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Analysis of the Advances of RDC 611/22 in relation to Ordinance 453/98 in the Focus of Radiation Protection

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ABSTRACT

Almost twenty years after the publication of Ordinance 453, the National Health Surveillance Agency (ANVISA) approved Resolution 611 of the Collegiate Board of Directors (RDC 611), which establishes the basic guidelines for Radiation Protection (RP) in diagnostic and interventional radiology and regulates the the use of X-ray diagnostic methods throughout the national territory. Therefore, when observing the radiodiagnostic service and its changes in recent decades, the addition of new modalities is evident, as well as changes in the flow of service, brought about as a result of the advancement of new technologies. 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. Among the INs, IN58 and IN59 can be mentioned, which provide for sanitary requirements for quality assurance and safety in ultrasound and nuclear magnetic resonance systems, respectively, which makes quality control mandatory. 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. 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.

Keywords: **Ordinance 453, RDC 611, radiation protection, quality control, radiodiagnostic.**

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1. INTRODUCTION

For years, despite the high frequency of radiodiagnostic exams and their significant contribution to the collective dose, no official standard has been dedicated to the radiation protection (RP) of patients and health professionals.

However, this scenario began to change in June 1, 1998, with the publication of Ordinance SVS/MS 453/98 by Ministry of Health (MS), the Directive on Radiation Protection in Radiodiagnosis and Dentistry, which discusses the basic guidelines for RP in medical and dental radiodiagnosis and the use of X-ray diagnostic 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 parameters established in Ordinance 453, one can mention the licensing requirements, definition of responsibilities and minimum requirements for X-ray and performance equipment [2].

In 2006, the Resolution 1016/2006 by National Agency of Sanitary Surveillance (ANVISA) was published, which served as an orientation guide for the minimum set of quality control tests in radiodiagnostic equipment, having as references the international standards [1-2].

Despite this, with the advancement of digital technology and the publication of new international recommendations for quality control and RP, a review and update of Ordinance 453 became necessary. Thus, more than twenty years after the publication of Ordinance 453, the ANVISA approved, after public consultation, the Resolution of the Collegiate Board of Directors 330 (RDC 330) on December 20, 2019 [3] – currently revoked by RDC 611 of March 9, 2022.

The RDC 611 establishes the health requirements and basic guidelines for RP in diagnostic and interventional radiology, regulating the control of medical exposures and the use of X-ray diagnostic methods throughout the national territory and through Normative Instructions (INs) that have on the requirements for quality control and equipment safety [4].

This evolution was necessary because when observing the radiodiagnostic service and its changes in recent decades, for example, 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, such as the computerized radiography (CR) system – which digitizes the conventional X-ray system – and the digital radiography system (DR) – where the X-ray equipment is already digitized [1-2].

In addition, with the constant implementation of teleradiology, for example, new working relationships were established, diversifying more and more the performance of the radiology service, as in itinerant services with a service truck, remote report center, remote control of equipment and obtaining reports and viewing images online.

On the other hand, old practices are becoming obsolete, such as the image processing system with chemicals and the reports of radiographic film films in negatoscopes, and are being replaced by a digital display system (CR and DR) with a network of PACS, for example, which contribute to better diagnostic results and provide greater safety for professionals and patients [1-3].

This is because the radiological images provide important information for the decision of the future steps of a diagnosis, a treatment or follow-up of a procedure. So, the necessary level of image quality for the correct diagnosis has to be obtained at the lowest possible radiation dose to the patient [5; 6].

Therefore, an image without adequate quality must be repeated and there are some costs involved in this process that must be avoided, and the main one is the doubling of the dose in the same patient. Thus, the adoption of quality concepts in radiology becomes very useful, since it helps to control the image acquisition process with the reduction of predictable errors [5].

2. **MATERIALS AND METHODS**

In this sense, the present paper aims to make a comparison between Ordinance 453 of 1998 and RDC 611 of 2022 and their respectiveNormative Instructions (INs), in order to verify the advances in technologies and new modalities added in the new regulations regarding the RP of patients, population and workers exposed to ionizing radiation.

This paper is a qualitative research, because it is understood that the direct source of data (in this case, documents) are the fundamental instrument for the research, having a descriptive and

comparative function, using an inductive approach to data analysis, involving the obtaining descriptive data [7].

3. RESULTS AND DISCUSSION

Published in the Federal Official Gazette (D.O.U.) on 12/26/19, ANVISA's RDC 330, of December 20, 2019, and later revoked by RDC 611 of March 9, 2022, both revoked the SVS Ordinance 453/98 by MS (Directive on Radiation Protection in Radiodiagnosis and Dentistry), of June 1, 1998, and Resolution 1016/06 by ANVISA, of April 3, 2006 (Figure 1).

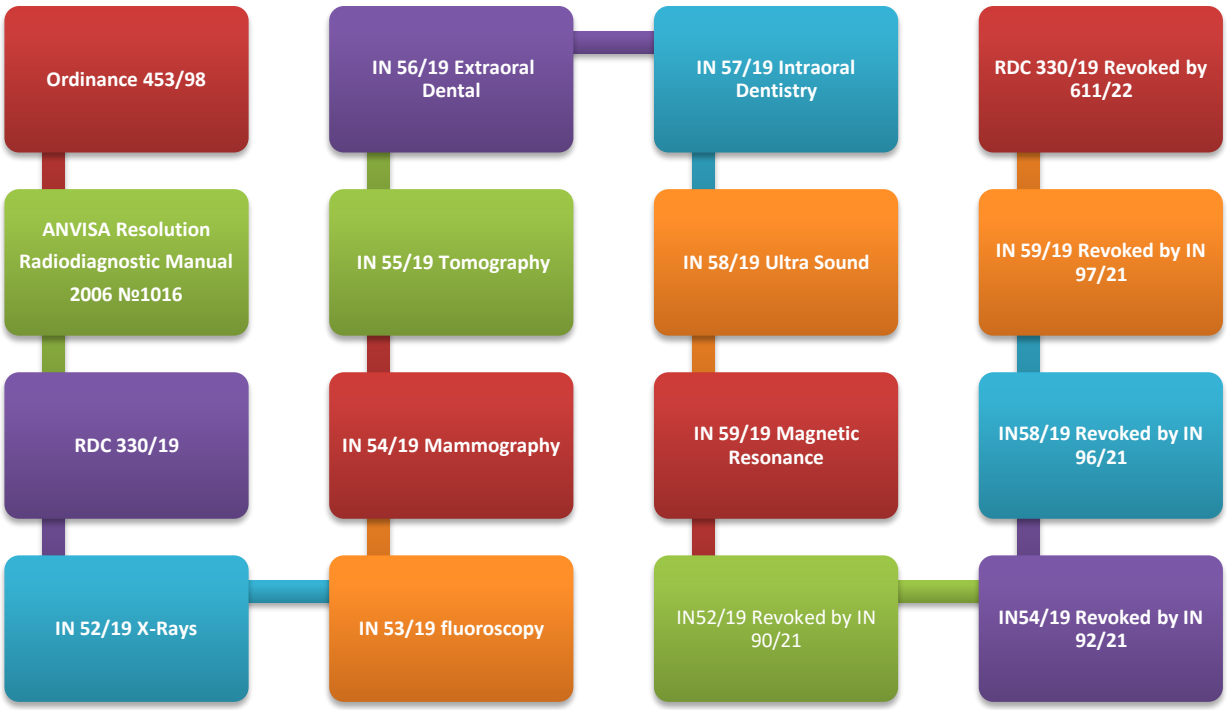

Figure 1:*Evolution since the Ordinance 453 to RDC 611on Radiation Protection.*
Source: The authors

The RDC 611 came into force on the date of its publication and established a period of 12 months from its publication for adequacy. This RDC applies to clinics, hospitals and other services, whether public or private, civil or military, that provide diagnostic or interventional radiology services, manufacture or sell radiology equipment, and teaching and research institutions.

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. Thus, 8 (eight) INs (IN52 to 59) were published, with 1 (one) for each technology described below:

1) Conventional radiology (normative instruction No. 52, of December 20, 2019[1]) [8];
2) Fluoroscopy and interventional radiology (normative instruction No. 53, of December 20, 2019) [9];
3) Mammography (normative instruction No. 54, of December 20, 2019[2]) [10];
4) Computed tomography (normative instruction No. 55, of December 20, 2019) [11];
5) Extra-oral dental radiology (normative instruction No. 56, of December 20, 2019) [12];
6) Intraoral dental radiology (normative instruction No. 57, of December 20, 2019) [13];
7) Ultrasonography (normative instruction No. 58, of December 20, 2019[3]) [14];and
8) Magnetic Resonance (normative instruction No. 59, of December 20, 2019[4]) [15].

Furthermore, it can be noted that the major change brought about by RDC 611 was the regulation of three main points, which will be discussed below: Quality Management; People Management and Permanent Education Program; and Risk Management.

3.1. Quality Management

Among the INs, IN96 and IN97 can be mentioned, which provide for sanitary requirements for quality assurance and safety in ultrasound and magnetic resonance systems, respectively, which now makes quality control mandatory, previously not required by the Ordinance 453.

Both Ultrasonography (US) and Magnetic Resonance Imaging (MRI) did not have Quality Control here in Brazil, considering that Ordinance 453 only brought in its scope protection and

[1]Revoked by normative instruction No. 90 of May 27, 2021.
[2]Revoked by normative instruction No. 92 of May 27, 2021.
[3]Revoked by normative instruction No. 96 of May 27, 2021.
[4]Revoked by normative instruction No. 97 of May 27, 2021.

quality control for ionizing radiation, but due to technological advances in recent decades and the increasing amount of US and MRI services started to be charged for the quality control of these non-ionizing radiation equipment.

In addition, in techniques that obtain digital radiographs, monitors are used to visualize the images. The current scenario in quality management had a signicant change with the introduction of quality control on monitors provided largely by the American Association of Physicists in Medicine (AAPM) [16]. These must have specific characteristics and cannot use any monitor for this purpose.

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

The Resolution 1016 by ANVISA guided in its radiodiagnostic guide in international standards and guides the tests performed, periodicity, but cited the instruments and method and calculations to perform them (Figure 2).

Information related to acceptance tests, quality control, tolerances and restriction levels are present in the INs, but the methods used to carry them out are not mentioned on their pages, requiring the reading of international protocols (Figure 2).

However, in July 2021, the International Atomic Energy Agency (IAEA) published the TECDOC-1958 [17], which lists quality control protocols in both digital and analog radiodiagnostics.

Despite this, there is still a need to create a guide document for these INs, as RDC 611 does not mention quality control methods for US and MRI, which will be of paramount importance for RP and image quality, since that the main objective of RDC 611 is to regulate the control of medical, occupational and public exposures.

The RDC 611 also determines the basic health requirements for diagnostic and interventional radiology services, maintaining the health violation in force, under the terms of Law No. 6.437, of August 20, 1977, in case of non-compliance with the new rules.

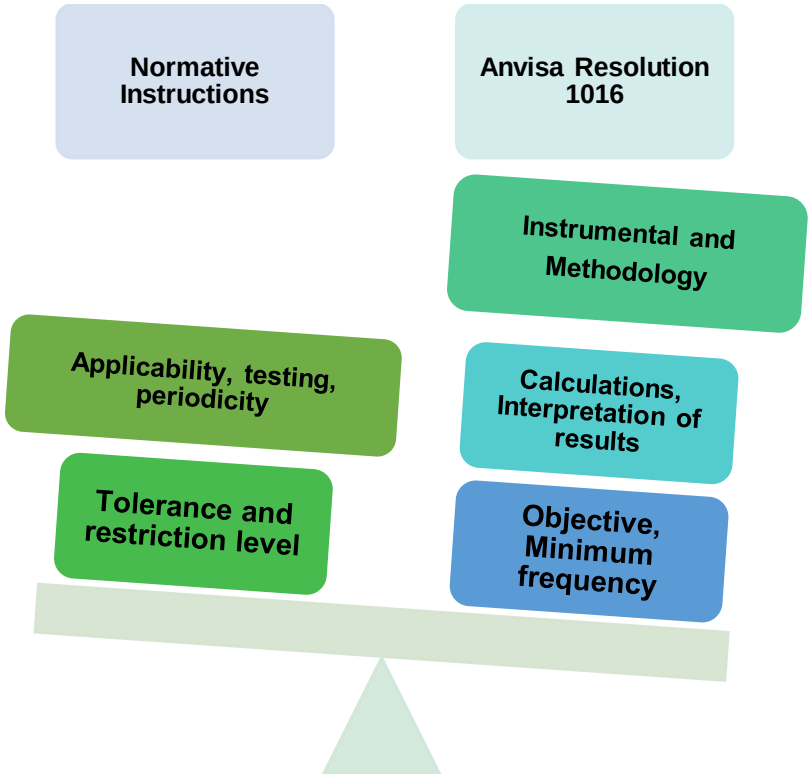

Figure 2:*Comparison of the equipment quality control system in the INs and Resolution 1016*
Source: The authors

3.2. People Management and the Permanent Education Program

It is noted, therefore, that many points formerly regulated by Ordinance 453 are now in charge of the service in terms of carrying out studies and definitions. What does not change with the change in radiodiagnostic legislation is the need for all Occupationally Exposed Individuals (IOEs) to annually carry out a refresher training in RP, required in the Permanent Education Program, so that, in all their routine practices, the highest concept of RP is promoted and disseminated.

It appears that many points formerly regulated by Ordinance 453 are now in charge of the service. Personnel management, which had its definitions listed, now only mentions that their training must be at a higher or technical level, with their competences assigned by law and that they meet all legal requirements to exercise the profession. Therefore, there is no longer a definition of the Technical Responsible (TR), who used to be a doctor or dentist (Figure 3).

The radiation protection supervisor (RPS), previously mentioned in Ordinance 453 as being the physicist responsible for such titulation, as well as the need for a radiology technician to be present at the workplace, was replaced by the requirement that the service must have a multidisciplinary team (Figure 3).

On the other hand, requests for radiodiagnostic exams, previously defined only by doctors and dentists, can now be performed by legally qualified professionals, without defining who these professionals are (Figure 3).

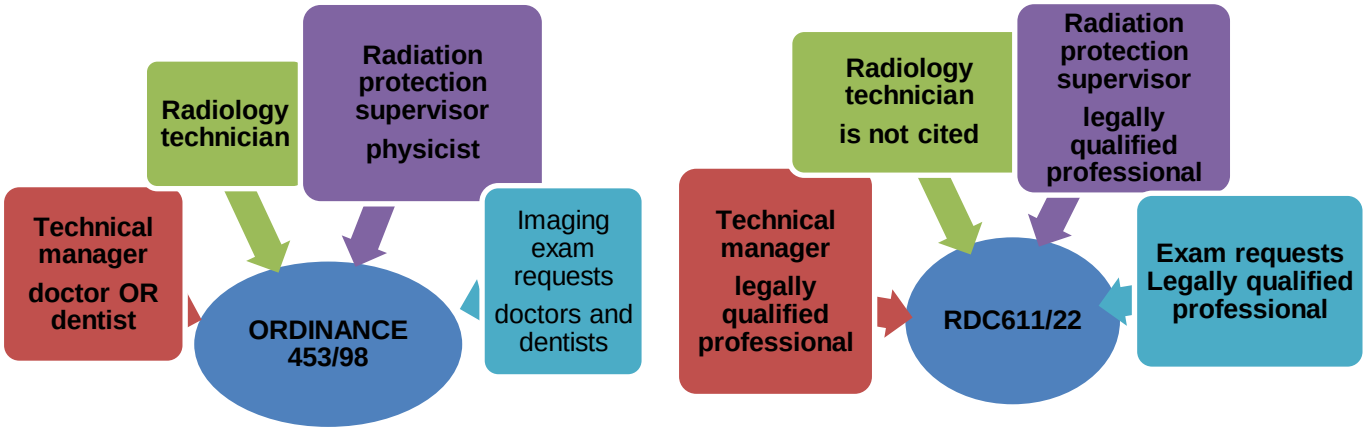

Figure 3:*Comparison of personnel management and work processes*.
Source: Theauthors

3.3. Risk Management

The key point in this program is the risk management inherent to the new technologies used, considering that this demand may be one of the responsible for the increase in the dose in patients due to the lack of training and professional qualification.

This is because the digital radiology system has greatly improved the results of the exams. The introduction of digital imaging systems, when compared to conventional radiology, represents a

significant advance in the field of imaging, as they have advantages such as electronic storage, wide dynamic range[5] and image post-processing.

For example, conventional systems have a small dynamic range; therefore, exposure variation can make the image darker and noisy; that is, with either overexposure or underexposure the images could not be used.

On the other hand, in the digital system, which has a wide dynamic range, an underexposure can have a noisy and poor image, but with an overexposure, due to the wide dynamic range, there is an improvement in the image quality, which can be affected in a way that a overexposure and an open collimation can be corrected in post-processing. Thus, professionals in radiological techniques tend to abuse exposure factors and collimation [18].

Thus, with this growing technological evolution, quality control programs need to undergo constant revisions to always evaluate and implement their main objective: the improvement of image quality with the lowest possible dose to all those involved in the diagnostic process.

For example, in bedside examinations at Ordinance 453/98, patients who were not removed from the environment should be indicators so that no part of the body was less than 2 meters or the image receptor (Figure 4).

In RDC 611, this factor no longer exists, giving way to that established by environmental monitoring, being lower than that defined for free area through radiometric survey, that is, less than 0.5mSV/year (Figure 4).

Regarding the use of the dosimeter, it was up to the service to decide whether it will be used under or over the lead apron, with the possibility of using two dosimeters applied to estimate the effective dose in an individual (Figure 5).

All individuals or legal entities involved in the provision of diagnostic or interventional radiology services; manufacturing and marketing of equipment and accessories; and human health research and teaching activities must also adapt to new developments as soon as possible, so that a structure for the development of a radioprotection safety culture is implemented.

[5]Dynamic range can be defined as the minimum and maximum ratio of exposure that an imaging device can receive without deteriorating or distorting the image [10].

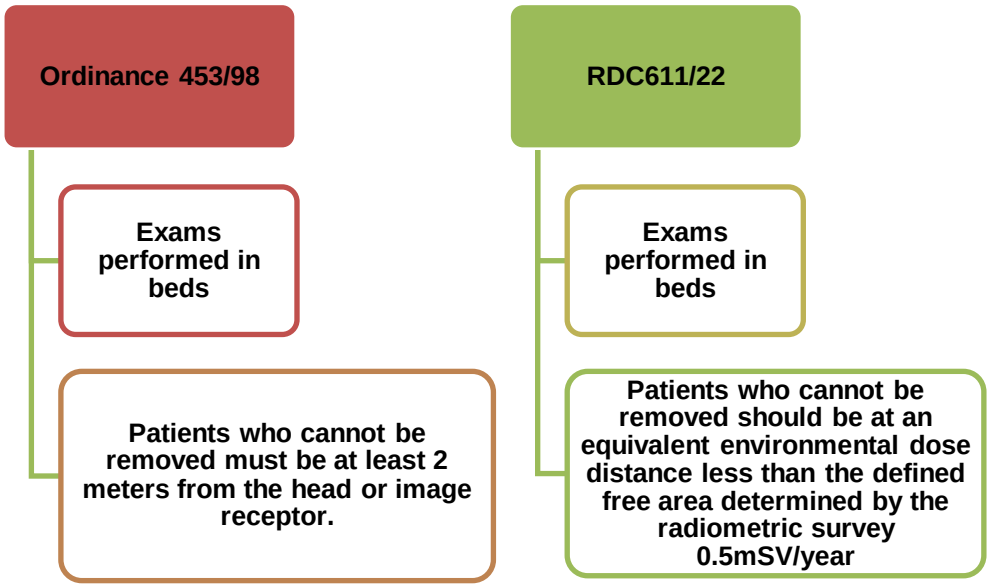

FigurE 4:*Comparison between the methodology of exams performed with mobile equipment in beds.*
Source: The authors

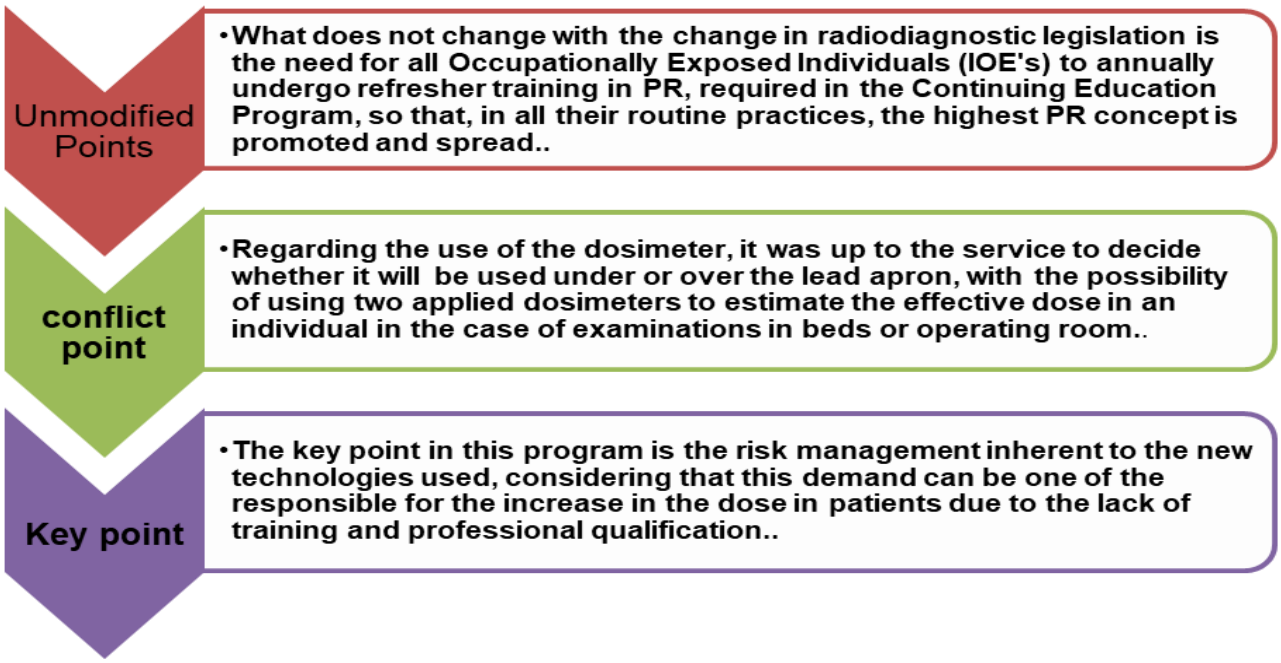

Figure 5:*Unmodified, conflict and key points between Ordinance 453 and RDC 611.*
Source: The authors

4. **CONCLUSION**

Therefore, in view of the reasons presented, it is noted that the replacement of Ordinance 453 (1998) by RDC 611 and its INs (2022) - which were previously subject to public consultation - had a very favorable acceptance.

It is observed that both RDC 611 and the INs have already undergone changes and should have even more updates due to the large number of new tests and new technologies, in addition to the fact that Brazil is a signatory of international quality control guides in radiodiagnostics.

It is worth noting that while Ordinance 453 contained in its content RP principles, responsibilities and all the technical aspects of RP in the various specialties - including conventional radiology, mammography, computed tomography, fluoroscopy, dentistry, in addition to the radiodiagnostic manual that listed the quality control and the methods to carry them out – there was still no premise for dealing with new technologies, such as CR and DR systems and digital mammography, which increase image quality.

However, at the same time, there was a significant increase in the dose, since without training and quality control of the new technologies, imaging services ended up being scrapped.

Therefore, quality controls related to technological advances could not be demanded by the health surveillance, as they had no legal support or training for such. It is worth noting that with the publication of RDC 611, the risk management of new technologies was created, which began to be charged on its pages, in addition to the INs adopting tests of constancy of CR and DR digital equipment, which were not mentioned in Resolution 1016, where there were only X-ray tests and conventional mammography.

The RDC 611 came to facilitate the understanding and performance of practices according to the areas and specialties within institutions that use radiological technology for diagnostic and therapeutic purposes, but there are still points of conflict that need to be analyzed between the professional categories involved and ANVISA itself.

Therefore, for managers and those responsible and the entire multidisciplinary team, it is important to adapt to the news as soon as possible, so that a structure is implemented for the development of a safety culture in radiation protection.

So, in view of the reasons presented, it is defended the replacement of Ordinance 453 (1998) by RDC 611 (2022). The RDC 611 is important due to the need for agile adaptation that can guarantee improvements in the quality of imaging services, dose optimization and quality control of radiodiagnostic equipment, promoting the safety of patients, population and workers exposed to ionizing radiation.

Finally, it is hoped that this paper will help to understand the RDC 611 with regard to RP, as well as help with future discussions and improvements in this extremely relevant document for radiodiagnostic practices carried out in the country.

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