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

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Abstract: High diagnostic efficiency as well as the optimization of patient and staff doses in positron emission tomography (PET) can be achieved by implementing quality assurance program. This study was focused on the requirements and basic aspects of quality assurance (QA) in PET combined with computed tomography (CT), that include equipment quality control (QC). QA systems include methods of image QC, examination protocols, radiation monitoring and optimization of radiation protection of the staff and patients. This paper contains the proposals for the QC of equipment and diagnostic images, as well as values of diagnostic reference levels (DRLs) for identification of abnormally high patient doses and optimization of radiation protection. Authors propose the system of quality assurance in PET considering the features of Russian healthcare and radiation protection.

Keywords: positron emission tomography, computed tomography, quality assurance, quality control, diagnostic reference levels, radiation protection

1. Introduction

Positron emission tomography (PET) is a diagnostic method, which is based on gamma-rays emitted from radiopharmaceuticals injected into the patient. The distribution of radiopharmaceuticals in organs and tissues modulates pathological and biochemical processes. The PET modality is used for diagnostics of endocrinological, neurological, cardiological and other diseases. However, PET is mainly used for diagnostics

and staging of oncological diseases as well as the assessment of treatment effectiveness of oncological patients. Modern PET systems are commonly combined with computer tomography (CT), which provides additional information of the structure that can be combined with PET images of functions of the investigated organs.

The amount and quality of diagnostic information obtained by PET depends on the different medical and technical factors. The medical factors include methods of patient preparation and examination protocols, which should be standardized and executed by the medical staff. Technical factors include detector's characteristics, settings and calibration of diagnostic and measuring equipment, acquisition and processing protocols. Different methods of patient preparation, examination protocols and different PET equipment can provide incomparable quantitative results if the examinations are performed in different medical facilities [1,2]. This is especially important for oncological patients, who have to repeat the examination after the treatment, which should be done at the same hospital using the same equipment as prior to the treatment. The inaccessibility of specific equipment can postpone necessary examinations and lead to negative consequences for the patient.

The PET method is rapidly developing in the Russian Federation [3,4]. In the past decade the number of PET departments in the country has increased by a factor of 5. Currently, there are about 37 departments and their number continues to increase. An availability of the PET method makes it possible to perform PET/CT

examinations for the same patient at different stages of treatment in various medical facilities. This expansion requires that national quality assurance (QA) system in PET diagnostics is developed. Such system should include harmonization of examination protocols, consider the features of national clinical and regulatory aspects of PET diagnostics, and should be harmonized with international standards and guidelines [5,6].

The European Association of Nuclear Medicine (EANM) developed a program for the accreditation of PET departments (EARL) [7–9] based on the control of quantitative parameters of a PET image using a standard phantom. Departments that fulfil the requirements of that program receive a certificate of compliance to the EANM standard. That program allows harmonizing examination protocols of PET equipment from different vendors and obtaining comparable results. Accreditation in that program additionally allows participating in the different international clinical trials without an additional equipment testing.

Unfortunately, only some vendor specific quality control (QC) procedures has been published in Russia, as a draft of QA programs in PET and CT separately. The standardized QA system for combined PET/CT examinations is not available in Russia. Hence, the aim of this study was to analyse the existing requirements for QA in PET/CT and to present proposals for developing a unified QA system to harmonize clinical practice and protocols in various Russian PET departments.

2. General requirements for QA in PET

The QA system should include QC of diagnostic and measuring equipment, image QC, standardization and optimization of examination protocols, as well as radiation protection of patients and staff by applying the principles of justification, optimization and dose limits [10,11]. Existing Russian national requirements are aimed only at ensuring the integrity of diagnostic equipment [12–14]. It is implemented mainly as a part of an acceptance tests and periodic monitoring of parameters.

2.1. QC of the equipment

QC of equipment is one of the main parts of the QA in diagnostics. QC procedures allow to identify equipment malfunction and its source. Constant QC allows monitoring the stability of the PET/CT system and its components as well as providing the possibility to plan and adjust the calibration and maintenance schedule and order of spare parts.

QC of the measuring equipment

The PET departments should be equipped with a radiometer or other equipment for measuring the administered activity of the radiopharmaceutical [11]. The activity administered to the patient is considered during the reconstruction of the PET image and affects the examination result. In addition, the correct measurement of activity during packaging of radiopharmaceuticals is important for proper accounting of the radionuclides in the department. Hence, it is

necessary to have reliable equipment for such measurements.

According to the national requirements, a radiometer or other measuring equipment have to pass an annual calibration according to an approved methodology [11]. In addition, it is necessary to perform periodic QC procedures of that equipment according to the user manual. According to the international recommendations, the radiometer have to pass a mandatory QC to verify the accuracy and stability of measurements with the following frequency [15]:

- 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).

The radiometer has to be calibrated for all radionuclides intended for use in the department.

One of the problems in national clinical practice is the lack of knowledge and non-fulfilment by the staff of appropriate QC measuring equipment. To ensure a continuous diagnostic process in a department, it is recommended to have additional measuring equipment for replacement in case of malfunction of the main one.

QC of diagnostic equipment

The local concentration of the radiopharmaceutical administered to the patient is measured during a PET examination. The detection system counts the number of annihilation photons in the coincidence mode and single events that have occurred in the field of view. After that, the image reconstruction starts, including normalization, correction for scattering and attenuation, based on calibration files and transmission (CT) scanning [16]. Climate changes in the room can affect the characteristics of the detection system, received signal and the resulting image. Hence, constant QC of the diagnostic equipment is required to identify deviations of the system and its timely recalibration.

The vendor specific acceptance tests and tests in accordance with the standards of the of National Association of Electrical Equipment Manufacturers [17] as well as national required tests have to be performed during commissioning. Due to the lack of the clear requirements in Russia, control of the PET/CT characteristics is currently limited to the QC procedures declared by the vendor. That complicates the standardization and harmonization of PET diagnostic in the country [6].

All commissioning procedures of the equipment are performed by the vendor engineers. The results of acceptance tests of the equipment are used as the basic values for comparison with the periodic QC results [16,18]. For the new equipment, after replacing parts of the detecting system or after the relocation of the equipment, the assessment of scatter contribution,

random and lost events, checks of the sensitivity, spatial resolution of the system and PET image quality are performed. For PET/CT units, monitoring of CT parameters and check of the coincidence of PET and CT images are added. A constant QC is necessary to maintain the stability of the system, which is performed periodically (daily/weekly/quarterly/annually), in the case of suspected malfunction and after replacement or repair of the major components. CT QC includes assessing the quantitative characteristics of a CT image: CT units, image noise, uniformity, spatial resolution, slice thickness, table position accuracy and verification of dosimetric characteristics (CTDI – CT dose index and DLP - dose length product) [13–14]. Daily PET QC is the basis on assessing the capacity of the system. It can be performed automatically and includes scanning a standard phantom or an embedded source. The results of daily QC are compared with the reference values obtained after calibration, and can be used as indicators for a calibration or normalization.

The activity or standardized uptake value (SUV) which reflects the radiopharmaceutical accumulation in the area of interest (in a pathological tissue) is used for interpreting PET examinations in clinical practice [19–21]. That requires the comparable activity administered to the patient and the one measured in the PET image. Hence, one of the important QC procedures is the cross-calibration of the radiometer and the PET: time synchronization and verification/calibration of the activity value [2,6,17].

2.2. Image QC

PET image

In practice, physicians have to determine the patient treatment tactics based on the results of the PET examinations and the amount of radiopharmaceutical accumulated in the lesion. The accuracy of the estimating accumulated activity in a PET image depends on the following parameters: the design and characteristics of the detection system, the acquisition and reconstruction protocols, the characteristics of the investigated object, the level of activity accumulated in the lesion [22]. The partial volume effect (PVE) is manifested in the PET

image due to the non-ideal detection system and reconstruction algorithms [19–23]. The reconstructed PET image needs to correspond to the radionuclide distribution with an uniform accuracy over the field of view. However, due to the PVE, the activity in the reconstructed PET image depends on the size of the lesion and the ratio of activity in lesion to the surrounding structures. The maximum PVE manifested with small lesions leads to an underestimation of the accumulated activity in the lesion.

To assess PVE the influence on PET image and to compare and harmonize the PET protocols, the image QC is performed. Image QC involves monitoring and comparing the parameters of the PET image of standard phantom with the defined criteria and is based on the estimation of the recovery coefficient (RC). The RC is a quantitative parameter of the PET image, which is defined by the following equation 1:

$$RC = \frac{A_{image}}{A_{injected}}, \quad (1)$$

where: A_{image} is the activity in lesion imitator on the image (kBq/ml); $A_{injected}$ is injected activity calculated to the scan time (kBq/ml) [19,22,24]. The RC varies with the size of the lesion and is specific for each acquisition, reconstruction and processing protocols. Hence, an important part of the QA of PET is the estimation and monitoring of RC for analysis and comparison of protocols. The NEMA IEC [7,17] or the MADEIRA [19,23] phantoms with spherical or conical imitators of lesions of different sizes are commonly used for the evaluation of PET images quality.

Figure 1 presents the examples of the dependences of RC values on the size of the lesions obtained with the NEMA IEC phantom. In case of comparable results, obtained on different model/protocols, the values of activities in the lesion determined on the models/protocols will coincide with each other. That provides the possibility to monitor the treatment process of patients undergoing PET examinations on different PET systems.

Table 1 presents the RC for the mean and maximum values of activity in the spheres of the NEMA IEC phantom. That criteria for RC was proposed based

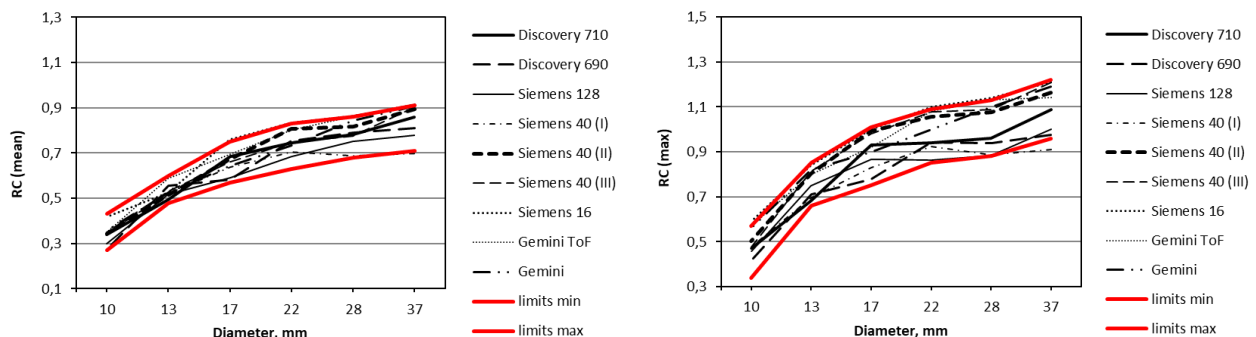


Fig. 1. Examples of the relationship between the recovery coefficient (RC) and the lesion size. Data is presented for different PET models with the NEMA IEC phantom [21]: to the left - mean values of activity; to the right - maximum values of activity.

on the results obtained in Russian PET departments and the EARL accreditation program [7–9]. If the RC value does not fall within the intervals, an investigation should be performed. The most common causes are procedural errors during the QC, an un-calibrated equipment or non-standard reconstruction algorithms.

Table 1. Ranges of recovery coefficients (RC): mean (RC_{mean}) and maximum (RC_{max}) obtained with the NEMA IEC phantom.

Lesion size, mm	RC_{mean}	RC_{max}
10	0.27 - 0.43	0.34 - 0.57
13	0.48 - 0.60	0.66 - 0.85
17	0.57 - 0.75	0.75 - 1.01
22	0.63 - 0.83	0.85 - 1.09
28	0.68 - 0.86	0.88 - 1.13
37	0.71 - 0.91	0.96 - 1.22

CT image

The CT method is based on the attenuation of X-rays by an object and the resulting image depends on the protocol parameters [25]. Based on CT (transmission) scanning, the attenuation coefficients matrix is created. It is used in the reconstruction of the PET image. Hence, the results of the CT scans affect the PET image.

For a visual and quantitative assessment of the structure density by the CT method an X-ray attenuation scale is used (the Hounsfield unit, HU). There are two ways to evaluate CT images: objective and subjective methods. The objective method involves evaluating the quantitative parameters of the CT image, such as image uniformity, image noise, and spatial resolution with test objects and phantoms [13,14]. Subjective methods such as ROC or FROC involve evaluating image quality by experts (radiologists) [26]. Objective methods are suitable for assessing the calibration and comparing CT protocols with each other. However, when introducing a new protocol an expert is needed for assessing the image quality.

3. Harmonization of the standard operating procedures

Diagnostic examination is performed according to standard operating procedure (SOP) that is developed according to national standards and approved by hospitals. The SOP include:

- prerequisites for the examination;
- requirements for preparation of the patient for the examination;
- methods for calculating the administered activity of radiopharmaceutical;
- requirements for radiopharmaceutical injection;
- time from the injection to the scanning;
- acquisition and reconstruction protocols, as well as image processing;
- staff involved at each stage of the examination.

Different SOPs of the PET/CT examinations and different diagnostic equipment can lead to incomparable results of the examination of the same patient, when obtained in different medical facilities. Currently, two different guidelines on whole body PET/CT

examinations with ^{18}F -FDG have been published in Russia [27,28]. Hence, it is necessary to harmonize SOPs and standards of examinations between different regions. In order to confirm the absence of contraindications the patients should be notified of the analyses, instructed in preparation for the examination and sign an voluntary information consent [11,29].

It is recommended to create different CT protocols for the different groups of patients (age, weight) and for different research purposes (for example, low-dose, diagnostic and multiphase) as a part of PET/CT examination. The choice of one or another CT protocol is justified by the physician prior to the examination.

4. Radiation monitoring and optimization of radiation protection

Constant radiation monitoring of the department and the surrounding environment should be performed [11,30] to record and control the doses of personnel, patients of other departments and public. Based on the results of radiation monitoring of the department and individual dose monitoring, the level of radiation protection in the department is assessed. The results of radiation and dose monitoring must not exceed the norms [10,11]. Based on the achieved dose rate levels, staff individual dose reference levels are developed in order to track changes in staff doses, identify the causes of overexposure and correct the staff behaviour to optimize radiation protection of staff and public.

To optimize the radiation protection of patients the diagnostic reference levels (DRLs) are used. DRLs are the criteria for comparing the typical doses or typical activities of patients with a common practice and are used to detect abnormally high and low doses. The assessment of DRLs in PET/CT considers the activity of radiopharmaceutical injected to the patients and external exposure from CT [31]. In Russian PET/CT diagnostic, up to 90% of the patient dose is generated by the CT scan, while typical activities are lower compared to the mean administered activity in other countries [1]. Hence, it is necessary to consider abnormally low activity values and high dose values from CT. Optimization of radiation protection of patients should involve the following next steps:

- typical dose/activity estimation and comparison with the DRLs;
- optimization protocols in case of abnormally low or high dose/activity values;
- evaluation of image quality by objective and subjective parameters.

Currently, DRLs for CT examinations are not implemented in Russia. However, based on the available data (60% of the operating departments), the DRL values for CT scans for PET/CT examinations of the brain and the whole body were proposed (Table 2) [1,32]. DRLs were established in two dose quantities: DLP and effective dose. That allows the staff and inspection bodies to identify systematic excesses of the DRLs and the causes of high doses.

Table 2. Proposed diagnostic reference levels (DRLs) of whole body and head computed tomography (CT) scans as a part of PET/CT examinations.

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

*From vertex of skull to high third of hip.

5. Staff requirements

The staff members have to comply with the professional requirements, attend professional training courses and pass through periodical tests. Staff of the department has to know and apply in daily practice basic principles of radiation protection (justification, optimization and dose limits). Physicians, medical physicists, engineers, technicians and nurses are responsible for the radiation safety of staff and patients and have to keep their radiation doses as low as possible (and not above 20 mSv/year).

It is important to have a medical physicist in PET department [33]. Medical physicists are responsible for the implementation of the QA system including acceptance tests and calibration of equipment, training of technicians in QC procedures and verification of the obtained results, monitoring of the diagnostic examinations, training of medical staff in the field of radiation protection, estimation of standard activities and doses and examination protocol optimization. Unfortunately, the number of medical physicists in Russian PET departments is limited; they are employed only in major national medical centres. Their responsibilities are mainly focused on the radiation control issues. The PET departments lack dedicated equipment for quality control. Hence, the implementation of QA system in PET in Russia should be accompanied by the promotion and employment of medical physicist in PET departments.

6. Conclusion

Development of nuclear medicine in Russia requires to improve radiation protection of patients and staff, as well as to add the equipment needed for proper QC and to develop standard SOP with acquisition, reconstruction and processing protocols.

This paper proposes the development and implementation of QA system in PET diagnostics in Russia, which includes:

- QC of diagnostic and measuring equipment;
- a systematic evaluation of PET and CT image quality, based on objective parameters and subjective methods with involvement of experts;
- SOP maintenance;
- systematic analysis of staff performance to identify procedural errors;
- estimation of staff doses, determination of typical patient doses and their comparison with the DRLs;

- optimization of PET and CT protocols in order to reduce the typical dose or improve image quality.

Implementation of the QA system in practice will improve the efficiency of PET diagnostic in Russia. It is necessary to have medical physicists in PET department in order to implement that system into the practice. Proposed QA system in PET/CT is compatible with the EARL accreditation program; its implementation in medical practice will provide harmonization of national and international PET diagnostics. The QA system in PET presented in this paper was published in 2019 in Russia and is currently being reviewed by the ministry of healthcare and the radiation protection authorities.

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