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Comparative analysis of performance in quality control in nuclear medicine

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Introduction: Nuclear medicine uses radionuclides combined with pharmaceuticals to obtain images and to treat diseases. To obtain these images equipment capable to detect and process the radionuclide emissions are required.

In Brazil there are actually 464 Nuclear Medicine Services (NMS) licensed. In the beginning of 2018 there were approximately 100 NMS with therapeutic rooms for 131-Iodine (^{131}I) and Lutécio-177 (^{177}Lu) treatment when it is necessary that the patient remains isolated until the decay of the radioactive material administered. There are also other therapies that do not require hospitalization, such as those using Samarium-153 (^{153}Sm), Yttrium-90 (^{90}Y), Lutécio-177 (^{177}Lu) and Radio-223 (^{223}Ra) [1].

Around the country there are NMS with 464 Single Photon Emission Tomography (SPECT) in operation, in a total of 939 gamma cameras, about 10 Single photon emission tomography associated with X-ray computed tomography (Single Photon Emission Tomography/Computed Tomography-SPECT/CT), about 150 Positron Emission Tomography (PET) and 18 Cyclotrons are also installed for the production of radiopharmaceuticals distributed in the South, Southeast, Northeast and Midwest regions: Federal District, Salvador, Curitiba, Porto Alegre and Campinas [2].

There are two regulatory bodies for NMS, the National Nuclear Energy Commission (CNEN) [3] and the National Health Surveillance Agency (ANVISA)[4], both having the power to authorize and to ensure compliance with the national standards and regulations.

To ensure equipment's performance, image reliability and to promote accurate diagnosis a set of measurements and analyzes, known as quality control (QC), is established. QC is a routine practice where essential performance of an equipment or procedure is evaluated comparing results with a predefined acceptable range. [5]

In the CNEN Nuclear Medicine Standard (NN) 3.05 - Annex II, III, IV and V, the tests that should be performed for the cameras gamma (Planar and SPECT), uptake and surgical probes, positron emission tomography (PET) and dose calibrators are described with recommended frequency. [3]

The Resolution of the Collegiate Board (RDC) 38 from ANVISA requires the procedures for quality assurance in nuclear medicine, describing the same tests and frequencies established by CNEN.

Regulatory bodies, however, do not establish guidelines for testing. There are no recommendations on the best methodology to be used, nor the recommended bibliography. IAEA documents are used by operators for this purpose.

The American Association of Physicists in Medicine (AAPM) uses the IAEA documents as basis for the achievement of QC. The IAEA uses the International Electrotechnical Commission (IEC) documents, which is an international standardization organization for electrical, electronic and related technologies. Some of its standards are developed together with the International Organization for Standardization (ISO).

The international documents establish a minimum performance for the equipment, however, Brazilian Standards do not present values.

This paper aims to evaluate information on the performance limits for quality control tests in nuclear medicine requested in Brazilian standards and compare with what is available in international recommendations. And so, examine whether there is discrepancy in what is available in these documents that serve as a basis for the professionals who perform the quality control.

Methodology: The comparison was made based on the documents presented below. The norms of Brazilian regulatory bodies in nuclear medicine (CNEN NN.3.05), a standard approved in December 2013, which deals with the "Safety Requirements and Radiological Protection of Nuclear Medicine Services" and also (ANVISA RDC 38) in June 2008 which "Provides for the installation and operation of Nuclear Medicine Services" in vivo".

In order to make the comparison, we used five specific international documents for each type of quality control test; we used TECDOC-602 of the International Atomic Energy Agency (IAEA), 1991, which deals with "Quality Control of Medical Instruments Nuclear". In order to carry out the comparison as set forth in the international documents, we use TECDOC-602, from 1991 of the International Atomic Energy Agency (IAEA), which deals with "Quality Control of Nuclear Medicine Instruments"[6]. This document, which provides detailed guidance on the quality control of the various instruments used in nuclear medicine, stems from the work of two Consultative Groups convened by the International Atomic Energy Agency.

Another technical and scientific publication of the IAEA, known as the Human Health Series No. 1, 6, 17 and 27, documents the National Electrical Manufacturers Association No. NU3-2004 (NEMA 9), NEMA (2007, document 6 of The American Association of Physicists in Medicine (AAPM) and International Electrotechnical Commission No. 26,020, 61675-1, 61675-2, 61675-2 [7, 8 e 9].

Results: It is possible to identify in the Brazilian norms that the quality control tests do not have a brief description of the performance limit to evaluate the QC nor the description of the methodology to be followed. The lack of general guidelines that should be in Brazilian standards and the non-reference of a document that serves as a basis, and that could be described in Brazilian legislation, compromises a more concise analysis of its results.

References:

- [1] Instalações autorizadas. Available at: <<http://www.cnen.gov.br/index.php/instalacoes-autorizadas-2>>. Last accessed: 25 de abril 2019.
- [2] Departamento de Informática do Sistema Único de Saúde (Datasus). **Sistema de Informações da Saúde**. Available at : <<http://www2.datasus.gov.br/DATASUS/index.php?area=02>>. Last accessed : 25 april 2019.
- [3] Comissão Nacional de Energia Nuclear, "CNEN/NE-3.05 – **Requisitos de Radioproteção e Segurança para Serviços de Medicina Nuclear**", Norma Técnica, 1996
- [4] Ministério da Saúde. Agência Nacional de Vigilância Sanitária. **"Dispõe sobre a instalação e o funcionamento de Serviços de Medicina Nuclear in vivo, Resolução de Diretoria Colegiada – RDC nº 38"**. ANVISA, 2008.
- [5] Zanzonico, P. (2008). **Routine Quality Control of Clinical Nuclear Medicine Instrumentation: A Brief Review**. Journal of Nuclear Medicine, 49(7), 1114–1131.
- [6] International Atomic Energy Agency. **Quality control of nuclear medicine instruments**. Vienna: IAEA-TECDOC-602, 1991. Available at: <https://www-pub.iaea.org/MTCD/publications/PDF/te_317_prn.pdf>. Last accessed: 25 april 2019.
- [7] National Electrical Manufacturers Association. NEMA NU 4. **Performance measurement of small animal positron emission tomographs**. Rosslyn, VA: National Electrical Manufacturers Association; 2008.
- [8] National Electrical Manufacturers Association. NEMA NU 3. **Performance measurements and quality control guidelines for non-imaging intraoperative gamma probes**, Rosslyn, VA: National Electrical Manufacturers Association; 2004.
- [9] International Electrotechnical Commission. IEC/TR 61948. **Nuclear medicine instrumentation – Routine tests – Part 3: Positron emission tomographs**. Geneva: International Electrotechnical Commission; 2005.

[10] International Atomic Energy Agency. ***Quality assurance for PET and PET/CT systems***. Human Health Series, No. 1. Vienna: International Atomic Energy Agency; 2009. Available at: <http://www-pub.iaea.org/MTCD/publications/PDF/Pub1393_web.pdf>. Last accessed: 15 april 2019.