Advances of RDC 611/22 in relation to Ordinance 453/98: a preliminary analysis on compliance

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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 brazilian territory. Specifically in relation to the state of Rio de Janeiro (RJ), in Brazil, 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 in the state. Thus, this work aims to assess whether the institutions surveyed in the state of RJ that use Ionizing Radiation (IR) are in compliance with 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. 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 IR.

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. In 1998, an important initiative in this area was the publication of Ordinance 453 of the Ministry of Health (MS). Until then, there were only a few state regulations [1].

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, of the MS, which discusses the basic guidelines for RP in medical and dental radiodiagnosis and the use of diagnostic X-rays throughout the national territory [1].

In this sense, the ordinance 453 was a landmark of the normative reference in Brazil for the use, with safety and quality control, of radiodiagnostics, since these practices were only guided by international or state norms that defined the RP criteria [1].

Among the requirements established in the Ordinance, we can mention: licensing requirements, definition of responsibilities and minimum requirements for X-ray and performance equipment [1].

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 [1].

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, we can mention: non-recognition of the importance of radiological protection in radiodiagnosis, lack of qualified human resources and scarce financial resources [1].

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 [1].

Therefore, 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.

RDC 611 came with several changes even in its format: a document with basic radiation protection guidelines and several Normative Instructions (NIs) – one for each technology in diagnostic imaging. Among the NIs, NI 58 and NI 59 can be mentioned, which provide for sanitary requirements for quality assurance and safety in ultrasound and magnetic resonance systems, respectively, which makes quality control mandatory [1].

RDC 611 and its respective NIs were developed to meet all these needs, contextualizing the principles already established for raising the RP culture and diagnostic quality.

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) [1].

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.

Thus, 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.

Thus, this study aims to assess whether the institutions surveyed in the state of RJ that use IR are in compliance with current regulations and whether the LCR can meet all demand for diagnostic services.

2. Materials and Methods

This paper is based on a qualitative approach [2] 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 institution has a database of registration information of establishments that use IR sources:
( )Y ( )N;

6. What is the number of employees who carry out activities to inspect the services for the issuance of the report?

7. What type of training does this professional have? Do you have any kind of specialization to work in the area of radiodiagnostics?

8. Is there a need to increase the number of employees?
( )Y ( )N;

9. Which forms are used to carry out the evaluations of the different services in the radiology sector (X-rays, mammography, computerized tomography);

10. Results obtained in the last 12 months:

A. Number of surveys carried out;

B. No of compliant and non-compliant imaging services;

C. Number of reports issued.

It is important to highlight that these interviews were carried out in 2020, therefore, before the COVID pandemic and the implementation of RDC 611.

3. Results and Discussion

3.1. Interview with the LCR Group

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

The group understands that there 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.

Without the requirements established in a normative regulation, it is difficult for them to act in the services. LCR recognizes the need to increase the number of professionals. The forms used in the evaluations of the services and the respective performance tests are prepared for each type of X-ray equipment.

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 reluct ant to pay or question the value, believing that this service is not necessary.

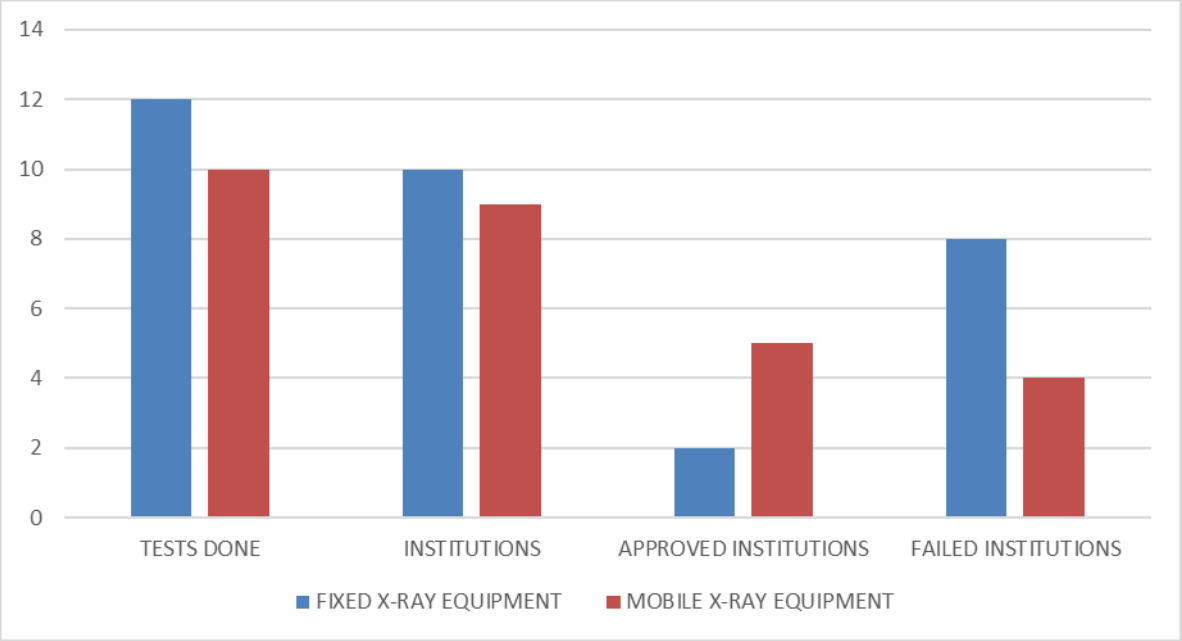
To meet RJ's demand, LCR established a database with institutions that have IR emitting equipment. The team of the health radio protection program is composed of five employees, among them are physicists and radiology technologists with a postgraduate degree in radiodiagnosis. The tests performed by the LCR are:

1. Documentation and Structure;
2. Radiographic Processing;
3. Device Identification;
4. Room Evaluation;
5. Appliance Evaluation;
6. Collimation System;
7. Kilovoltage Assessment;
8. Current variation;
9. Exposure Time;
10. Filtration System;
11. Head Leakage;
12. Radiometric Survey.

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

The Figure 1 presents the percentage of fixed and mobile X-rays equipment that passed. Twelve performance tests were performed on each equipment in ten different institutions.

Figure 1. Tests performed on conventional fixed and mobile X-rays



Source: The author

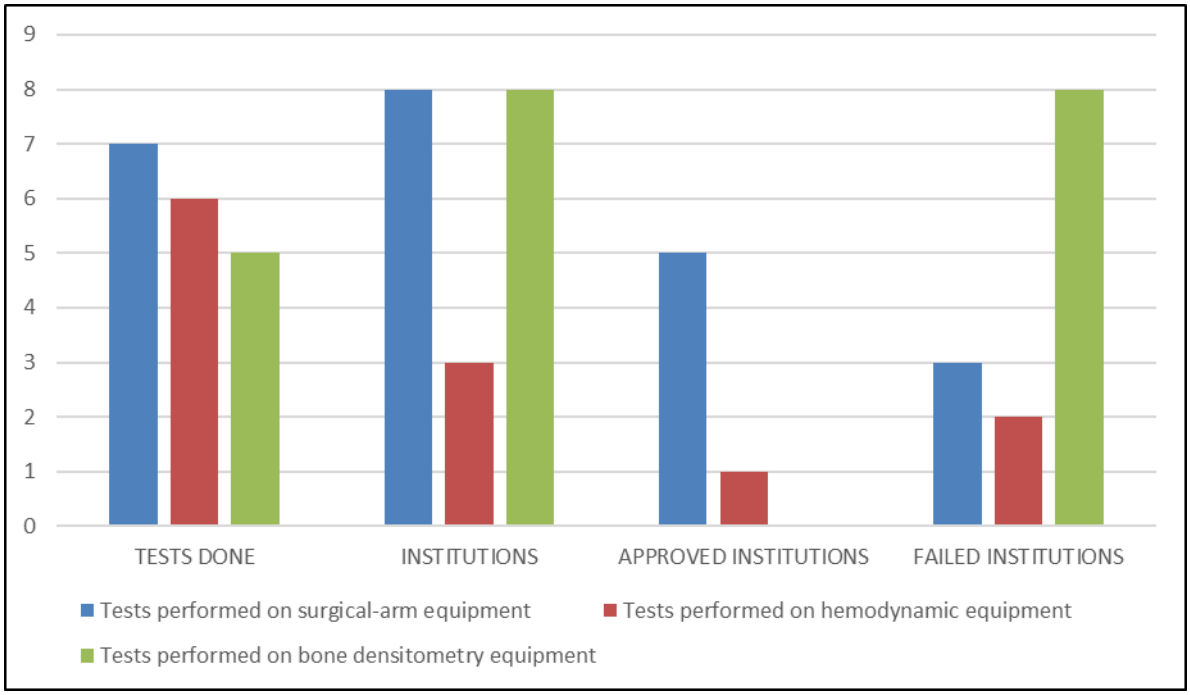
The Figure 1 shows the tests performed on conventional X-rays equipment with only two approved institutions. The test of greatest non-compliance is the examination room assessment tests, which mainly consist of evaluating the signs and warnings for patients and companions.

Tests performed on mobile X-rays equipment are also observed. In these, only 5 institutions were approved. 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 2 shows the percentage of regarding Hemodybamics, Surgical Arch and Bone Densiometry equipmenta that were approved. Twelve performance tests were performed on each equipment in ten different institutions.

Figure 2. Tests performed on Hemodynamics, Surgical Arch and Bone Densitometry equipments



Source: The author

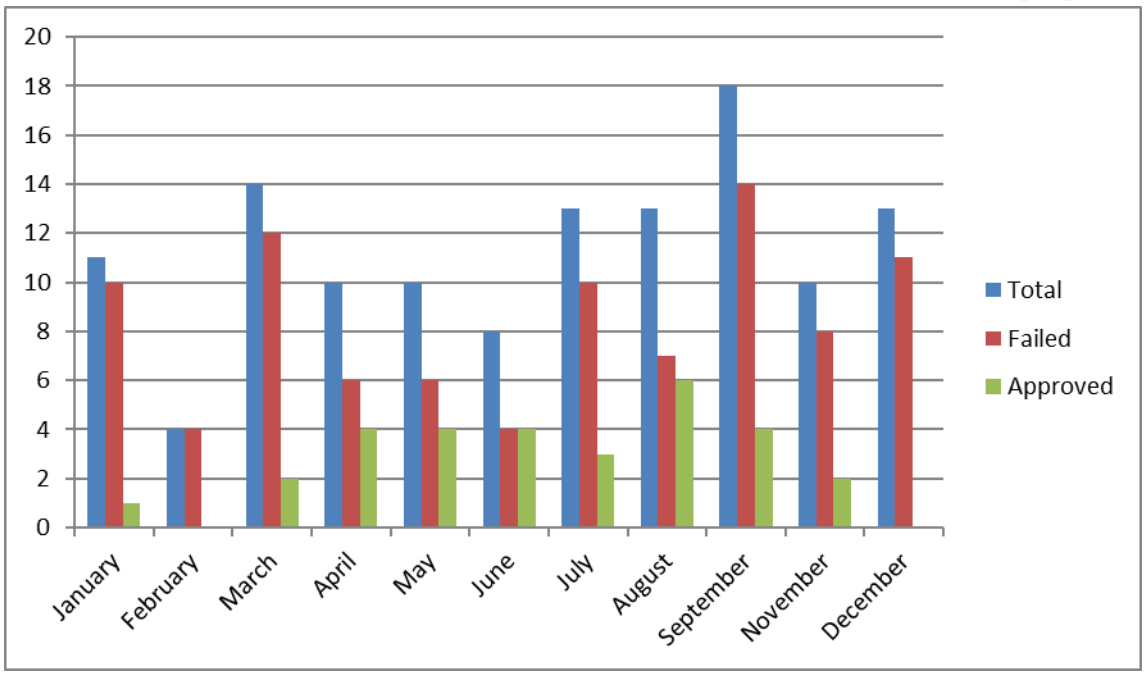
In figure 2, in the hemodynamic equipment of 3 institutions, only 1 was approved. It is also noted that in bone densitometry equipment all 8 institutions evaluated failed. The tests of greatest non-compliance in both equipment is the evaluation of the examination room regarding the signaling and warnings 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 was one of the most technologically advanced radiodiagnostic equipment and was also responsible for the highest dose to the patient. Figure 3 shows the number of approved and disapproved CT scanners.

Figure 3. Statistics of CT Scanners approved



Source: The author

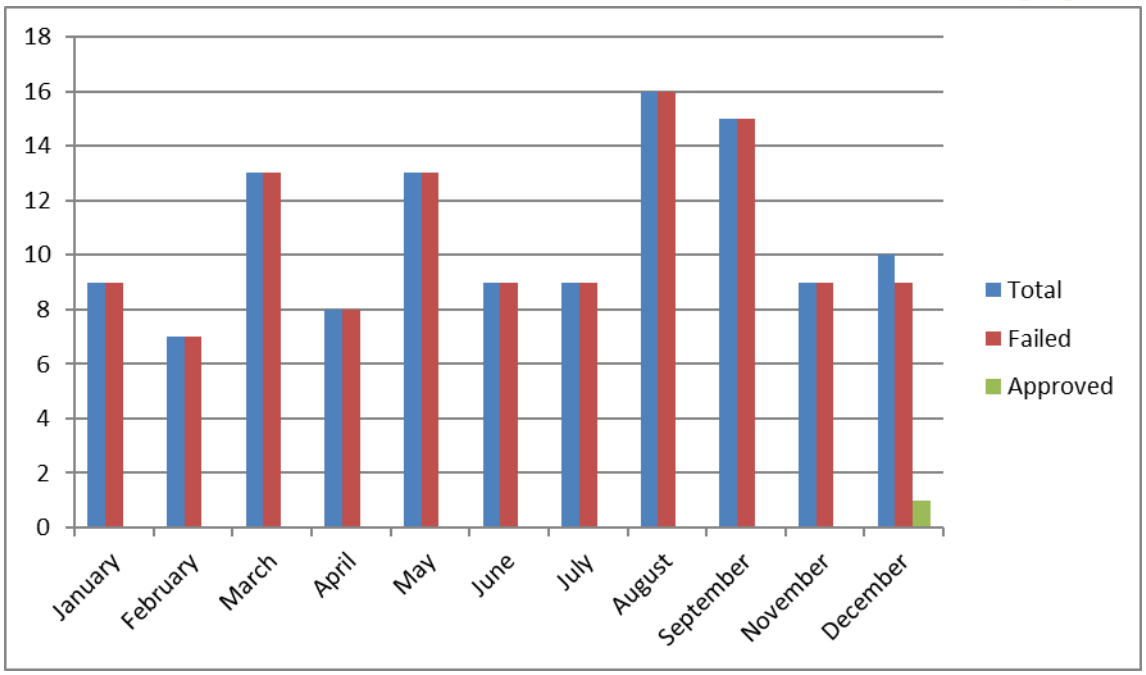
The Figure 3 shows the graph with the tests carried out, demonstrating that in all the months of tests carried out there were non-conformities tomographs. Of the 136 tomographs inspected, only 37 were approved, that is, 73% of the equipment showed non-conformities.

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 ins tests carried out in institutions on Computed Tomography (CT Scanners)

The Mammogram is probably the most important and the most capable of detecting breast cancer at an early stage. Figure 4 shows the tests performed on the Mammography machines.

Figure 4. Number of approved Mammograms



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 was on-conforming in December.

4. Conclusion

This paper aimed to evaluate the current situation of hospitals inspected by the LCR according to the new recommendations of RDC 611/22 and, mainly, to verify the need to adapt radiodiagnostic services to recent technological advances.

It was found that many radiodiagnostic equipment that were inspected by the LCR do not have an efficient quality control, as most of them were disapproved in 2017 and 2018 and have pending issues to be able to comply with the care of the population, which is a very worrying scenario.

Thus, without proper maintenance, the dose in the patient is increased. In addition, many hospitals have professionals without adequate training to perform the procedures, especially in the most modern equipment.

Despite these important deficiencies and the risks associated with them, the services continue to serve the population that has minority access to private hospitals or better quality public services.

In addition, with technological advances, it became evident that Ordinance 453/98 should be updated. Several items were questioned by several specialists, among them the lack of quality control and safety criteria in modalities not covered, such as ultrasound and magnetic resonance, as well as in veterinary radiology.

It was identified that the main problems in the strategy for the implementation of RDC 611/22 are the lack of a broad change in the policy in the health area, which includes the restructuring of professional training programs and the awareness of the importance of the radiological protection culture by the holders of institutions and health professionals.

Despite the importance of regulatory standards as well as an efficient inspection system, the current scenario will not change just with the publication of a new ordinance. It is suggested that research be carried out on the theme of radiological protection culture, because only then will an adequate and efficient modification be possible so that not only can radiological protection and the quality of diagnosis

be improved, but also that this culture can be consolidated in teaching. of health professionals that will benefit patients, workers and society as a whole.

References

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