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Proposal of Brazilian National Program for Quality Control in the small animal PET scanners

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ABSTRACT

In Brazil, currently there are six preclinical molecular imaging centers and seven different small animal PET systems in use. However, there is still no national specific legislation for research laboratories focused on preclinical molecular images, unlike clinical nuclear medicine centers. A standardization of quality control protocols is needed to harmonize the use of small animal PET scanners in the research field. Thus, the aim of this work was to propose a National Program for Quality Control (NPQC) for the preclinical PET imaging systems in Brazil. This work was based on the quality control tests performed in Molecular Image Laboratory LIM/CDTN based on NEMA NU 4-2008 as described and presented in doctoral thesis of GONTIJO, 2019. The proposal of the NQCP was based on the CNEN NN 3.05 Publication (2013) and includes fundamental tests to be adopted, if possible, in laboratory practice to corroborate the experimental data. The Quality Control Program implemented in LIM/CDTN is an innovative and unprecedented proposal in the scope of preclinical molecular imaging services in Brazil. Therefore, the LIM/CDTN Program was carried out as a pilot to evidence the applicability and viability of the NQCP using small animal PET scanners. Summarizing, this work presents a viable set of Quality Control tests and their periodicities like a proposal for standardization to harmonize the use of this imaging technology in the field of research. Therefore, a National Quality Control Program (NQCP) applied to small animal PET scanners.

Keywords: **preclinical PET; quality control program; NEMA NU 4-2008.**

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INTRODUCTION

Positron emission tomography (PET) is an important molecular imaging technology tool for preclinical studies. Small-animal PET scanner refers to imaging of animals such as rats and mice using specific PET scanner. [1] Because of widespread use and commercial availability of preclinical PET scanners, the National Electrical Manufactures Association (NEMA) published its NU 4/2008 standards, a consistent and standardized methodology for evaluation of scanner performance parameters for small-animal PET imaging. [2]

Quality Control (QC) is a set of safety and performance tests executed periodically to assess whether the radiation measuring device continues to meet the requirements of current national and international resolutions and the reference values established during acceptance test [3]. QC is part of the Quality Assurance (QA) program that allows functional image acquisition for correct measurements and analysis.

In agreement with NEMA NU 4/2008 publication, small animal PET scanners performance should be evaluated by the following parameters [2]: i) Spatial Resolution; ii) Sensitivity; iii) Scatter Fraction, Count Losses, and Random Coincidence; and iv) Image Quality, Accuracy of Attenuation and Scatter Corrections. The NEMA NU 4/2008 presents all the methodological parameters and needs for the small-animals PET scanners quality control.

In this context, it is important to perform a minimum set of quality tests for small animal PET scanners that confirms their performance or indicates the need for corrective maintenance [4].

Regulatory agencies in Brazil do not yet have any similar publication to establish in detail all necessary tests for preclinical equipment. In addition, there is a lack of knowledge for some methodological aspects of small-animals PET [5]. However, in Brazil, currently there are six preclinical molecular imaging centers and seven different PET systems in use (Figure 1) and a standardization of quality control protocols are needed to harmonize their use in the research field [6, 7].

Thus, the aim of this work was to propose a National Program for Quality Control for the preclinical PET imaging systems in Brazil.

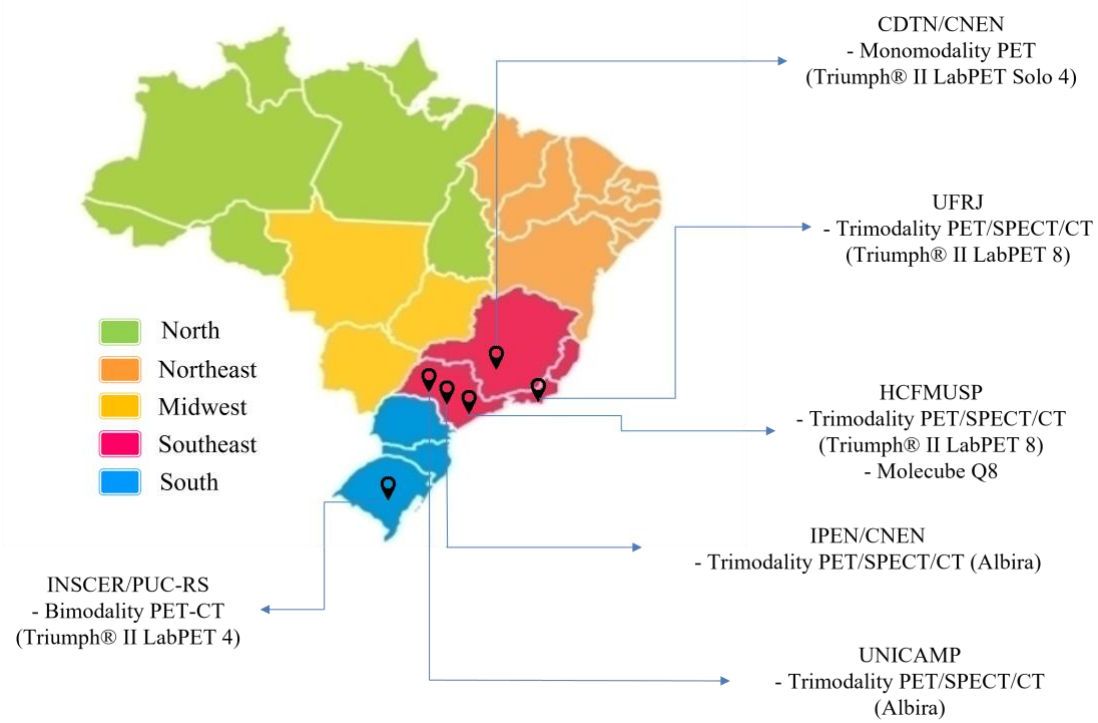

Figure 1: *Brazilian preclinical molecular imaging research centers and respective PET systems.*

1. MATERIALS AND METHODS

This work was based on the quality control tests performed in Molecular Image Laboratory LIM/CDTN based on NEMA NU 4-2008 as described and presented in doctoral thesis mentioned in reference 5. In this thesis were used the LIM/CDTN/CNEN small animal PET scanner and specific phantoms to evaluate counts rate performance and image quality as well as a sealed radioactive source of Sodium-22 to evaluate spatial resolution and sensitivity. All the materials (phantoms and source) and procedures of how to do the tests are described on NEMA NU 4-2008 specific standard for small animal PET. The periodicities presented in table 1 were proposed based on the CNEN NN 3.05 Brazilian standard, and assessment of different results of the thesis mentioned in reference 5.

After implementation of different tests for LIM/CDTN small animal PET scanner and evaluation of respective results, an assembly of test as well as their respective periodicities were defined as a Quality Control Program (QCP). This QCP is presented here as a proposal of standardization in Brazil to create a National Quality Control Program (NQCP) applied to small animal PET scanners.

2. RESULTS AND DISCUSSION

Table 1 presents the set of quality control tests and their periodicity to evaluate preclinical system performance and to compound a small animal PET scanners National Quality Control Program (NQCP). All referred tests are based on NEMA NU 4-2008 publication.

Table 1: Set of QC tests and respective periodicity to compound the Brazilian National Quality Control Program for small animal PET scanners

Test		**Periodicity**		**Objective**
Image Quality	Uniformity	A	Q	Verify the ability to quantify radioactive concentrations for quantitative analyses of preclinical studies.
	Spillover Ratio			Check accuracy against scatter corrections.
	Recovery Coefficient			Check the ability to recover radioactive concentrations in different structures.
Coincidence Events Rate	True Events	A	An	Check the rate of true coincidence events detected.
	Random Events			Check the rate of random coincidence events detected.
	Scatter Events			Check the rate of scatter coincidence events detected.
	Equivalent Noise Count rate (NEC)			Check the noise equivalent count rate (RNEC) detected.
	Count Loss			Check the loss count rate from the true event rate.
	Scatter Fraction			Check the rate of scattered coincidence events.
Sensibility	Percentage and Absolute	A	B	Check the intrinsic and geometric efficiency.
Spatial Resolution	Directions (Axial, Radial and Transverse)	A	B	Check the spatial resolution in the 3 directions of the PET system.

Table 1 Note: Abbreviations

A = Acceptance or after maintenance and/or correction services, or when the values are outside the tolerance range with respect to the reference value.
Q = Quarterly.
B = Biannual.
An = Annual.

It is important to mention that proposal of the NQCP was based on the CNEN NN 3.05 Publication.

This proposal does not replace the manufacturer's recommendations or prevent the procedures for monitoring and calibration of imaging systems. However, includes fundamental tests to be adopted, if possible, in laboratory practice to corroborate the experimental data. It is important to consider that some NEMA NU 4-2008 test should be adapted due to intrinsic PET scanner characteristics.

In previous work [6] results showed that all Brazilian centers stated that are familiar with NEMA NU 4-2008 and its performance evaluation methods specific to small animal PET scanner. However, only one center has quality control program implemented (PET imaging system and activimeter).

The Quality Control Program implemented in LIM/CDTN is an innovative and unprecedented proposal in the scope of preclinical molecular imaging services in Brazil. Therefore, the LIM/CDTN Program was carried out as a pilot to evidence the applicability and viability of the NQCP using small animal PET scanners. An example of this can be easily found in references 5 and 8.

There is still no Brazilian specific legislation for research laboratories focused on preclinical molecular images (quality tests for PET imaging system neither for dose calibrators), unlike clinical nuclear medicine centers [4].

The authors think that the absence of national guide weakens the importance of monitoring the performance of imaging systems and consequently the quality of the results. Thus, the NQCP proposed in this work can be a fundamental tool for the reliability of the data generated in molecular imaging laboratory.

3. CONCLUSION

Quality Control Program consists in perform quality control tests during the use of PET imaging systems and should be conducted at periodic intervals according to a previously standardized and established program. The Quality Control Program implemented in LIM/CDTN is unprecedented in Brazil.

This work presents a viable set of Quality Control tests and their periodicities like a proposal for standardization to harmonize the use of this imaging technology in the field of research. Therefore, a National Quality Control Program (NQCP) applied to small animal PET scanners.

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