accurate calibration factors for radionuclide activity meters".
Applied Radiation and Isotopes 94 (2014) 158–165



Calibration Factors

“Historical” approach: relative factors

- The total ionization current produced in the detector is proportional to the activity of the sample and to efficiency of the detector itself.
- The efficiency depends on photon's energy and on the gas pressure



$$\text{Activity } A = K_R \frac{I}{y \cdot I_{\text{Ref}}}$$

K_R relative calibration factor



K_R can be determined on the basis of the response to one single certified source of known activity for a long lived radionuclide (e.g. ^{137}Cs)

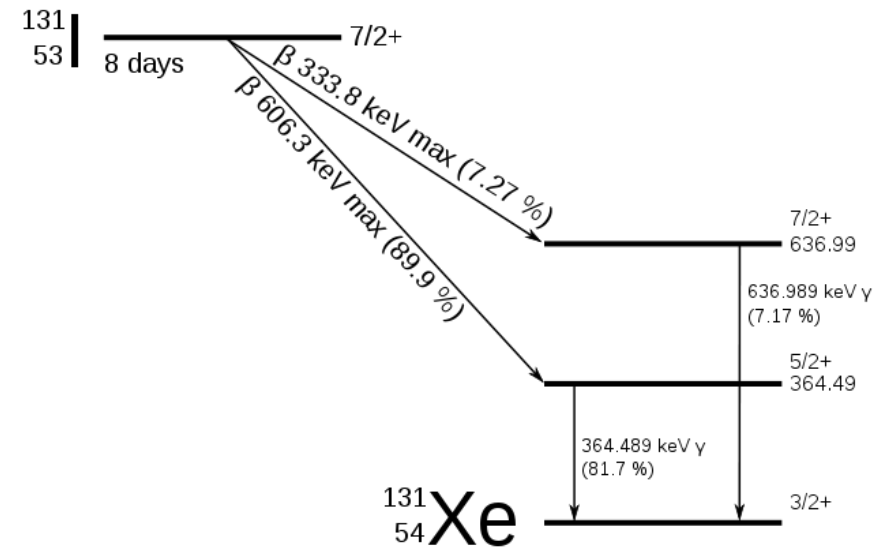
Calibration Factors

“Historical” approach: relative factors

The Calibration Factor depends on:

- Type of radiation
- Energy
- Relative abundancy

$$A = \frac{I}{I_{\text{Ref}}} \sum_i \frac{K_{R,i}}{y_i}$$



- Problems for multi-peak radionuclides
- The process is not traceable to international standards of activity.



Calibration of activity meters



IAEA Requirements

IAEA BSS Requirement 38: Optimization of protection and safety Registrants and licensees and radiological medical practitioners shall ensure that protection and safety is optimized **for each** medical exposure.

IAEA BSS 3.154 Registrants and licensees shall ensure that: ... For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, ... are fulfilled by or under the oversight of or with the documented advice of a medical physicist ...

Calibration

IAEA BSS 3.167. In accordance with para. 3.154(d) and (e), the medical physicist shall ensure that:

- (a) **All sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;**
- (b) Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body;
- (d) Calibrations of radiation therapy units are subject to independent verification⁴⁵ prior to clinical use;
- (e) **Calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory.**



Calibration and QA/QC of activity meters

While calibration of activity meters is described in a variety of relevant international documents,

- INTERNATIONAL ELECTROTECHNICAL COMMISSION, Medical Electrical Equipment: Radionuclide Calibrators – Particular Methods for Describing Performance, IEC 61303(1994-10), IEC, Geneva (1994).
- INTERNATIONAL ELECTROTECHNICAL COMMISSION, Calibration and Usage of Ionization Chamber Systems for Assay of Radionuclides, IEC 61145(1992-05), IEC, Geneva (1992).
- AMERICAN NATIONAL STANDARDS INSTITUTE, Calibration and Usage of 'Dose Calibrator' Ionization Chambers for the Assay of Radionuclides, ANSI Std N42.13-1986, ANSI, Washington, DC (1986).
- IAEA, Quality Assurance for Radioactivity Measurement in Nuclear Medicine. Technical Reports Series No. 454, IAEA, Vienna, 2006.

in practice it is still not always understood and correctly propagated.

IAEA SSG-46, para. 4.53. The nuclear medicine facility should have equipment, ... activity meters (dose calibrators), ..., check sources, Where applicable, such instrumentation should adhere to relevant IEC standards or national equivalents. Further guidance on appropriate equipment, instruments and test objects is given in Refs [215, 224, 227, 230].



Why calibration of activity meters is so relevant ?

- As a difference compared to Radiology, in Nuclear Medicine the exposure of the patient do not happens at the time of imaging (*or at least, in the case of multi-modality systems, not only*)
- The exposure is determined by the act of administering the radiopharmaceutical
- This may happen hours before the examination
- The effective dose absorbed by the patient is determined by the the activity administered (*type of radiopharmaceutical, route of administration, patient size, eventual modifiers of the bio-distribution, ecc.*)



The activity meter is the equipment used to measure the physical quantity determining patient's effective dose.

Its role in optimization of patients exposures in NM is fundamental.

Calibration of activity meters

Basically, an activity meter should be calibrated:

➔ for each radionuclide of clinical interest, by either:

(a) using a certified reference source of the same radionuclide, traceable to international standards. This approach is feasible for many radionuclides (^{131}I , ^{90}Y , ^{177}Lu , ^{67}Ga , ^{51}Cr , ... and also ^{18}F). Traceable, certified sources (or, in some cases, “mock” sources) are commercially available.

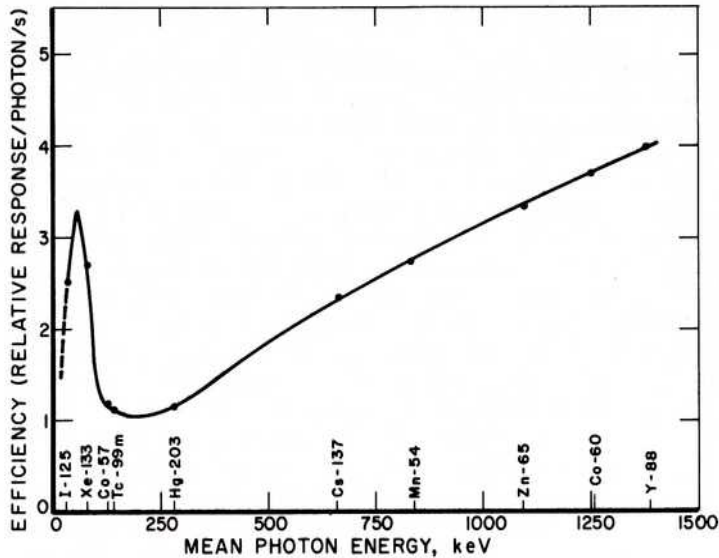
(b) by intercomparison with another instrument, independently calibrated. This results better feasible for some relevant short lived radionuclides ($^{99\text{m}}\text{Tc}$, ^{11}C). The intercomparison may be against another calibrated activity meter, or to a calibrated gamma-ray spectrometry system (allowing for decay time, to obtain acceptable count frequencies).

It should be noted that “calibration factors” supplied by the manufacturer with each new instruments, are only indicative values:

- Unless not accompanied by a certificate of calibration of a Secondary Standard accredited laboratory
- “Calibration” performed at the factory, is in general not traceable to international standards



What is not a traceable calibration



- Routine control of the calibration e.g. with long lived sources do not represent a valid proof of calibration for the radionuclides in clinical use
- The use of “calibration factors” derived from an Energy – Efficiency curve, even if obtained using certified sources, is not traceable to standards
- Calibration with a traceable source of ^{137}Cs , means the the instrument can accuately measure this radionuclide, but do not means that the activity meter is calibrated for $^{99\text{m}}\text{Tc}$, ^{18}F or ^{131}I .

What is not a traceable calibration

- In many Countries, a periodical calibration of activity meters is already mandatory
- In several Countries this has to be made in a specific National Laboratory (for a cost)
- Some National Laboratories, continue to issue “Calibration certificates” based on testing activity meters with a set of long lived certified sources (typically ^{137}Cs , ^{57}Co , ^{133}Ba , ^{60}Co).
- These represent a good test of the equipment, but **do not correspond to a calibration for the radionuclides of clinical use.**
- The same type of test could be done by the final user, simply acquiring the same set of standard sources.
- While this practice grants a formal management of the calibration process, **it do not answer to the BSS requirements in terms of calibration and optimization of patients exposures.**



Typical sources used for periodical accuracy testing

Radionuclide	$T_{1/2}$	E_{γ} (keV)
^{137}Cs	30 years	662
^{57}Co	271 days	122, 136
^{60}Co	5.27 years	1173, 1332
^{133}Ba	10.5 years	35, 81, 303, 356

It is strongly recommended that at least one ^{137}Cs is available in every NM Department, to test activity meters.

It is advisable that more sources are available.

Test sources should be calibrated, with accuracy stated (typically < 5 %) , and be traceable to international standards.



How to transfer a calibration in time

Performing a calibration for a short lived radionuclide may be cumbersome, due to availability of a certified source, cost, etc.

However, once a similar calibration has been made, it can be “transferred” in time:

1. Consider ^{99m}Tc ; the calibration is performed (e.g. by intercomparison with a calibrated gamma ray spectrometry system)
2. A long lived standard source (e.g. ^{137}Cs) is measured selecting as the radionuclide ^{99m}Tc
3. The result obtained in this way (that is not in “correct” Bq) is stored for future comparison
4. After a period of use (e.g. 1 year), the measure of the same long lived source is repeated, again selecting the ^{99m}Tc pushbutton
5. If the reading is constant (taking into account decay), it can be considered that performance on the instrument is stable and the calibration factor for ^{99m}Tc is still valid (has been “transferred” in time).



Further correction factors

- Further correction factors can be applied to the equipment reading to take into account for the specific shape (syringe, vial), volume of filling and material (glass, plastic) of the container
- These correction factors depend strongly from the energy of the radiation emitted by the radionuclide of interest
- for ^{99m}Tc , “syringe” correction factors for the range of volumes used in clinical practice, are typically 0.9 – 1.1 (e.g correction is less than 10%)
- In the case of radionuclides emitting relatively intense low energy X-rays (e.g. ^{123}I), correction factors for the container may be significant, and change considerably from vial to syringe and from one type of syringe to the other
- For radionuclides emitting only β particles (e.g. ^{90}Y), the measurement is based on the detection of bremsstrahlung X-rays; correction factors depend strongly on the volume of the sample, type and material of the container. They should be carefully determined case by case.



Calibration and QA/QC of activity meters

- The modalities of calibration are well known and documented in relevant international standards
- In particular in IAEA TRS 454 (2006)
- However, the propagation of measurement units (the Bq) according to modalities traceable to international standards for the radionuclides of clinical use, still encounter difficulties
- An effort is necessary to improve quality standards, both from final users in clinical activity AND national standardization laboratories



Conclusions - I

- Radionuclide activity meters are the fundamental instrument to measure the activity of radiopharmaceuticals.
- At least one activity meter should be available in any Nuclear Medicine Department.
- It is the equipment most directly connected with radiation protection of the patient in Nuclear Medicine, since the physical quantity measured (the Activity) is the one determining the exposure of the patient.
- Activity meters are the fundamental to assess Diagnostic Reference Levels for Nuclear Medicine examinations.
- The use of radionuclide activity meters is apparently simple, but in order to obtain accurate and reliable results it is necessary to understand their principle of operation and calibration modalities.
- As for all equipment used in the radiological area, activity meters need to be part of a well designed program of routine Quality Control.



Conclusions - II

DRLs should be established Nationally **AND** Locally; Scientific Associations and end users (WE !), **together** with Health Authorities and Regulatory Bodies, have the responsibility to set out them, under the supervision and control of National Authorities.

IT systems are nowadays fundamental to support data collection for assessment and review of DRLs.

The DRL process should be used to evaluate whether, in routine circumstances, the amount of ionising radiation applied for a medical imaging procedure at a local healthcare facility, when assessed for a representative sample of patients for a defined clinical task, is too high or too low.

A DRL value is considered to be consistently exceeded when the local median value of the appropriate DRL quantity for a representative sample of patients within an agreed weight range is greater than the local, national, or regional DRL value.

mario.marengo@unibo.it

