

**UMA ANÁLISE DA CONFORMIDADE DAS INSTALAÇÕES
RADIOLÓGICAS DO RIO DE JANEIRO ANTES DAS NOVAS
DIRETRIZES DA RDC 611**

**AN ANALYSIS OF THE COMPLIANCE OF RADIOLOGICAL
FACILITIES IN RIO DE JANEIRO BEFORE THE NEW RDC 611
GUIDELINES**

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Resumo: Em 2022, a Agência Nacional de Vigilância Sanitária (ANVISA) aprovou a Resolução da Diretoria Colegiada 611 (RDC 611), que estabelece as diretrizes básicas para Proteção Radiológica (PR) em radiologia diagnóstica e intervencionista e regulamenta o uso de métodos diagnósticos de raios X no Brasil. Especificamente em relação ao estado do Rio de Janeiro (RJ), o Laboratório de Ciências Radiológicas (LCR) da Universidade do Estado do Rio de Janeiro (UERJ) é responsável pela emissão de laudos técnicos das instalações radiológicas. Assim, este trabalho tem como objetivo avaliar se as instituições pesquisadas no estado do RJ que utilizam Radiação Ionizante (RI) estão em conformidade com a nova RDC 611. A ideia é de que este artigo sirva como um panorama de como era a situação antes da RDC 611. Este artigo baseia-se em uma abordagem qualitativa por meio de entrevistas com funcionários do LCR e da aplicação de um questionário com dez perguntas. O grupo LCR realiza cerca de três mil fiscalizações por ano em instituições públicas e privadas. O maior número de não

conformidades encontradas está relacionado à falta de sinalização e avisos na área controlada dentro e fora das salas de exames, principalmente em clínicas odontológicas.

Palavras-chave: RDC 611/22, LCR, radiação ionizante, Rio de Janeiro, Brasil.

Abstract: In 2022, the National Health Surveillance Agency (ANVISA) approved Collegiate Board Resolution 611 (RDC 611), which establishes the basic guidelines for Radiological Protection (RP) in diagnostic and interventional radiology and regulates the use of diagnostic methods of X-rays in Brazil. Specifically, in relation to the state of Rio de Janeiro (RJ), the Laboratory of Radiological Sciences (LCR) of the University of the State of Rio de Janeiro (UERJ) is responsible for issuing technical reports for radiological facilities. Thus, this work aims to assess whether the institutions surveyed in the state of RJ that use Ionizing Radiation (IR) are in compliance with the new RDC 611. The idea is that this paper serves as an overview of what the situation was like before the RDC 611. This paper is based on a qualitative approach through interviews with the staff of the LCR and the application of a questionnaire with ten questions. The LCR group carries out approximately three thousand inspections per year in public and private institutions. The largest number of non-conformities found is related to the lack of signs and warnings in the controlled area inside and outside the examination rooms, especially in dental clinics.

Keywords: RDC 611/22, LCR, ionizing radiation, Rio de Janeiro, Brazil.

1. INTRODUCTION

For years, despite the high frequency of radiodiagnostic examinations and their significant contribution to the collective dose, little attention has been devoted to the radiation protection (RP) of patients and healthcare professionals. Until then, there were only a few state regulations (1-3). So, in 1996, the Health Radiation Protection Program was created to fulfill this role, which was endorsed by the State Health Surveillance Coordination as a reference for gauging the radioprotection conditions of radiodiagnostic services (1-4).

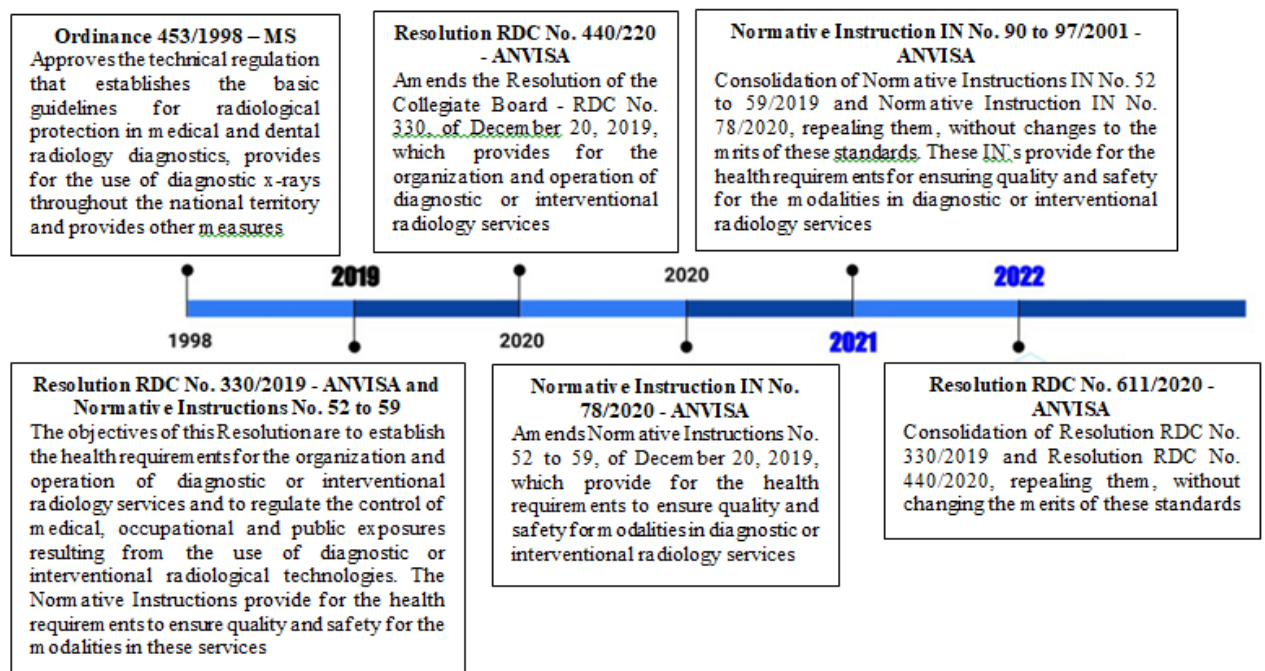
However, this scenario began to change in 1998, with the publication of Ordinance SVS/MS 453/98 (Directive on Radiological Protection in

Radiodiagnosis and Dentistry), of June 1, 1998, by the Ministry of Health, which discusses the basic guidelines for RP in medical and dental radiodiagnosis and the use of diagnostic X-rays throughout the national territory (1-4). In this sense, the ordinance 453 was a landmark of the normative reference in Brazil for the use, with safety and quality control, of radiodiagnostic, since these practices were only guided by international or state norms that defined the RP criteria (1-4).

Among the requirements established in the Ordinance, can be mentioned: licensing requirements, definition of responsibilities and minimum requirements for X-ray and performance equipment (1-4). With the advancement of technology and the publication of new international RP recommendations, it became necessary to review and update the Ordinance. However, just twenty years after the publication of Ordinance 453, the National Health Surveillance Agency (ANVISA) made the new document available for public consultation (5; 6).

Thus, in 2022, ANVISA approved Resolution 611 of the Collegiate Board of Directors (RDC 611), which establishes the basic guidelines for RP in diagnostic and interventional radiology and regulates the use of X-ray diagnostic methods throughout the national territory (5; 6). The temporal advances in relation to changes in legislation can be seen in Figure 1.

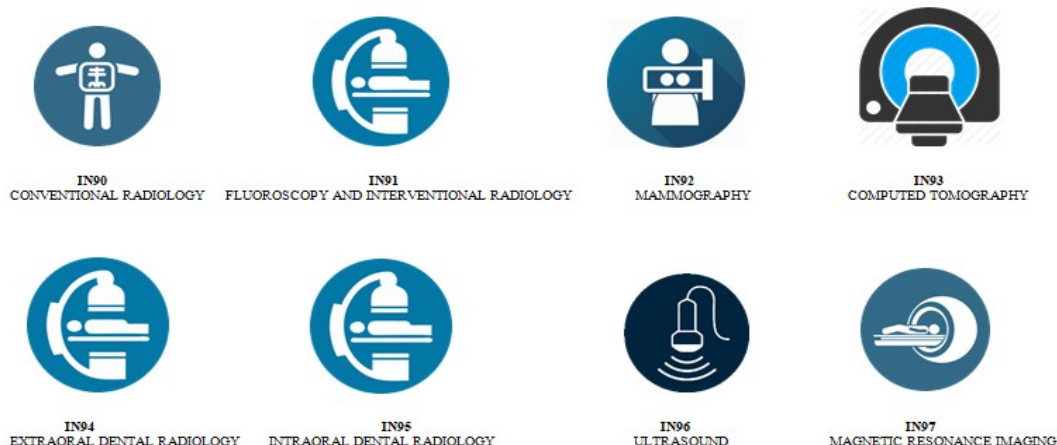
Figure 1: The temporal advances of the legislation on health requirements for diagnostic or interventional radiology services



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The RDC 611 came with several changes even in its format: a document with basic radiation protection guidelines and several Normative Instructions (INs) – one for each technology in diagnostic imaging (6-15). The INs no. 90 to no. 97, of May 27, 2021, from ANVISA, establish the health requirements for Quality and Safety Assurance in Conventional Medical Radiography Systems, Fluoroscopy and Interventional Radiology, Mammography, Computed Tomography, Extraoral and Intraoral Dental Radiology, Ultrasonography and Magnetic Resonance Imaging, as well as the minimum list of acceptance and quality control tests that must be carried out by health services, determining their respective frequency, tolerances and restriction levels (figure 2).

Figure 2: The INs



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So, the RDC 611 and its respective INs were developed to meet all these needs, contextualizing the principles already established for raising the RP culture and diagnostic quality (5). Therefore, the implementation of RDC 611 is defended, in view of the need for an agile adaptation that can guarantee improvements in imaging services, dose optimization and in the quality control of radiodiagnostic equipment, promoting the safety of patients, population and workers exposed to ionizing radiation (IR) (5; 6).

However, when observing the radiodiagnostic service and its changes in recent decades, the addition of new modalities, as well as changes in the flow of service, brought about as a result of the advancement of new technologies, is evident (5). Despite the great advances observed in this period, many hospitals still do not meet the RP requirements. In this way, the concern is not just to have a revised standard, but that it is duly complied with by the services. Among the various difficulties in implementing the standard by public hospitals, can be cited: non-recognition of the importance of radiological protection in radiodiagnosis, lack of qualified human resources and scarce financial resources (5).

Specifically, with regard to the state of Rio de Janeiro (RJ), in Brazil, from 1980 to 2005, radiodiagnostic inspections were carried out by the Institute of Radiation Protection and Dosimetry (IRD). In 1994, through decree nº 21.231 of SES/RJ, the Laboratory of Radiological Sciences (LCR) of the University of the

State of Rio de Janeiro (UERJ) received authorization to also issue technical reports for radiological facilities in the state (1-3; 5).

The LCR is a scientific reference in the study of ionizing and non-ionizing radiation, leading numerous research projects in the health sector, in which these types of radiation have wide application in the diagnosis and treatment of diseases. Legal control carried out by government bodies has allowed users of radiodiagnostic services and occupationally exposed workers to have protection against these risks. In the State of Rio de Janeiro, the LCR is a qualified entity to study, promote and execute the set of activities that comprise radioprotection, acting in harmony with health surveillance providing support, technical knowledge and diagnosis of conditions of use, being of vital importance for the study of the areas of Radiotherapy, Radiology and Radiobiology (16).

The Health Radioprotection Program (PRS) is responsible for evaluating technical quality parameters related to radiation doses used in medical, veterinary, educational and dental radiodiagnostic procedures carried out in public and private health institutions. The Program aims to reduce the radiation dose, as well as improve image quality, through the use of techniques referenced in current legislation and academic studies. The Program is carried out by the Radiological Sciences Laboratory at UERJ, which has developed its own operational expertise over 20 years, which periodically undergoes review in technical and operational aspects. Dentistry, tomography, mammography, general X-ray, hemodynamic, surgical arc, or other ionizing and non-ionizing radiation equipment used in diagnostic health must undergo inspection every two years. During the inspection, a survey is made of technical and environmental issues arising from the presence of radiological equipment. Fixed or mobile equipment must be subject to inspection, even if installed in mobile units (16).

Thus, this study aims to evaluate the Compliance of Radiological Services in Rio de Janeiro carried out during 2020 by the LCR. It is important to highlight that these analyses were carried out in 2020, shortly after the implementation of RDC 611. In other words, this article will serve as a portrait of how the Institutions were before the implementation of RDC 611. Thus, it can serve as a basis for

future analyses in a comparative manner between before and after the implementation of the RDC 611 guidelines.

2. MATERIALS AND METHODS

This paper is based on a qualitative approach (7) through interviews with the team of professionals from the RP in Health Program of the LCR. A questionnaire with ten questions was applied to verify if the institutions surveyed are in compliance with current regulations and if the LCR can meet all the demand for diagnostic services in the state of RJ. The questions were:

1. On average, how many radiology services per year can the LCR inspect in public and private hospitals in the state of Rio de Janeiro?
2. What is the LCR's expectation with the implementation of the revised Ordinance 453?
3. What are the main non-conformities found in radiology services?
4. The report issuance service is paid for by the hospital. Are there any questions from hospitals and clinics regarding the values?
5. The number of employees is sufficient to carry out activities to inspect the services for the issuance of the report?
6. Is there a need to increase the number of employees?
7. What type of training does this professional have? Do you have any kind of specialization to work in the area of radiodiagnostics?
8. Which forms are used to carry out the evaluations of the different services in the radiology sector?
9. The institution has a database of registration information of establishments that use IR sources?
10. Results obtained in the last 12 months in relation to X-rays in institutions (in this case, involving tests carried out regarding Hemodybamics, Surgical Arch and Bone Densiometry; Computed Tomography - CT Scanners; and Mammography).

3. RESULTS AND DISCUSSIONS

3.1. Interview with the LCR Group

The LCR Group carries out approximately three thousand inspections per year in public and private institutions (question 1).

The group understands that their vision of Ordinance 453, with the consequent application of RDC 611, will be fundamental for the evaluation of radiodiagnostic services that already have new technologies (question 2).

The largest number of non-conformities found in the services is related to the lack of signs and warnings in the controlled area inside and outside the examination rooms, especially in dental clinics (question 3).

The LCR report is a health surveillance requirement for issuing an operating license. This service is paid. Due to users' lack of understanding of RP and quality control, they are often reluctant to pay or question the value, believing that this service is not necessary (question 4).

Without the requirements established in a normative regulation, it is difficult for them to act in the services. The LCR recognizes the need to increase the number of professionals. For instance, the team of the health radio protection program is composed of five employees, among them are physicists and radiology technologists with a postgraduate degree in radiodiagnosis (questions 5 to 7).

The forms used in the evaluations of the services and the respective performance tests are prepared for each type of X-ray equipment: conventional X-ray; Hemodynamics, Surgical Arch and Bone Densiometry; Mammography; and Computerized Tomography (question 8).

To meet RJ's demand, LCR established a database with institutions that have IR emitting equipment. The tests performed by the LCR are (question 9): a) Documentation and Structure; b) Radiographic Processing; c) Device Identification; d) Room Evaluation; e) Appliance Evaluation; f) Collimation System; g) Kilovoltage Assessment; h) Current variation; i) Exposure Time; j) Filtration System; k) Head Leakage; and l) Radiometric Survey.

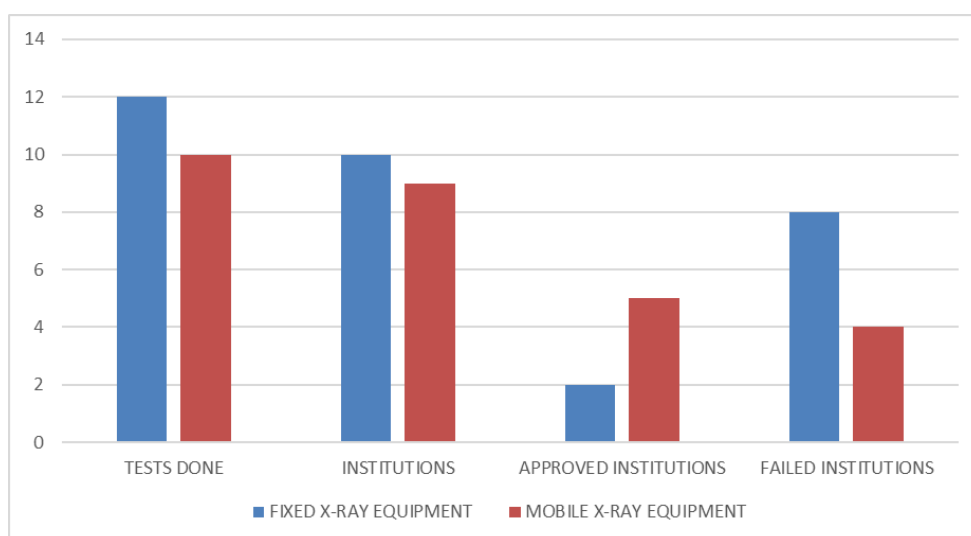
The answers to question 10 will be presented below (about tests carried out regarding Hemodybamics, Surgical Arch and Bone Densiometry; Computed Tomography - CT Scanners; and Mammography).

3.2. Results of tests carried out in relation to conventional X-rays in institutions

The figure 3 shows the results of performance tests carried out on conventional fixed and mobile X-rays equipments.

Ten institutions that had fixed and 9 mobile X-rays were evaluated. Twelve tests were carried out for fixed and 10 for mobile. The excess number of tests in relation to the number of institutions indicates that a given institution has more than one piece of equipment.

Figure 3: Tests performed on conventional fixed and mobile X-rays



Source: The author.

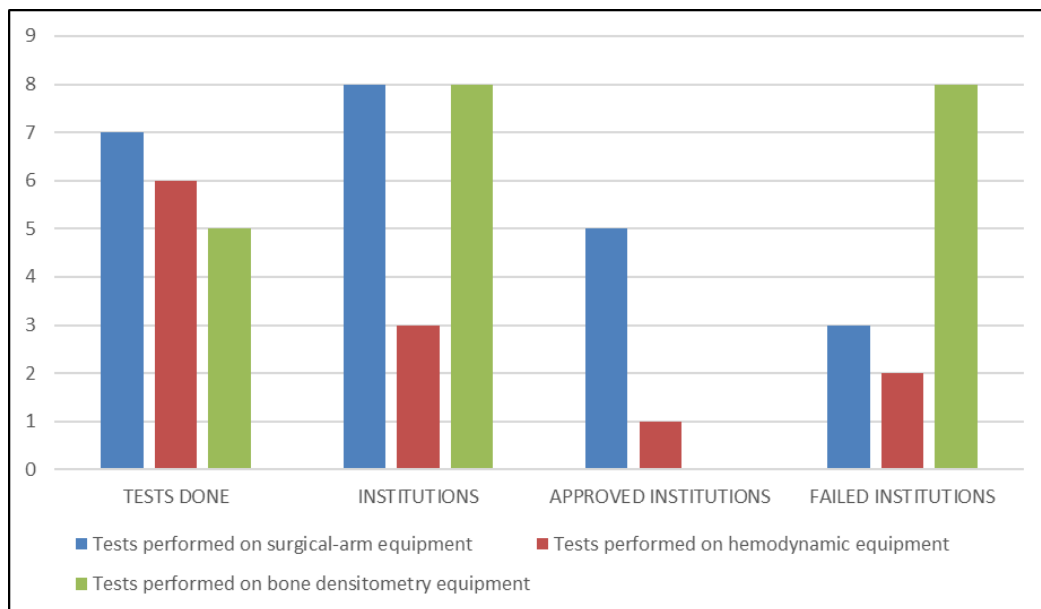
According to the LCR, 2 (20%) institutions were approved for fixed and 5 (50%) for mobile. The test with the greatest non-compliance is the examination room assessment tests, which mainly consist of signs and warnings for patients and companions. Tests carried out on mobile x-ray equipment are also

observed. The device evaluation tests were the item with the greatest non-compliance.

3.3. Results of tests carried out regarding Hemodybamics, Surgical Arch and Bone Densiometry

The Figure 4 shows the tests performed on Hemodynamics, Surgical Arc and Bone Densiometry equipment. Performance tests were carried out for the following equipment and the following institutions: 7 surgical arches, in 8 institutions; 6 of hermodynamics, in 3 institutions; and 5 bone densiometry in 8 institutions. The excess number of institutions in relation to tests indicates that the institution claims to have the equipment, but it is inoperative.

Figure 4: Tests performed on Hemodynamics, Surgical Arch and Bone Densitometry



Source: The author.

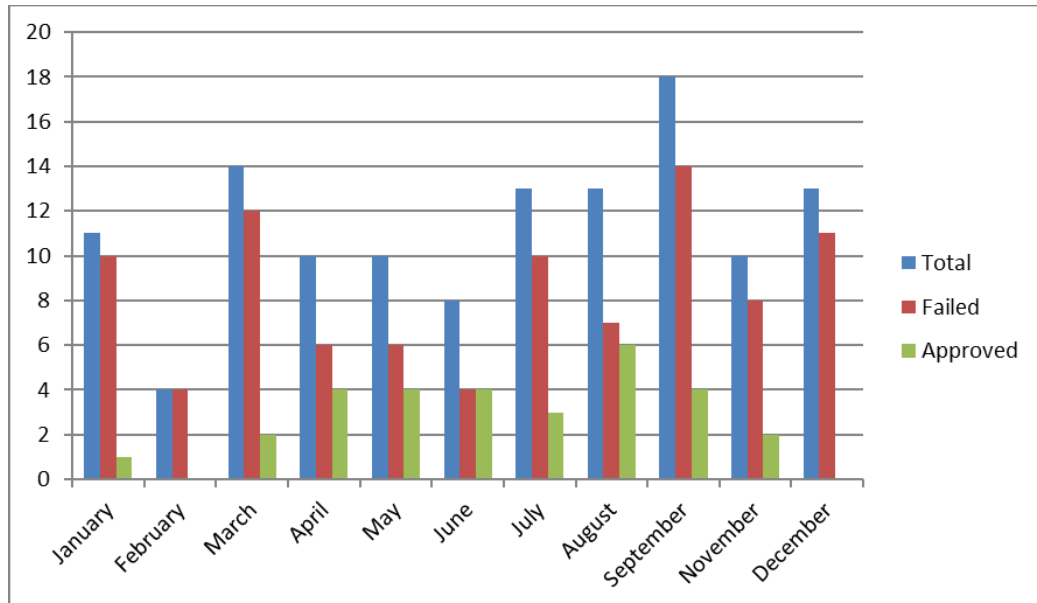
Of this total, according to the LCR criteria, 5 (62.5%) institutions would be approved for surgical arch, 1 (16.7%) for hemodynamics and none for bone densiometry. The tests of greatest non-compliance in both equipment is the evaluation of the examination room regarding the signaling and warnings to the patient. Surgical-arm equipment had 8 institutions evaluated and 3 failed. The lack of identification of the device was the item of greatest non-compliance.

3.4. Results obtained ins tests carried out in institutions on Computed Tomography (CT Scanners)

The Computed Tomography (CT) was one of the most technologically advanced radiodiagnostic equipment and was also ends up being responsible for

the highest dose to the patient. The Figure 5 show the tests performed on CT scanners.

Figure 5: Tests performed on CT Scanner



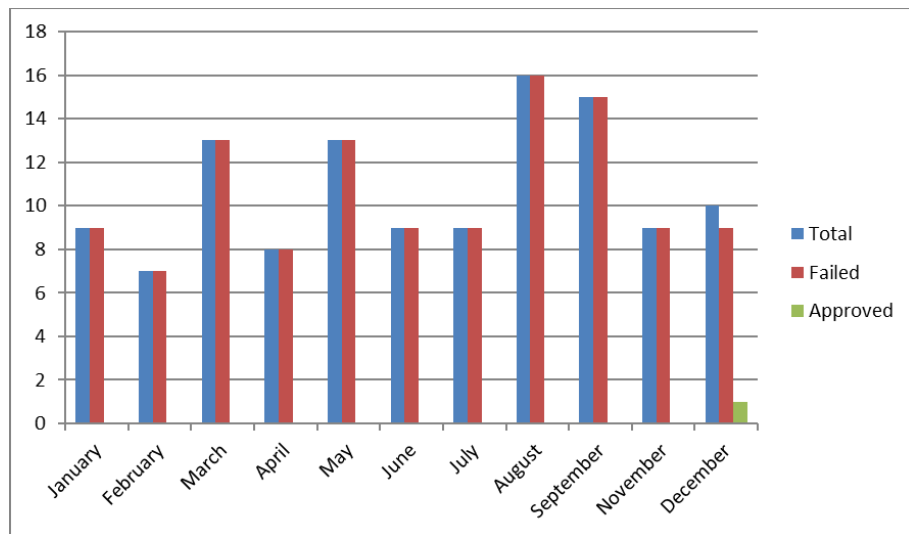
Source: The author.

During all the months of tests carried out there were non-conformities tomographers. Of the 136 tomographs inspected, only 37 were approved, that is, 73% of the equipment showed non-conformities. In the month of February, all the tomographers inspected were rejected, which means a bad statistic from the point of view of quality control and radiological protection, considering that the tomography has the greatest contribution to the dose to the patient.

3.5. Results obtained in tests carried out in institutions on Mammography

The Mammogram is probably the most important and the most capable of detecting breast cancer at an early stage. Figure 6 shows the tests performed on the Mammography machines.

Figure 6: Tests performed on Mammography



Source: The author.

The mammography exam requires the image of anatomical structures with adequate information for the diagnosis, but it also needs quality control and calibrated equipment for dose optimization and image interpretation. Of the 134 mammograms inspected, only 1 (0.8%) was on-conforming in December.

4. CONCLUSIONS

This paper aimed to assess the situation of hospitals inspected by the LCR in Rio de Janeiro before the implementation of RDC 611, taking as reference studies carried out on the same subject in other states and conducting a critical evaluation of the proposal for the new RDC 611, in order to point out the need to adapt radiodiagnostic services to recent technological advances.

According to the data collected, there is also a lack of a culture and training in radiological protection for health professionals and the need for an active and present regulatory authority. This is because it was found that many radiodiagnostic equipment inspected by the LCR do not have efficient quality control, since most of them were rejected in previous years, with pending issues to be able to comply with the requirements for serving the population.

In addition, with technological advances, it became clear that Ordinance 453/98 should be updated, and that some points of RDC 611 need to be updated.

Several items had already been questioned by several experts, including the lack of quality control and safety criteria in non-covered modalities, such as ultrasound, magnetic resonance imaging and veterinary radiology.

The new wording of RDC 611 did not clearly define the training required for professionals to act as TR (technical manager) or SPR (radiological protection supervisor), matters previously defined by Ordinance 453/98. It is also necessary to include other ways of regulating the performance of services that emerged with technological advances, such as teleradiology, in addition to having suggested that the definitions be in accordance with the definitions already described and established by other entities in the area, such as the National Atomic Energy Commission (CNEN), the Brazilian Association of Technical Standards (ABNT), the International Atomic Energy Agency (IAEA) and the International Commission on Radiological Protection (ICRP), for example.

It was identified that the main problems in the strategy for implementing RDC 611 may be the lack of a broad change in health policy, which includes restructuring professional training programs and raising awareness of the importance of a culture of radiological protection among the heads of institutions and professionals in the health area. Despite the importance of regulatory standards and an efficient inspection system, the current scenario will not change simply with the publication of a new ordinance. It is suggested that research be carried out on the topic of radiological protection culture, as this is the only way to achieve an adequate and efficient change that can not only improve radiological protection and the quality of diagnosis, but also consolidate this culture in the education of health professionals.

Finally, as previously mentioned, the interviews were conducted in 2020, shortly after the implementation of RDC 611. The initial idea was to survey the situation of the institutions before the implementation of RDC 611, to verify the real situation. The aim now, 4 years after the implementation of RDC 611, is to carry out a new round of interviews to compare the data presented in this article with the current situation.

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