



## Analysis of the Advances of RDC 330/19 in relation to Ordinance 453/98 under the Focus of Radiological Protection

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### 1. Introduction

For years, despite the high frequency of radiodiagnostic tests and their significant contribution to the collective dose, little attention was paid to the radiological protection (RP) of patients and healthcare professionals. 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, and the resolution of the National Surveillance Agency Sanitary (ANVISA/RE 1016/06), of April 3, 2006, which discusses the basic guidelines for PR in medical and dental radiodiagnosis and the use of diagnostic X-rays throughout the national territory. Therefore, when observing the radiodiagnostic service and its changes suffered in recent decades, the addition of new modalities is noticeable, as well as changes in the service flow, brought about as a result of the advancement of new technologies, such as the CR system (computed radiography) – which digitizes the conventional X-ray system – and the DR (digital radiography) system – where the X-ray equipment is already digitized. In addition, with the constant implementation of teleradiology, for example, new work relationships were established, with the radiology service increasingly diversifying, such as itinerant services with service truck, remote reporting center, remote control of equipment and withdrawal of reports and images online. On the other hand, old practices are becoming obsolete, such as the chemical image processing system, which is being replaced by new modalities that contribute to better diagnostic results and provide greater safety for the professional and the patient [1-3].

### 2. Methodology

This study aims to make a comparison between Ordinance 453 of 1998 and RDC 330 of 2019, in order to verify the advances related to the RP of patients, population and workers exposed to ionizing radiation.

### 3. Results and Discussion

Published in the Federal Official Gazette (DOU) on 12/26/19, ANVISA's RDC (Resolution of the Collegiate Board) 330 of December 20, 2019 revoked Ordinance SVS/MS 453/98 (Guideline for Radiological Protection in Radiodiagnosis and Dental), of June 1, 1998, and the resolution ANVISA/RE 1016/06, of April 3, 2006, which discusses the basic guidelines for radiological protection in medical and dental radiodiagnosis and the use of diagnostic X-rays throughout the

national territory. RDC 330 entered into force on the date of its publication and established a period of 12 months from its publication for adaptation. 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 educational and research institutions. The RDC 330 came with several changes even in its format: a document with the basic guidelines for radioprotection 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 the guarantee of quality and safety in ultrasound and magnetic resonance systems, respectively, which now makes quality control mandatory, previously not required by the ordinance 453. The RDC 330 and its respective IN were developed to meet all these needs, contextualizing the principles already established for the elevation of the PR culture and diagnostic quality. The main objective of the RDC 330 is to regulate the control of medical, occupational and public exposures. The resolution determines the basic health requirements for diagnostic and interventional radiology services. However, what still remains in force is the sanitary infraction, under the terms of Law n° 6.437, of August 20, 1977, in case of non-compliance with the new norms. It is noted, therefore, that many points formerly regulated by Ordinance 453 are now in charge of the service regarding the carrying out of studies and definitions. What does not change with the change in the legislation on radiodiagnosis is the need for all Occupationally Exposed Individuals (IOE's) to annually undergo refresher training in PR, required in the Continuing Education Program, so that, in all their routine practices, the highest PR concept is promoted and spread. 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 comply with all legal requirements to exercise the profession. Therefore, there is no longer a definition of the Responsible Technician (RT), who was previously a doctor. The radiological protection supervisor (SPR), previously mentioned in ordinance 453 as the physicist responsible for such a degree, as well as the presence of a radiology technician, was replaced by the requirement that the service must have a multidisciplinary team. On the other hand, requests for radiodiagnostic tests, previously defined only by physicians and dentists, have in RDC 330 that these diagnostic radiology procedures can be performed by legally qualified professionals, without defining who these professionals are. The key point in this program is the risk management inherent to the new technologies used, considering that this demand can be one of the responsible for the increase in the dose in patients due to the lack of training and professional qualification. Other points that are worth mentioning is that RDC 330 mentions the effective dose limit that makes investigation necessary: what was previously 1.5 mSv became 20 mSv. 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 applied dosimeters to estimate the effective dose in an individual. In the examination area known as the out-of-room command, it is no longer considered a controlled area if it does not present dose levels in the radiometric survey compatible with that defined in the Radiological Protection Plan. All individuals or legal entities involved in providing diagnostic or interventional radiology services; manufacture and sale of equipment and accessories; and research and teaching activities in human health must also adapt to the news as soon as possible, so that a framework for the development of a safety culture in radiation protection can be implemented.

#### 4. Conclusions

Therefore, in view of the reasons presented, the need to replace Ordinance 453 (1998) by RDC 330 (2019) is defended. The RDC 330 is important due to the need for agile adaptation that can guarantee improvements in the quality of imaging services, dose optimization and in the quality control of radiodiagnostic equipment,

promoting the safety of patients, population and workers exposed to ionizing radiation. Finally, it is worth noting that while Ordinance 453 contained PR principles, responsibilities and all technical aspects of PR in the various specialties, including conventional radiology, mammography, computed tomography, fluoroscopy, dentistry, in addition to the radiodiagnostic manual that listed the quality control tests and the methods to carry them out, RDC 330 only summarizes in its content the basic principles of PR, risk management of new technologies. Definitions and responsibilities, the most technical part, are at the discretion of the NI. However, these do not clearly mention who these professionals are. The part relating to acceptance tests, quality control, tolerances and restriction levels are present in the INs, but they also do not mention the methods used to carry them out in their pages, requiring the reading of international protocols. The need to create a guide document for these NI will be of paramount importance for PR and image quality. The new RDC 330 came to facilitate understanding and practice according to areas and specialties within institutions that use radiological technology for diagnostic and therapeutic purposes. Therefore, for managers and responsible persons, knowing all the guidelines of the RDC 330 is essential, being a requirement to be in agreement with the Sanitary Surveillance.

### References

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