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PROPOSAL OF QUALITY ASSURANCE SYSTEM FOR POSITRON EMISSION TOMOGRAPHY IN THE RUSSIAN FEDERATION

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Current status of PET in Russia

- 50 PET units in operation in 2019
- 10+ PET units to be installed in 2020
- 50% with local radiopharmaceutical production with cyclotron
- Equipment is diversified by vendor and generation (age)
- Differences in clinical protocols and radiologist training
- Incomparable quantitive results in different PET departments

QA in regulatory documents

SanPiN 2.6.1. 3288-15:

QA program should include:

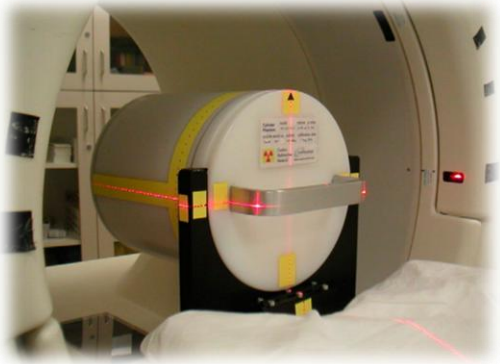
- QC
- Patient preparation
- Optimization of the acquisition protocols
- Reporting
- Collecting and removing the waste
- Training of the staff in the field of radiation protection
- QC of radiopharmaceuticals

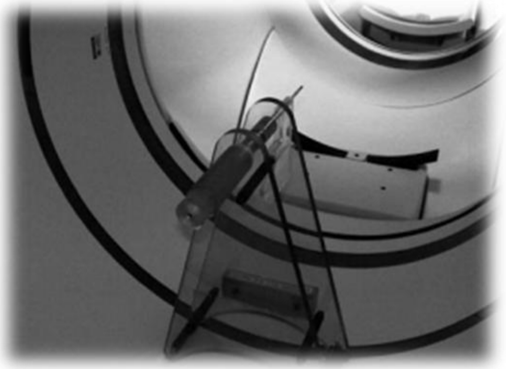
In practice

- The lack of requirements on the acceptance and periodical tests of diagnostic equipment
- The lack of requirements of the QC of radiometers and measurement equipment
- The lack of recommendations for the protocol optimization
- The lack of dedicated staff (medical physicists)

QC of diagnostic equipment

- Acceptance tests
  - At the installation to estimate the baseline characteristics
    - PET (vendor specific / NEMA standards (international) / GOST R MEK 61675-1 – 2013 (for vendor engineers)
    - CT (GOST R MEK 61223-3-5 – 2008)
- Periodical tests
  - Focused on the constantly of the parameters and characteristics
    - PET (vendor specific)
    - CT (GOST R MEK 61223-2-6 – 2001)

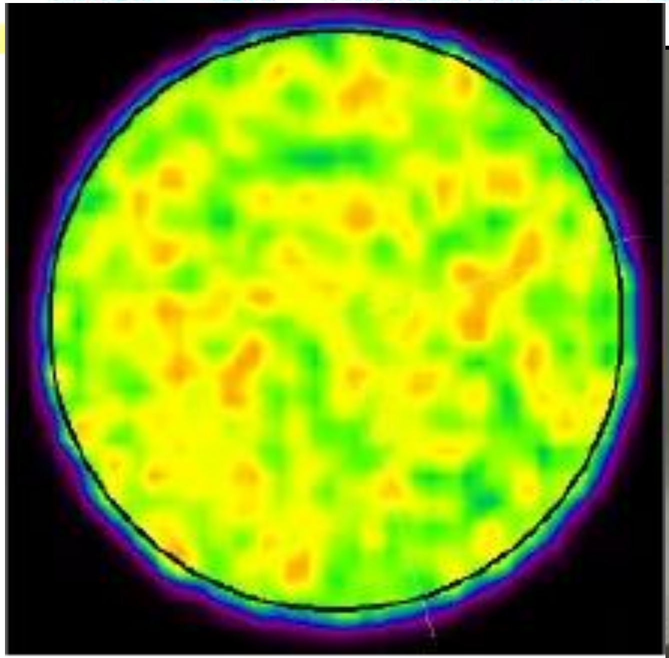




QC of measurement equipment

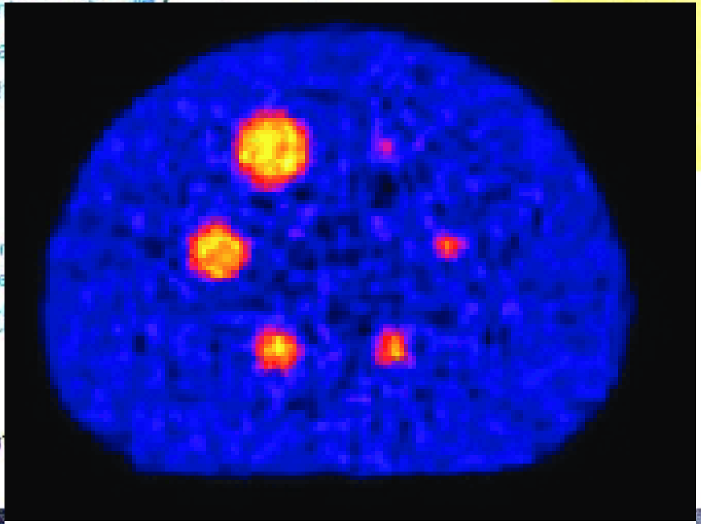
- calibration should be performed for all radionuclides that are used in the department
- annual calibration according to an approved methodology
- constant monitoring of the zero value
- daily stability control with the same radioactive source (for example, ^{137}Cs)
- annual accuracy control with calibration sources preferably in the range of low, medium and high energies (for example, ^{57}Co - 122 keV, ^{133}Ba - 356 keV and ^{137}Cs - 662 keV)
- annual linearity control covering the entire range of work activities (usually from a few GBq for daily package to the lowest diagnostic activities - tens of MBq)

Cross-calibration (quarterly)

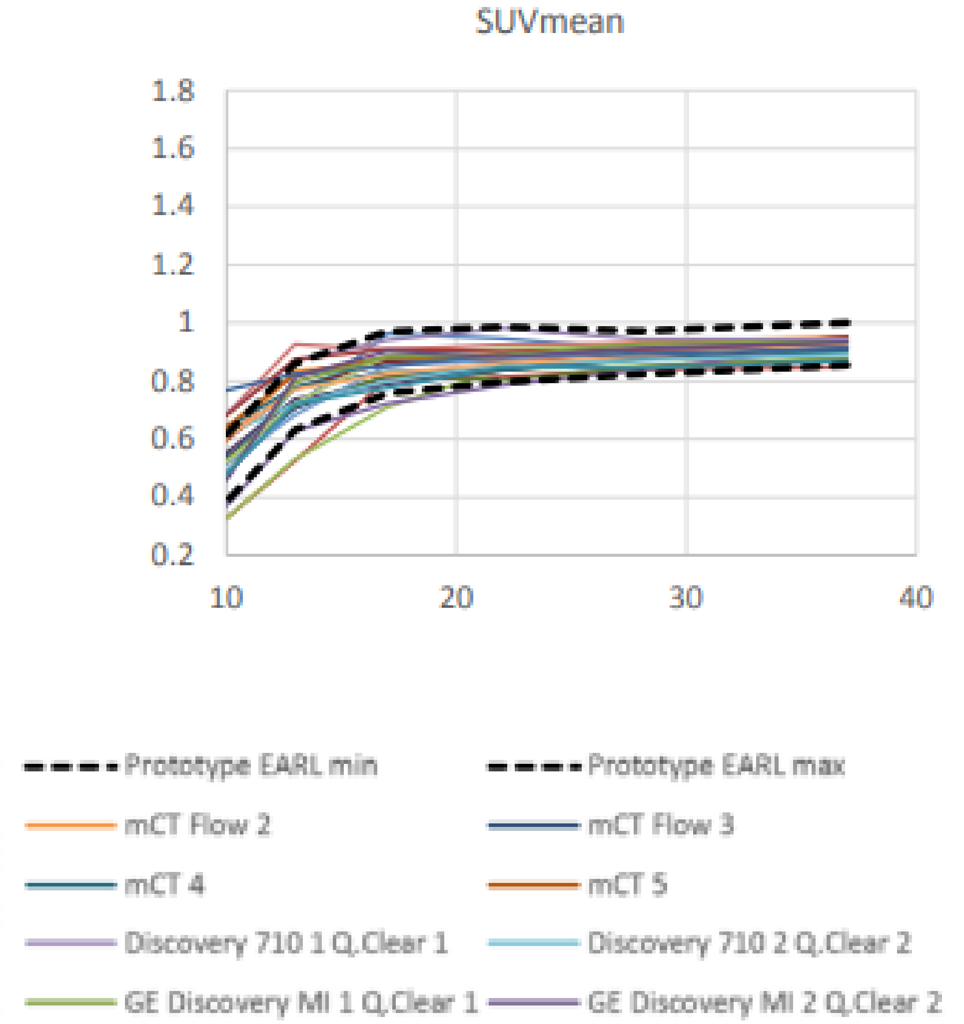


QC of diagnostic images

NEMA IEC Body phantom



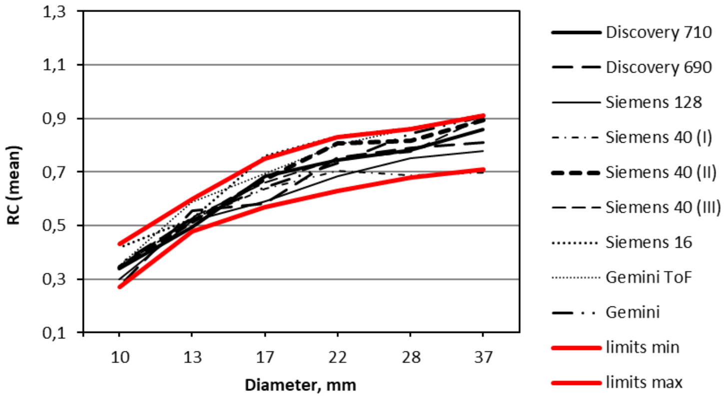
PET image (axial slice) of NEMA IEC Body phantom



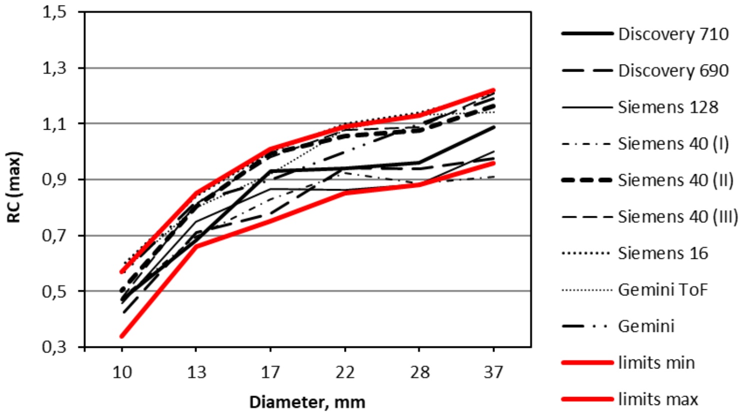
QC of PET images with NEMA IEC Body

$$RC = \frac{A_{image}}{A_{true}}$$

RCmean



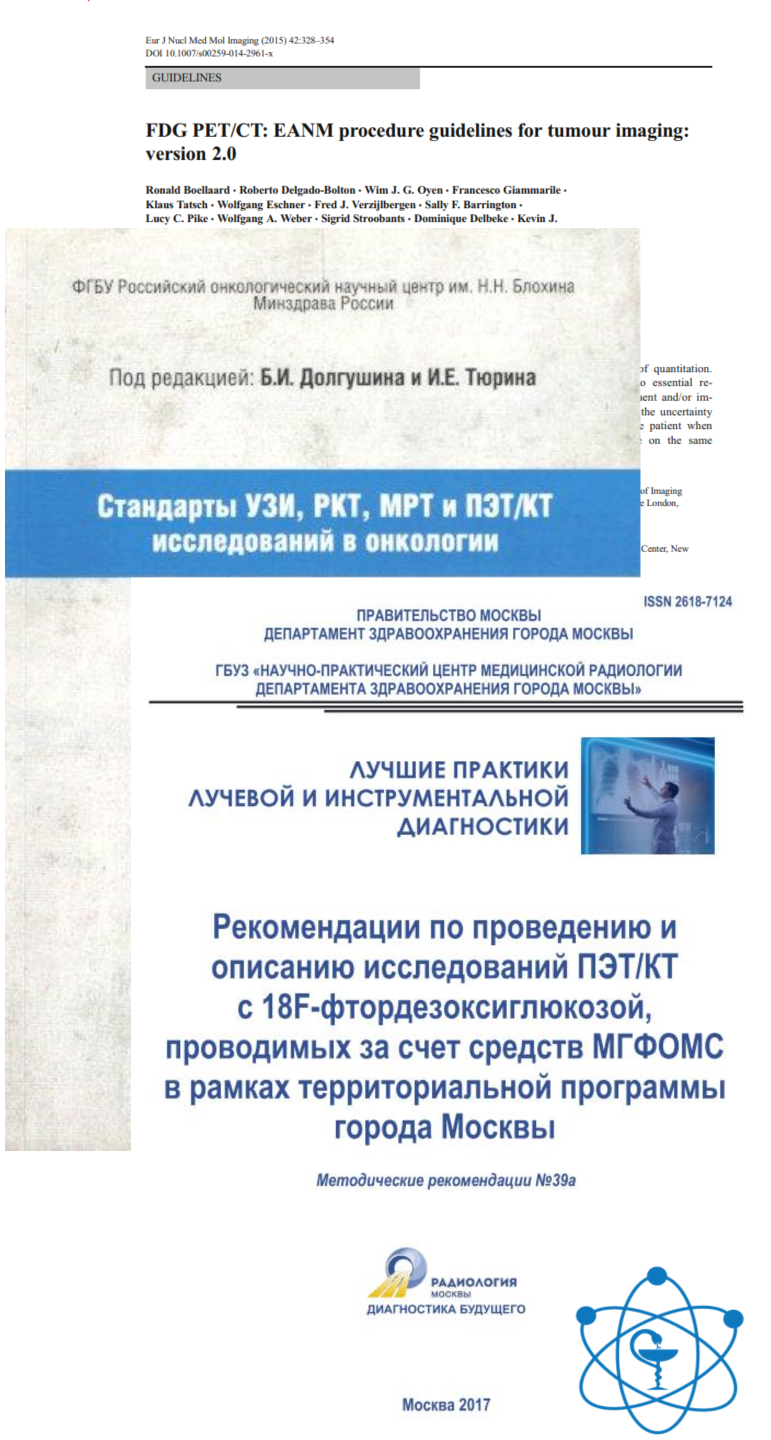
RCmax



- QC methodic:
  - Scanning of NEMA IEC
  - RC calculation
  - Comparison with the criteria
- RC (recovery coefficients) allow to:
  - Estimate the real activity accumulated in the lesion
  - Provide the opportunity to compare the results from different PET systems

Requirements of the development of standard operating procedures

- requirements for preparation of the patient for the examination
- methods for calculation of the administred activity of radiopharmaceutical
- requirements for radiopharmaceutical injection
- time from injection to the scan
- acquisition and reconstruction protocols, as well as image processing
- staff involved at each stage of the examination



НИИРГ

Patient dose monitoring

Radiopharmaceutical (MU 2.6.1.3151-13)

2.6.1. ГИГИЕНА. РАДИАЦИОННАЯ ГИГИЕНА. ИОНИЗИРУЮЩЕЕ ИЗЛУЧЕНИЕ, РАДИАЦИОННАЯ БЕЗОПАСНОСТЬ

Оценка и учет эффективных доз у пациентов при проведении радионуклидных диагностических исследований

Методические указания МУ 2.6.1.3151—13

Radiopharmaceutical	Dose coefficients, mSv/MBq				
	Adult	15 y.o.	10 y.o.	5 y.o.	1 y.o.
^{11}C-methionine	0,0084	0,011	0,017	0,026	0,047
^{11}C-choline	0,0043	0,0055	0,0086	0,014	0,026
^{13}N-ammonie	0,002	0,0024	0,0036	0,0067	0,011
^{18}F-FDG	0,019	0,024	0,04	0,06	0,1
^{18}F-NaF	0,024	0,03	0,046	0,076	0,15
^{18}F-DOPA	0,025	0,032	0,049	0,07	0,1
^{68}Ga-PSMA	0,020	-	-	-	-
^{68}Ga-DOTA TATE/NOC	0,026	-	-	-	-

CT (MU 2.6.1.2944-11)

2.6.1. ИОНИЗИРУЮЩЕЕ ИЗЛУЧЕНИЕ, РАДИАЦИОННАЯ БЕЗОПАСНОСТЬ

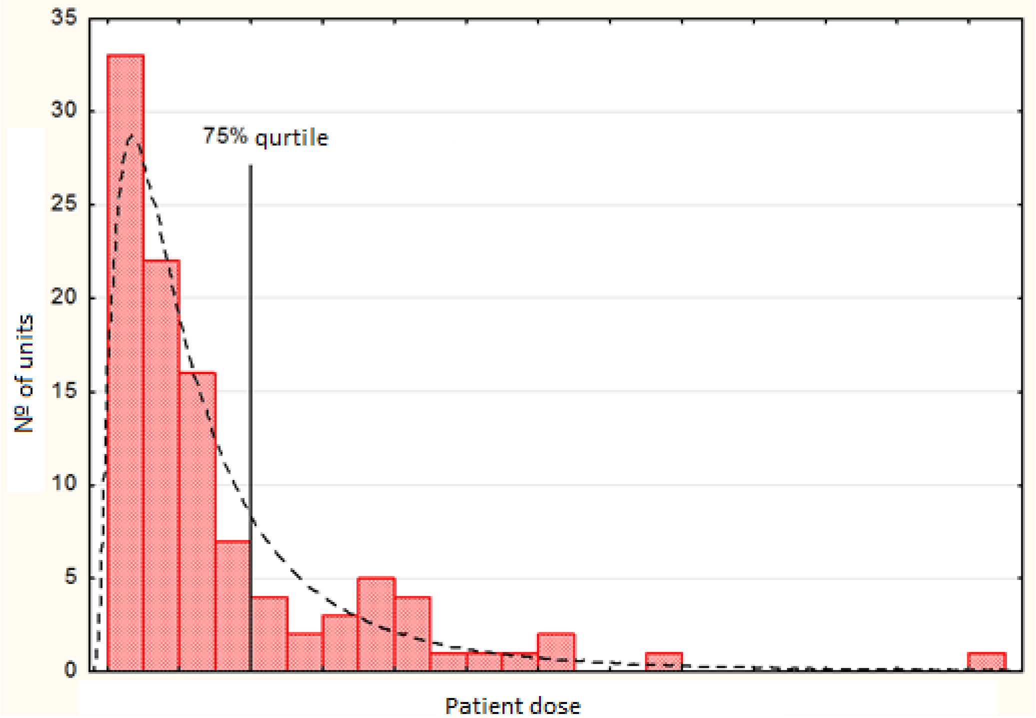
Контроль эффективных доз облучения пациентов при проведении медицинских рентгенологических исследований

Методические указания МУ 2.6.1.2944—11

Anatomical region	Dose coefficients, mSv/mGy cm					
	Adult	15 y.o.	10 y.o.	5 y.o.	1 y.o.	Newborn
Head	0,0023	X1,1	X1,3	X1,7	X2,2	X2,6
Neck	0,0054					
Chest	0,017	X1,1	X1,4	X1,6	X1,9	X2,2
Abdomen	0,015	X1,1	X1,5	X1,6	X2,0	X2,4
Pelvis	0,019					
Whole body	0,017	0,020	0,027	0,031	0,038	0,043
Chest/Abdomen	0,013	0,017	0,028	0,036	0,051	0,065
Abdomen/Pelvis	0,015	0,019	0,031	0,041	0,059	0,075
Extrimities	0,0002	0,0003	0,0007	0,0010	0,0018	0,0027

НИИРГ

Optimization of radiation protection. Diagnostic reference levels

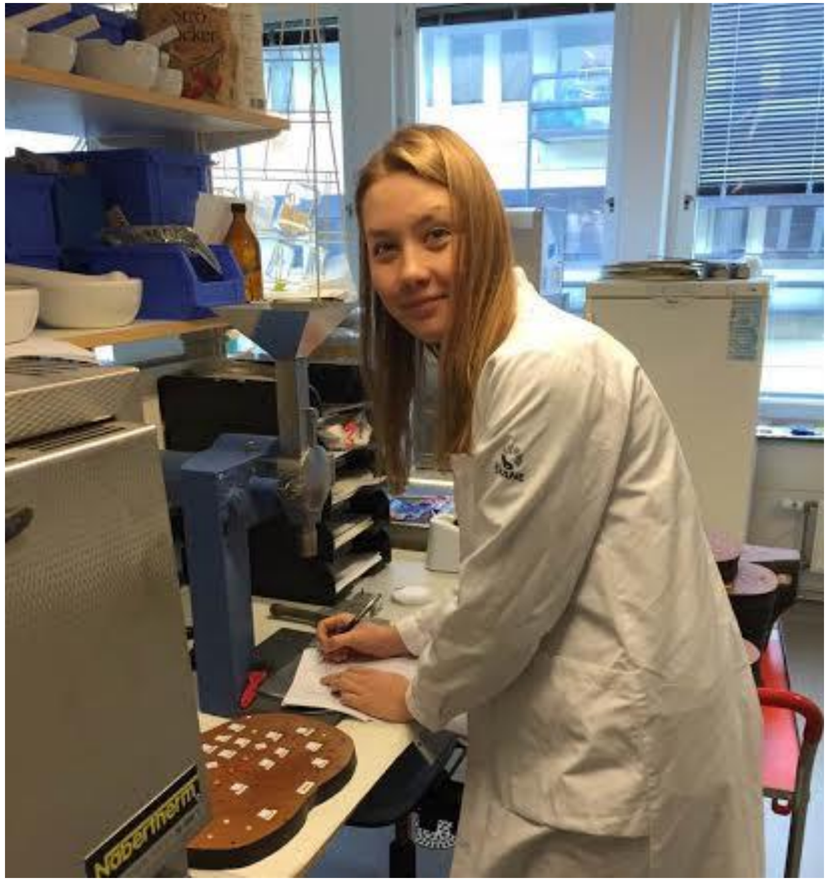


Diagnostic reference levels for CT in PET/CT in Russia

Anatomical region	DLP, mGy·cm	Effective dose, mSv
Head	1200	2
Whole body* (low-dose protocol)	600	9
Whole body* (diagnostic protocol)	1000	15

Conclusion

- Although the developed methodologies are not revolutionary and exist in European practice this is a major step in Russia
- It should be noted that the guidelines were developed jointly with the vendors, radiologists and NM physicians meaning that they would be implemented in practice
- The guidelines include the mandatory sets of tests for the equipment that would be included into the service contract
- The guidelines are maximally harmonized with the EANM accreditation program this will allow promoting EANM program in Russian medical facilities



Thank you for your attention!

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