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# Nuclear Medicine in Brazilian Health System

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**Abstract** *Nuclear Medicine plays an important role in the management of patients with chronic diseases, especially oncological and cardiovascular conditions. In this study, an analysis of the evolution of this field in Brazil was conducted within the framework of the Unified Health System. Retrospective analyses from 2015 to 2021 of public data were performed. Although Brazil has a considerable number of facilities, their geographical distribution is uneven. The same disparity is observed in relation to units that produce and distribute radiopharmaceuticals, limiting access for the Brazilian population, particularly to those with a half-life of less than two hours. There is a noticeable high technological dependence on foreign companies, with little or no domestic production, contributing to a deficit in the trade balance. Despite the increasing demands due to factors such as population aging and epidemiological changes, the area did not expand. It is crucial to implement social and economic policies to reduce vulnerabilities in the public healthcare system, ensure its sustainability, and promote equal and universal access to Nuclear Medicine.*
**Key words** *Nuclear Medicine, Diagnostic Imaging, Radiopharmaceuticals, Positron Emission Tomography Computed Tomography, Radionuclide Imaging*

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## Introduction

Nuclear medicine (NM) has developed rapidly in the last two decades considering the number of installed imaging equipment, available radiopharmaceuticals and qualified human resources. The introduction of new radionuclides (especially positron emitters) and the strengthening of theranostic medicine are some of the factors that boosted this medical specialty[1]. Actions by the International Atomic Energy Agency (IAEA), through the Regional Cooperation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean (ARCAL) and others were fundamental to the development of the region.

According to Orellana *et al.*[2], in Brazil, the number of installed gamma cameras almost quadrupled between 2014 and 2020. This growth did not occur homogeneously in all countries, due to insufficient human resources and limited availability of radiopharmaceuticals. These can be grouped into two groups, based on their half-lives: greater than 2h and less than 2h.

Those in the first group ($T_{1/2}$>2h) can be gamma or particle emitters and are used in NM for diagnostic and therapeutic purposes, respectively; The radiation emitted by radiopharmaceuticals is captured using gamma cameras, mainly in the modality known as single photon emission tomography (SPECT). The equipment to obtain these images can be coupled to a computerized tomography (SPECT/CT)[3]. Images are predominantly obtained using radiopharmaceuticals labeled with technetium-99m ($^{99m}$Tc), but thallium-204 ($^{204}$Tl), iodine-131 ($^{131}$I) and gallium-67 ($^{67}$Ga) are also used to acquire physiological information from the brain, lung, heart and bones, for example[3]. Sometimes this area is called the conventional NM. Therapeutic radionuclides include $^{131}$I, samarium-153 ($^{153}$Sm), radium-223 ($^{223}$Ra), actinium-225 ($^{225}$Ac), yttrium-90 ($^{90}$Y), and lutetium-177 ($^{177}$Lu). They are obtained by activation of neutrons or nuclear fission in nuclear reactors or, to a lesser extent, in cyclotrons[4]. Those with a half-life of less than 2h ($T_{1/2}$<2h) are positron emitters and the detection of their distribution leads to positron emission tomography (PET). This equipment can also be associated with CT (PET/CT) or magnetic resonance imaging (PET/MR)[5,6]. The radiopharmaceuticals most used worldwide are those radiolabeled with fluor-18 ($^{18}$F), especially deoxyglucose ([$^{18}$F]FDG). They are produced in cyclotrons, delivered ready for use or via radionuclide generators for local marking. Currently, Brazilian legislation allows the production and commercialization of radiopharmaceuticals in the country by the private sector[7].

The Brazilian population's access to NM services is directly related to the availability of these services in public health establishments within the scope of the Unified Health System (SUS) and to the contracting of services from the private sector. NM is regulated by the Ministry of Health (MS), from a health point of view, and by the Ministry of Science, Technology and Innovation (MCTI), through the National Nuclear Energy Commission (CNEN), from a radiological protection point of view.

The Department of Information and IT of the Unified Health System (DATASUS) maintains various administrative, health and economic information, essential to the processes of planning, operation and control of the SUS. Secondary and administrative data are continuously recorded in different databases, such as the Ambulatory Information System (SIA), the Hospital Information System (SIH), the SUS Procedures, Medications and OPM Table Management System (SIGTAP), or the National Registry of Health Establishments (CNES). This data is collected by the State Health Departments.

Clinical, diagnostic and therapeutic procedures can be reimbursed by the federal component of the SUS after approval by the Secretary of Science, Technology, Innovation and Health Complex (SECTICS/MS) based on extensive discussion and analysis carried out, on demand, by the National Commission for the Incorporation of SUS Technologies (CONITEC)[8]. This must contain Health Technology Assessment (ATS) documentation with a description of the new technology and scientific evidence comparing it with the existing technology (already incorporated by the SUS), economic evaluation and budge impact. One of the fundamental requirements for technologies to be evaluated at CONITEC is that the health products used are registered with the National Health Surveillance Agency (ANVISA), that they are not considered experimental and have the price fixed by the Medicines Market Regulation Chamber (CMED), in the case of medicines[9].

ANVISA maintains databases of health products with commercial and use authorizations. The regulations for radiopharmaceuticals are continually being updated to consider new production possibilities, such as in-house mode and commercialization by notification (without definitive registration with the Agency). After

marketing authorization, the medicine industry must request an analysis to be carried out by CMED, which establishes the maximum price that can be charged. Since radiopharmaceuticals are considered medicines by ANVISA regulations, their prices should also be analyzed by CMED.

CNEN also maintains public databases with information on establishments, permitted inputs (type and quantity) and authorized personnel for the use of ionizing radiation in healthcare.

The Ministry of Finance (MF) and the Ministry of Development, Industry, Commerce and Services (MDIC) also play an important role in the maintenance and possible expansion of this area in the country through the activities of the National Council for Financial Policy (CONFAZ) and the Chamber of Foreign Trade (CAMEX), since a significant part of the inputs is imported.

In 2021, CONFAZ published ICMS Agreement No. 131 authorizing state governments to grant exemption from the Tax on Circulation of Goods and Services (ICMS) in operations with radioactive medicines used exclusively for radiolabeling for nuclear medicine procedures, carried out within the scope of SUS[10] which came into effect on January 1, 2023. As a member state of the Southern Common Market (MERCOSUR), Brazil adopts the MERCOSUR Common Nomenclature (NCM) and the MERCOSUR Common External Tariff (TEC)[11]. This is an import tariff charged by the bloc's countries on imports from external countries to stimulate the competitiveness of States Parties and its tariff levels should help avoid the formation of oligopolies or market reserves. As a general rule, Brazil adopts the TEC for all NCM codes, but there are exceptional instruments and rules. In the case of products subject to specific shortage episodes, Brazil does not apply the TEC.

The objective of this work is to analyze the evolution of the NM area from 2015 to 2021 from the perspective of the SUS, considering Brazilian public databases, the tariff situation and the trade balance.

## Materials and methods

The methodological approach adopted is exploratory research with a search for data in the main public databases related to NM in the SUS. This is a retrospective, descriptive study. Studies with this design are exempt from analysis by research ethics committees because secondary databases were used, without identifying individuals[12].

Searches were carried out in public databases to obtain information on: i) Panorama of NM and ii) Fiscal situation and trade balance.

To collect data on the NM panorama, data searches were carried out on authorized facilities (cyclotrons, centralized radiopharmacies and NM services); radiopharmaceuticals approved for use in humans; equipment; diagnostic and therapeutic procedures performed,approved and their geographic distribution; and costs and reimbursements from the federal component of the SUS. The databases consulted with their respective data provided were:

- CNES/MS[13]: Number and location of healthcare facilities that perform conventional NM and PET procedures; Total number of equipment in use (gamma cameras and PET tomographs); The total number of equipment in use in the SUS was estimated considering two scenarios: (1) only one piece of equipment per establishment and (2) all equipment per establishment that offers services to the SUS.

- SIA and SIH/MS[14,15]: Number of diagnostic and therapeutic procedures approved per year and per region;

- SIGTAP/MS[16]: Authorized procedures for diagnosis and therapy;

- ANVISA/MS[17,18]: Registered radiopharmaceuticals and those marketed by notification; Registration and marketing authorization for medical devices;

- CNEN/MCTI[19]: Number and location of radioactive installations with cyclotrons, centralized radiopharmacies and NM services;

- IBGE[20]: Population by year and state in Brazil.

To survey the trade balance, a search was carried out in the Brazilian foreign trade statistics database "COMEX STAT" from the MDIC, with detailed consultations on Brazilian imports and exports[21]. The tax changes were raised on the MF's CONFAZ[22] website.

All data was collected considering all Brazilian States, from 2015 to 2021, to consider the beginning of coverage of PET/CT procedures. Data were recorded and analyzed in commercial software spreadsheets (Microsoft Excel).

## Results

According to the CNEN database, in December 2021, there were 2 public establishments

with cyclotron installations in the Southeast region and only 3 private companies that group the other 9 producing establishments. Figure 1 shows the existence of 4 centralized pharmacies, which sell unit doses of various radiopharmaceuticals. There were 449 conventional NM services and 159 PET facilities in the country. While 55.2% of conventional NM facilities and 52.8% of PET facilities are located in the Southeast region, only 4.9 and 4.4%, respectively, are located in the North region. On the other hand, according to the CNES database, there were 614 facilities with gamma cameras and 102 with PET in Brazil. In addition, the survey identified 462 in vivo NM facilities in total, 145 in vitro NM facilities and 53 NM classified as "telemedicine". The number of authorized facilities, conventional NM and PET services, by Region is shown in Figure 1.

Figure 2 shows the total number of imaging equipment (gamma camera and PET/CT) in use and the estimates of equipment in use in the SUS per million inhabitants in scenarios 1 and 2 described previously. A reduction in the number of gamma cameras per million inhabitants in use has been noted, especially since 2019. However, estimates of the number of gamma cameras in use in the SUS fluctuated around 37.5% and 47.6% between 2015 and 2018, in scenarios 1 and 2 respectively, and around 39.6% and 52% between 2019 and 2021. On the other hand, there was a continuous increase in the number of PET equipment in use per million inhabitants, although this increase has not been observed proportionally in the SUS. The PET equipment in use in the SUS corresponded to 59.5% of the total in use in 2015 in the two estimated scenarios, but over the years this value was reduced and, in 2021, it reached 49.1%, in scenario 1, or 52.8%, in scenario 2.

According to the SIGTAP database, 54 MN diagnostic procedures are reimbursed by the federal component of the SUS, including images of the cardiovascular, digestive, endocrine, genitourinary, skeletal, nervous, respiratory, hematological systems and others such as dacryoscintigraphy. Currently, radioiodine therapy for differentiated thyroid carcinoma is reimbursed by the SUS, with reimbursement amounts depending on the radioactive activity administered and ranging from 1.11 GBq (30 mCi) to 1.85 GBq (50 mCi) (outpatient procedures) and from 3.70 GBq (100 mCi) to 9.25 GBq (250 mCi) (hospital procedures). There are also palliative treatments for bone pain and hyperthyroidism. PET/CT imaging procedures were incorporated into the SUS in 2014 for three indications using the radiopharmaceutical [$^{18}$F]FDG[23]: clinical staging of non-small cell lung cancer, detection of liver metastases

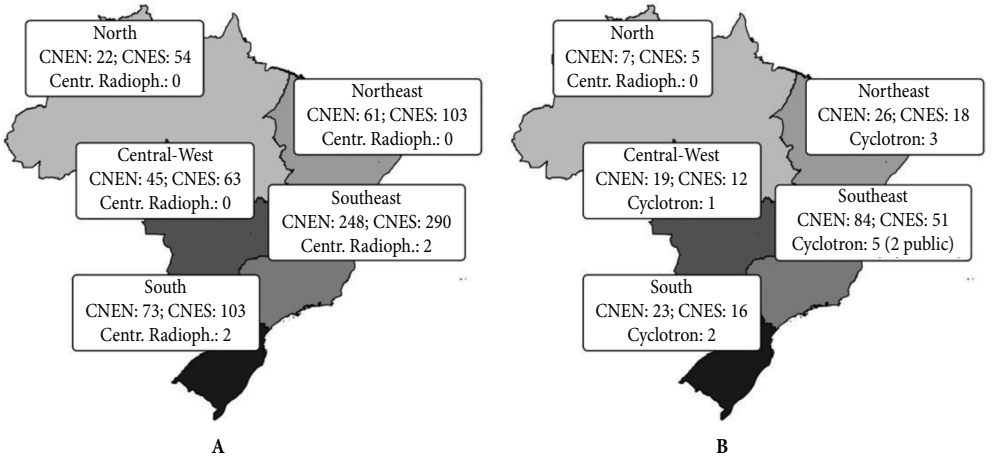


**Figure 1.** Radiation Facilities authorized by CNEN and Health Institutions authorized by the Health Authority with CNES number in December 2021 (code 151). Centralized radiopharmacies and conventional NM Services (A) and Cyclotron Facilities and PET Services (B).

Source: Authors.

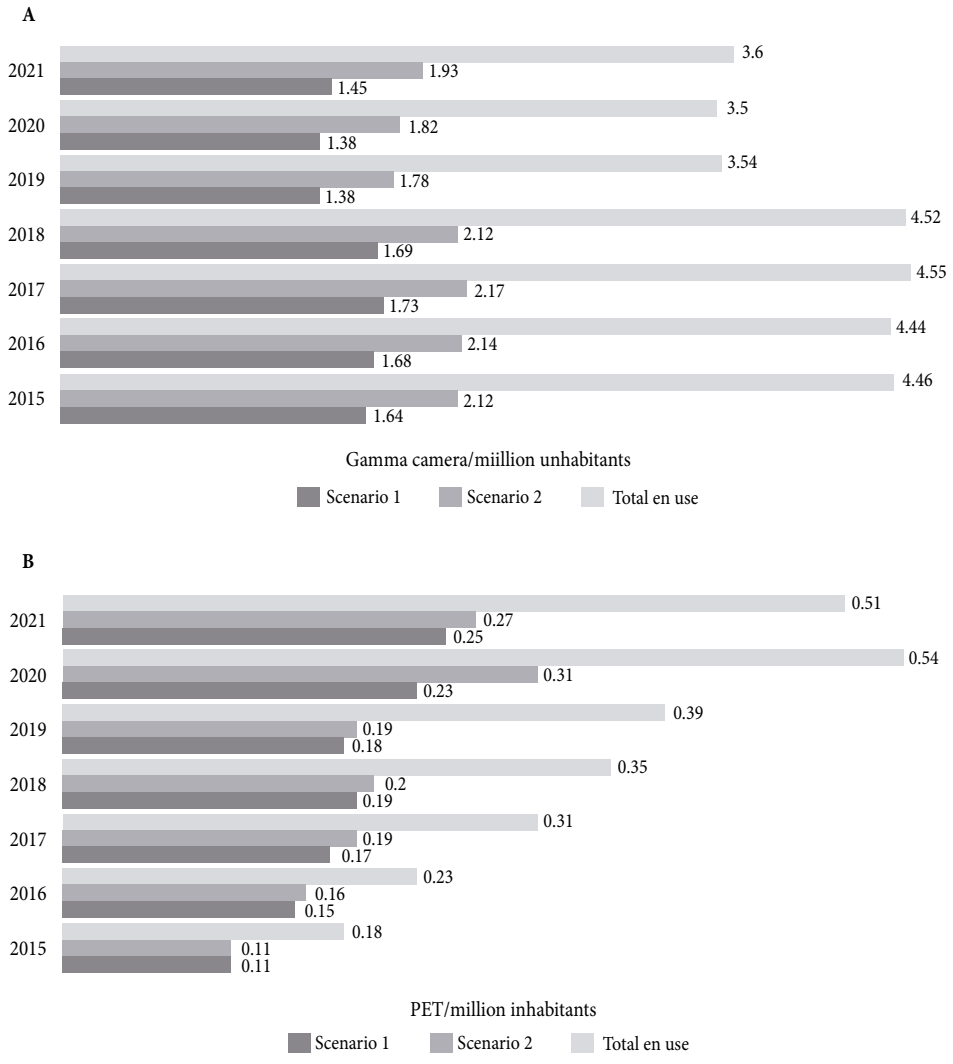


**Figure 2.** Gamma cameras (A) and PET/CT tomographs (B) in use in Brazil, per million inhabitants, in the period 2015-2021, classified as total in use and in use in the SUS in scenarios 1 and 2.

Source: Authors.

and potentially resectable colorectal cancer and staging and evaluation of response to treatment of Hodgkin and non-Hodgkin lymphomas.

The evolution of the total number of diagnostic and therapeutic procedures reimbursed by the federal component of the SUS per million inhabitants in the period evaluated is shown in Figure 3. It is noted that the South and Southeast regions had little variation in the number of diagnostic procedures approved in conventional NM, even during the pandemic phase, unlike other regions, which had a noticeable reduction. The main diagnostic procedures in NM continue to be bone scan, followed by stress and rest myocardial scintigraphy, with no major variation throughout the period in all regions of the country. These three procedures account for between 80.1% and 85.2% of the total number of procedures in the States. Diagnosis with PET maintained its growth trend despite variations between 2019 and 2021, except in the North region. The number of procedures approved per

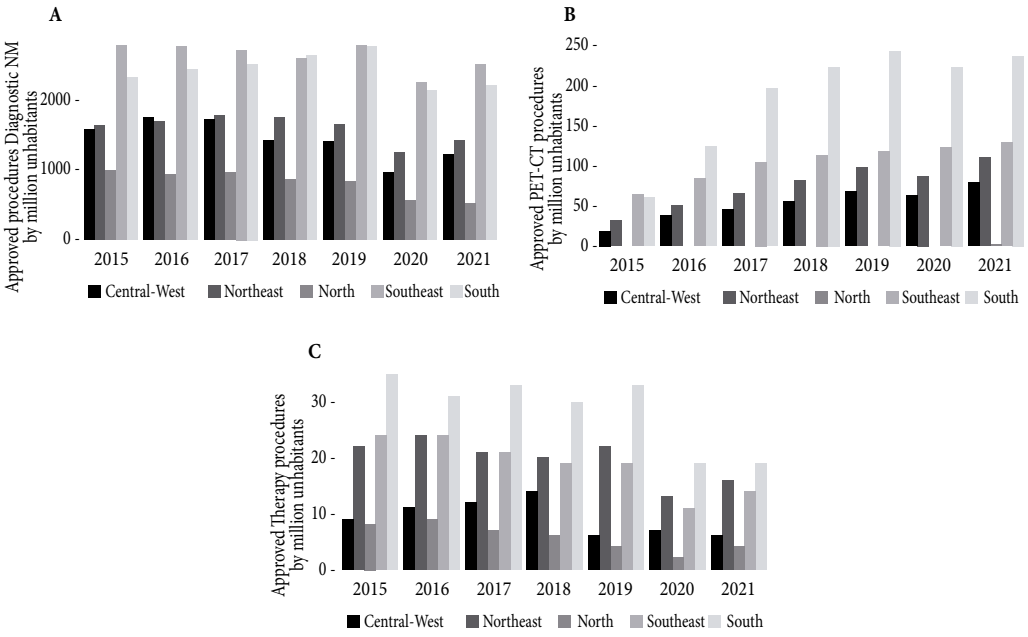


**Figure 3.** Number of approved diagnostic procedures in conventional NM (A), PET/CT (B) and therapy (C) per million inhabitants by region and year.

Source: Authors.

equipment in the SUS in scenarios 1 and 2 fluctuated around 5.3 and 4.1 respectively for conventional NM and 2.0 and 1.9 for PET.

Regarding the approved number of therapeutic procedures, the South region stands out among all other regions, although this number has shown a downward trend over the years.

The list of radiopharmaceuticals and equipment authorized for sale in Brazil is shown in Chart 1. There are seven radiopharmaceuticals for PET. Only one private company sells freeze-dried products marked with $^{99m}$Tc. There is no record of nationally produced gamma cameras or PET/CT. 12 records of groups of conventional NM equipment were found with 24 different models (two portable, seven dedicated to cardiology, eight SPECT and seven SPECT/CT) and five manufacturers in different countries: Spain (one record), Denmark (two records), Israel (seven records, of which two are shared with China) and USA (two records). Eight records of PET/CT equipment originating from 16 different models and six manufacturers were found. The manufacturing countries are: China (three registrations), USA (three registrations), Japan (one registration) and the Netherlands (one registration), highlighting the high technological dependence. There are also two registrations for hybrid PET/MR equipment, manufactured in the USA and Germany, and a PET registration dedicated to mammography, manufactured in Spain.

Other devices make up the NM scenario. The activimeter is essential for diagnostic accuracy and therapeutic efficacy, in addition to contributing to the radioprotection of patients and workers. But there is only one record with three models manufactured in the USA. There are also four records of systems for inhalation with radioactive material with three models and a shield, manufactured in Australia and Brazil. They are used for a specific inhalation lung scintigraphy procedure. Finally, there are four records of gamma probes used for radio-guided surgeries (especially for breast cancer), produced in France, Germany and Argentina.

The use of radiation detectors (imaging equipment, activimeter, radiation monitors and gamma probes) requires constant measurement and calibration with radioactive sources of different energies. There are ten records of activimeter calibration sources manufactured in the USA and Turkey.

**Chart 1.** Commercial authorization for health products linked to NM.

| Radiopharmaceuticals for conventional NM | Supplier |
|---|---|
| **Diagnosis (radioactive)** | |
| Sodium iodide ($^{131}$I) | IPEN CNEN-SP |
| Thallium Chloride ($^{201}$Tl) | |
| Chromic edetate ($^{51}$Cr)* | |
| Sodium technetium pertechnetate ($^{99m}$Tc) | IPEN CNEN-SP<br>Eckert & Ziegler |
| Gallium citrate ($^{67}$Ga) | IPEN CNEN-SP |
| Iodine metaiodobenzylguanidine ($^{131}$I MIBG) | |
| Pentetreotide indium ($^{111}$In)* | |
| **Diagnosis (Lyophilized reagents for marking with $^{99m}$Tc - cold kit)** | |
| Dextran-500* | IPEN CNEN-SP |
| Dextran-70* | |
| TIN (stannous fluoride)* | |
| ECD (ethyl cysteine dimer)* | |
| HSA (human serum albumin)* | |
| MDP (medronic acid)* | IPEN CNEN-SP<br>RPH |
| DMSA (dimercaptosuccinic acid)* | |
| FITA (phytate)* | |
| MIBI (methoxy isobutyl isonitrile)*<br>Tetrasodium pyrophosphate* | |
| DTPA (diethylenetriaminepentaacetic acid) | RPH |
| **Therapy** | |
| Samarium lexidronam ($^{153}$Sm)* | IPEN CNEN-SP |
| Lutetium tetraxetan octreotate ($^{177}$Lu) | |
| radium dichloride ($^{223}$Ra) | Bayer |
| **Diagnosis and Therapy** | |
| Sodium iodide ($^{131}$I) | IPEN CNEN-SP |
| **PET radiopharmaceuticals** | |
| [$^{18}$F]FDG (fluorodeoxyglucose) | Delfin Farmacos e Derivados Ltda<br>Cyclopet Radiofarmacos ltda Villas Boas<br>Radiofármacos do Brasil S/A<br>R2 Soluções em radiofarmácia LTDA<br>IBF - Indústria Brasileira de Farmoquímicos S.A.<br>Cyclobrás industria Comercio e serviços laboratoriais ltda<br>União Brasileira de Educação e Assistência - Hospital das Clínicas da Faculdade de Medicina da USP<br>CRCN-NE CNEN<br>CDTN CNEN-MG |
| [$^{18}$F]NaF (sodium fluoride) | União Brasileira de Educação e Assistência - Hospital das Clínicas da Faculdade de Medicina da USP<br>CDTN CNEN-MG |
| **No need for health registration – just notification from ANVISA** | |
| [$^{18}$F]F-PSMA-1007 | Cyclobrás industria Comercio e serviços laboratoriais ltda |
| [$^{18}$F]F-PSMA-1007 | R2 Soluções em radiofarmácia LTDA |
| [$^{68}$Ga]Ga-PSMA-11 | União Brasileira de Educação e Assistência - Hospital das Clínicas da Faculdade de Medicina da USP |
| PIB ($^{11}$C) | |
| [$^{68}$Ga]Ga-DOTATE | |
| [$^{18}$F]FBB | |
| [$^{18}$F]FLT | CDTN CNEN-MG |

it continues

**Chart 1.** Commercial authorization for health products linked to NM.

| IMAGING EQUIPMENT | |
|---|---|
| **Type** | **Manufacturer** |
| **Nuclear Medicine** | |
| Portable | Oncovision General Equipment for Medical Imaging S.A. |
| Dedicated (cardio) | DDD-Diagnostics A/S<br>Spectrum Dynamics Medical LTD<br>GE Medical Systems Israel, Functional Imaging |
| SPECT | GE Medical Systems<br>Siemens Medical Solutions USA, INC<br>GE Medical Systems |
| SPECT/CT | Ge Medical Systems Israel, Functional Imaging |
| **PET** | |
| PET/CT | Shanghai United Imaging Healthcare CO. LTD.<br>Siemens Medical Solutions USA, INC<br>Philips Medical Systems<br>GE Medical Systems LLC<br>Neusoft Medical Systems Co. Ltd.<br>Canon Medical Systems Corporation |
| PET/MR | GE Medical Systems LLC<br>Siemens Healthcare GmbH |
| PET (Mammogram) | Oncovision General Equipment for Medical Imaging S.A |

*Products discontinued since 2018 by IPEN CNEN-SP even if the registration appears as "valid" on the consultation website.

Source: Authors.

### Fiscal situation and trade balance

The tax changes resulting from changes in federal taxes (IPI, PIS and COFINS) and relief from state taxes (ICMS) did not include equipment used in the area. Radiopharmaceuticals, in particular, the $^{99m}$Tc generator, radioactive agents labeled with $^{131}$I, with $^{18}$F (for example, [$^{18}$F]FDG, [$^{18}$F]PSMA, [$^{18}$F]NaF), with $^{68}$Ga ([$^{68}$Ga]Ga-DOTA, [$^{68}$Ga]Ga-PSMA), with $^{177}$Lu ([$^{177}$Lu]Lu-PSMA, [$^{177}$Lu]Lu-DOTA), $^{223}$Ra and $^{225}$Ac are not taxed by IPI or ICMS. PET equipment and Gama-camara are subject to 1.3% IPI and ICMS varies according to the State. PIS and COFINS are the same for all products: 2.10% and 9.65%, respectively.

Regarding TEC, differences were observed in product rates, close to the minimum for radioactive agents (2%) and close to the maximum for the $^{99m}$Tc generator (10%).

The NCM values of nuclear medicine products, from 2015 to 2021, in dollars, were updated using the CPI/USA[24] Index. The trade balance deficit is around US$30 million per year (Figure 4) and corresponds to around 0.20% of the trade balance deficit of the Health Industrial Economic Complex (CEIS), currently close to US$ 15 billion/year[25]. The $^{99m}$Tc generator represents around 50% of the deficit, followed by radioactive agents with around 30%. Between 2015 and 2016, shortly after the procedure was approved by CONITEC, the deficit due to PET/CT equipment exceeded that of radioactive compounds, accounting for around 40% in the period.

## Discussion

Since 2006, Brazilian legislation has allowed private entities to produce and sell radiopharmaceuticals with $T_{1/2}$<2h in Brazilian territory. This flexibility allowed the number of cyclotrons in the country to grow[26]. However, this increase did not occur equally, with the Central-West (except the DF) and North regions remaining without accelerators. The existence of centralized radiopharmacies can be a solution to reduce the complexity of the area, since the establishment responsible for obtaining the images

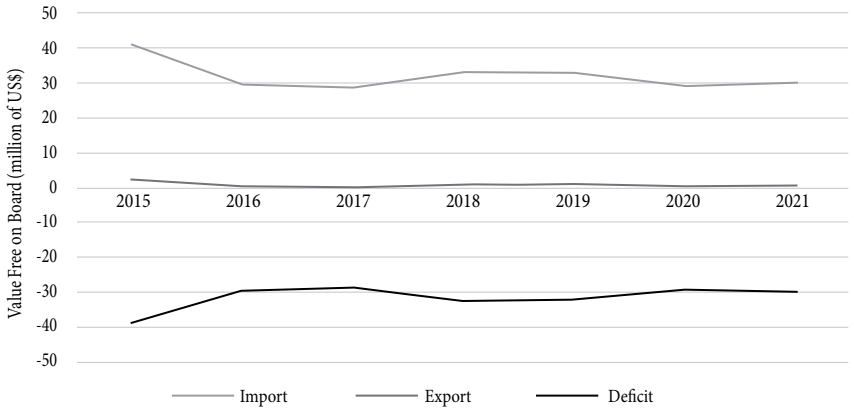


**Figure 4.** Trade balance of products linked to NM ($^{131}$I, $^{99}$mTc generator, other radionuclides, PET and gamma camera imaging equipment and others): Import, Export and Deficit.

Note: Free on board (FOB) is a commercial term used in the international transport of goods, where responsibility for the costs and risks of the goods is transferred from the seller to the buyer.

Source: Authors, based on the methodology developed by the Coordination of Prospective Actions of the Presidency/Health Innovation Group CP-GIS/Fiocruz, based on data from Comex Stat/MDIC, available at http://comexstat.mdic.gov.br/pt/geral/51972.

would not be obliged to maintain a laboratory for handling radioactive material. However, this work did not evaluate the possible relationship with the cost reduction that this reality would bring, especially in the SUS.

The consultation of the CNEN and CNES databases on NM and PET installations in Brazil reaffirms the discrepancies between the numbers reported in each of these databases already highlighted in 2015 by Pozzo *et al.*[27]. It is possible that some radioactive facilities are incorrectly registered with the CNES as NM facilities. Therefore, it is suggested the creation of a single database that integrates sanitary and radiological information to facilitate the bureaucratic process of obtaining and monitoring licenses and authorizations and speed up the material acquisition process.

Another aspect revealed in this consultation was the uneven geographic distribution of NM and PET facilities authorized in Brazilian territory. Although the greater concentration is linked to greater population density, there are still regions with little access to NM and no access to PET. Toscas *et al.*[28] and Hanna *et al.*[29] discuss within the scope of the radiotherapy expansion plan[30,31] that the high costs associated with PET equipment and its maintenance, transport and installation represent obstacles to the expansion of the area. This conclusion can be easily generalized to all nuclear medicine imaging equipment, as they are high-tech and high-cost equipment. In 2020, only three project approvals were found for the acquisition of PET/CT equipment financed by SUS[28].

However, the number of devices per million inhabitants is more informative, since an installation can have more than one piece of equipment. The values reported by CNES relating to the total number of equipment in use for the period studied (3.50 gamma cameras/million inhabitants and 0.54 PET/million inhabitants, in 2020, for example) are below the values obtained by Orellana *et al.*[2] for the USA (45.2 and 7.3, respectively, in 2020) and European countries (where this ratio varies from 6.7 to 16.0 and from 0.1 to 8.0, respectively). The values are also below the averages presented in the World Health Organization's Global Atlas of Medical Equipment (48.4 gamma-camera or other NM equipment/million inhabitants and 5.4 PET/million inhabitants) for the USA in 2022[31]. For the PET/CT equipment, the Secretary of Health Care of the MS[32] establishes the criteria of one PET/CT equipment per 1.5 million inhabitants at a distance that allows access to the radiophar-

maceutical (maximum two hours) for acquisition and management of this technology. The IAEA[33] publication indicates 1 equipment per million inhabitants in an initial approximation; in a more developed context, it considers reaching 2.0 to 2.5 equipment per million inhabitants. However, there is no consideration for gamma cameras in the two documents. Although the numbers presented in this work may be undersized, since the inclusion of information on the type and quantity of equipment in this database is not compulsory, a favorable scenario for expanding the infrastructure related to NM can be seen. Ciabattari and Menezes[34] evaluated the distribution of PET/CT equipment in Brazilian territory in 2020, taking into account the number of individuals potentially served by this equipment within a maximum distance of 100 km. 385 additional equipment would be needed (148 in places that already have PET/CT and 237 in places that do not have any equipment) to reach the average recommended by Páez *et al.*[35] of 500 thousand inhabitants per equipment. An important point to consider is that SPECT and SPECT/CT equipment and, on the other hand, PET, PET/CT and PET/MR equipment are quite different in terms of infrastructure, maintenance and training needs for specialized personnel. As a consequence, they present different efficacy and clinical effectiveness for each procedure adopted[5,6]. Within the scope of CNEN or ANVISA, these consequences are not considered, with CONITEC being responsible for its analysis for the purpose of incorporating the most cost-effective technologies.

In the present work, attention is drawn to the reduction in the total number of gamma cameras and the increase in the number of PET equipment in use in Brazil from 2015 to 2021. It is not possible to obtain the real number of equipment made available to the SUS as this information is not required from healthcare establishments. Even so, it can be stated that the estimated percentage of gamma cameras in use in the SUS during the studied period remained unchanged, while that of PET equipment decreased by approximately 10%, with the number of procedures per equipment remaining stable. This result is corroborated by the fact that the total number of NM procedures contracted by the SUS also fell during this period, while PET procedures increased. In other words, these results suggest that the equipment time dedicated to procedures reimbursed by the SUS was maintained.

Of the diagnostic procedures in NM, around 80% correspond to stress and rest myocardial scintigraphy and bone scan. This result can be understood considering that, in Brazil, cardiovascular diseases and cancer are two of the main causes of non-violent death[36]. It should be noted that the regionalized and stratified study by procedure was not the object of this work, but it would be important for a greater understanding of trends and needs.

The number of PET procedures reimbursed by the SUS at the federal level has been growing since its approval by CONITEC, even during the COVID-19 pandemic. Therefore, for indications accepted for reimbursement by the Union, this increase may be a good indicator that the objectives of Law No. 13,896/2019[37] are being achieved for these cases, at least in places with access to technology. However, it is also necessary to investigate whether the increase in diagnoses provided by PET has resulted in greater access to treatment, within 60 days, recommended by Law No. 12,732/2012[38].

According to SIGTAP, therapeutic procedures are not limited to iodine therapy. Regarding the approved number of therapeutic procedures, the South region stands out among all other regions. Based on data[39] on the incidence of thyroid cancer in different Brazilian regions, it can be inferred that a large number of outpatient cases (bone pain or benign conditions such as hyperthyroidism) are being treated in this region. It would be important to evaluate the distribution of each therapeutic procedure to better understand the care offered to the population according to their needs.

Practically all equipment and inputs used in NM are imported, resulting in a deficit of approximately US$30 million per year in the CEIS trade balance. It is important to note that this result was obtained before the amendment of the Federal Constitution that authorized the production and commercialization of Radiopharmaceuticals for the private sector in 2022[7]. Until that date, IPEN CNEN-SP was the main supplier of these inputs, with import tax facilities as it is a public body and prices are established by CNEN. Most radiopharmaceuticals for conventional NM are no longer offered by public institutions and are now sold by a small number of private companies that practice free negotiation and are exempt from various taxes as shown here, which impacts the transfer to municipalities (IPI) and social security (PIS and COFINS).

With the lack of personnel replacement and obstacles associated with the public management of a radiopharmaceutical production cen-

ter linked to the science and technology agenda, the main state entity responsible for supplying inputs to the NM area has been losing its capacity for research, development and production at a dizzying rate[40]. In 2021, faced with the possibility of shortages due to the lack of allocation of resources from the federal government to IPEN CNEN-SP, ANVISA allowed, under an exceptional regime, the import of radiopharmaceuticals without due registration by public bodies and entities and by legal entities of private law, including health establishments and services[41]. This resolution has been extended annually and is currently valid until March 31, 2024[42]. Given this scenario, it is likely that the trade balance deficit will increase in the coming years. On the other hand, the construction project of the Brazilian Multipurpose Reactor aims to eliminate external dependence on radioactive inputs for NM and radiotherapy, but it should not occur before 5 years, even with its inclusion in the new Growth Acceleration Program (PAC)[43] in 2023.

Imaging equipment is sold by foreign companies with representation in the country. Even though the sale of used and refurbished equipment is already regulated[44], to increase the technological park, the reduction of possible care gaps combined with technological and productive development could occur by adapting the radiotherapy expansion plan (PER-SUS)[29]. This plan called for the purchase of 80 new particle accelerators in 2012, but required a technological compensation agreement to reduce vulnerabilities, including technology transfer, development of local suppliers, installation of a manufacturing unit and training center.

## Conclusion

NM is a multidisciplinary, highly complex area, regulated in different ways by the Brazilian State. This work shows the need, present since the beginning of the period studied, to gather administrative data linked to compliance with the laws and regulations of radioactive and health establishments in an integrated database.

The supply of new radiopharmaceuticals for PET increased after Constitutional Amendment No. 49/2006. But this only translated into greater access for the population through the SUS after the incorporation of this procedure into the Unified Table in 2014 in which the radiopharmaceutical [$^{18}$F]FDG is used. None of the other six radiopharmaceuticals available for PET are routinely used in the SUS, which suggests the need for ATS studies to decide on incorporation. Establishments that provide PET equipment to the SUS reserve a small part of the usage time for it, which can be inferred from the low number of procedures approved per equipment estimated in this work.

The technology park maintained itself with approximately half of the equipment made available to the SUS. The number of imaging equipment available to the SUS per million inhabitants is low, which can result in unequal access to NM technologies. The high complexity of implementing and managing gamma cameras and PET/CT requires robust dissemination strategies so that the offer in the SUS occurs under equitable conditions. The adoption and publication of technical criteria and care parameters for offering gamma cameras in the SUS, as occurs with PET/CT, can contribute to the rational use of these technologies.

The NM procedures reimbursed by the federal component of the SUS remain the same, including the description of radiopharmaceuticals used and outdated protocols, which indicates the need to review the indication for incorporation.

The need to expand access to NM procedures, the large deficit in the trade balance maintained throughout the period studied, with the possibility of an increase with the exit of the public producer of radiopharmaceuticals, combined with the great technological dependence indicate the urgency of establishing a task force to evaluate the role of NM in the specific context of public health.

## Collaborations

L Pozzo and ML Oliveira are responsible for the conception, extraction, analysis and interpretation of data, writing of the article, its critical review and approval. FS Toscas is responsible for the extraction, analysis and interpretation of data, writing of the article, its critical review and approval. MO Menezes is responsible for the analysis and critical review of the article.

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