Ordinance 453/98: an analysis of its applicability in public and private hospitals of Rio de Janeiro after 20 years of its publication

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Abstract. After nearly twenty years of its publication, the Brazilian Health Regulatory Agency (Anvisa) is in the process of approving the revision of Ordinance 453, which establishes the basic guidelines for radiological protection in medical and dental radiology and provides for the use of diagnostic X-rays all over the national territory. The Ordinance is important due to the need for agile adaptation that can guarantee the improvement in the quality of imaging services and the quality control of radiodiagnostic equipment, promoting the safety of patients, population and workers exposed to ionizing radiation. This paper aims to verify the current situation of the diagnostic services of hospitals in Rio de Janeiro, by applying questionnaires in 2 (two) public hospitals and 2 (two) private hospitals in the state. The obtained results were used as a basis to identify the main problems in the strategy of implementation of this regulation, as well as allow to make a critical evaluation of the proposal of the New Ordinance.

Keywords: Ordinance 453/98; Public and Private Hospitals; Rio de Janeiro.

1. Introduction
1.1. Presentation
From X-ray discoveries to the present day, imaging is used for diagnostic and healing purposes, taking into consideration that ionizing radiation can cause harmful effects to the body [1].

So, all people are exposed to ionizing radiation, with over 80% of exposure coming from natural sources and only 20% from artificial (man-made) sources, mainly from medical applications of radiation [2].

Thus, the use of diagnostic radiology represents the major cause of human exposure to artificial sources of radiation. While technological advances lead to increasingly accurate diagnostics, the dissemination of these technologies leads to an increase in the collective dose, making it essential that medical practices using ionizing radiation be optimized, ensuring the benefits of this technology and ensuring reducing the associated risks [3].

Therefore, radiation measurements in this area are fundamental for X-ray equipment quality control programs and for measuring or estimating the doses to which patients are subjected, i.e., in patient dosimetry [4].

In this sense, measurements in the area of radiation should provide assurance, confidence to the consumer, that he has the best in terms of services, promoting the improvement of people's quality of life. Therefore, medical metrology is critical to maintain adequate levels of safety to support measurements covering health, industry, environment, agriculture and power generation [4].

In Brazil, millions of people are diagnosed and treated in radiotherapy, radiodiagnosis and nuclear medicine procedures. Each year, there are 63 million radiodiagnostic examinations, 9 million radiotherapy procedures, covering 450,000 patients per year [4].
Besides that, the use of ionizing radiation emitting equipment also continues to grow in Brazil. There are 72,039 ionizing radiation generating equipment. Among these, there are 3,057 tomographs representing 1.58 devices/100,000 inhabitants and 20,929 simple X-ray devices, representing 10.79 devices/100,000 inhabitants (equivalent to 16.28 devices/100,000 inhabitants) and 224 tomographs (equivalent to 2.55 devices/100,000 inhabitants) [5].

Thus, it is essential that the doses received by the patients are optimized and that radiation detection equipment make accurate measurements.

1.2. Justification
So, in 1998, the Ministry of Health, through the Brazilian Health Regulatory Agency (Anvisa), published Ordinance 453, which deals with the “Basic Guidelines for Medical and Dental Radiological Protection”. However, although many advances have been observed since its publication, it appears that most services have not met these guidelines, compromising the quality of service provided to the population [6].

This can be observed, for example, in a survey conducted by interviewing 8 (eight) radiology technicians from two public hospitals and 8 (eight) radiology technicians from two private hospitals in Recife. According to this work, a lack of interest and lack of knowledge of the current standards in the area of radiological protection was detected, since 75% of the interviewed professionals from the public network and 12.5% from the private network were unaware of Ordinance 453/98 [6].

Another survey conducted at a public referral hospital for traumatology in Santa Catarina in 2015 cites the absence of a Descriptive Memorial, a Radiological Protection and Quality Assurance Program. In addition, radiation protection supervisors and technicians are not officially appointed and professionals are unaware of their responsibilities and duties [7].

2. Methodology
This paper aims to address the current situation of the diagnostic services of hospitals in the state of Rio de Janeiro seeking to develop a project to identify the main problems to be prioritized and to make a critical evaluation of the proposal of the new ordinance, and verify what will be the strategy to be adopted by the regulatory agencies to achieve the desired success, that is, to improve the quality of the diagnostic service of hospitals provided to the society of Rio de Janeiro.

For this, a qualitative research was conducted for data collection. A field research was carried out between 21/06/2019 and 28/06/2019, which interviewed 7 (seven) radiology technicians from two public hospitals (one state and the other federal) and 7 (seven) radiology technicians from two private hospitals, all hospitals located in the metropolitan region of Rio de Janeiro.

The questionnaires to public and private hospitals (Annex 1) were basically composed of questions about Ordinance 453/98 and aimed to ascertain the level of knowledge of radiology professionals, based on previous surveys conducted in 2 (two) surveys [6; 7].

3. Results and Discussion
The results were acquired and analyzed quantitatively in relation to compliance with basic guidelines for radiological protection in hospitals (Figures 1 and 2).
Analyzing the answers of the questionnaires applied in public and private hospitals, it can be said that:

- Regarding the annual dose limit, 100% of respondents in the public hospital and 8% in the private hospital reported knowing its meaning;
- Regarding being aware or signing the dosimetry, 40% of the private sign or know, however in the public only 16% are aware or sign;
- Regarding knowledge of Ordinance 453/98, 100% of the public reported knowing, while 11% in the private network did not know;
- In the public, only 16% had training, while in private this value is 44%;
- Periodic examinations should be performed to evaluate the worker’s health every six months. However, 16% of workers in the public did not take the exams while in the private only 4% did...
not, i.e., 20% of workers between public and private without periodic control of their occupational health;

- Comparing public and private hospitals, it was observed that both public and private hospitals had 100% Personal Protective Equipment for patients and caregivers;

- Comparing public and private hospitals, about external signaling it was observed that 100% of signaling are visible to the Public Individual, while in internal signaling only in the private there is 4% without signaling for patients and caregivers;

- Regarding X-ray equipment in public hospitals, 8% are still conventional and only 4% in private, while in public 24% have PACS images, while in private only 4% do not have images. internet shipping system;

- Regarding private image processing 100% already have print and media (CD DVD), while in the public only 28%;

- Comparing the level of education of the interviewees, it appears that 29% in the public are technicians and in particular 29% are technologists, 28% of the public and 40% of the private have a specialization course in the area;

- Regarding being aware or signing the dosimetry, 40% of the private sign or know, however in the public only 16% are aware or subscribe.

4. Conclusions

This study aimed to evaluate the knowledge of Ordinance 453 and, especially, its application, in two public and two private hospitals in the city of Rio de Janeiro, having as reference work done on the same theme in other states.

In public hospitals in Rio de Janeiro, for example, there are quite contrasting scenarios, such as the availability of state-of-the-art CT scanners with very old conventional equipment and without proper maintenance.

In addition, many have professionals without adequate training to perform the procedures, especially on the most modern equipment. Despite these important shortcomings and the risk associated with them, services continue to serve the population who do not have access to private hospitals or better public services.

It is observed that the lack of commitment of the service holders, the little knowledge and training in radiological protection of health professionals and the need for a more active and present regulatory authority are some factors that hinder the implementation of radiological protection and control programs quality in health services.

Regarding some answers, it is observed that: in the public, only 16% had training, while in particular this value is 44%. It is understood that knowledge and training in radiology protection is a primary factor for protection; regarding image processing in the private 100% already has print and media (CD DVD), while in the public only 28%. It is because Technological advancement is crucial for diagnostics and avoids waste of radiographic films and unnecessary exposure of patients to ionizing radiation, more effective quality control is required in public hospitals; comparing the level of education of the interviewees, it appears that 29% of the public are technicians and in particular 29% are technologists, 28% of the public and 40% of the private have a specialization course in the area.

Professional qualification should be encouraged in both hospital spheres and encouraged, as a qualified professional will more plausibly serve patients with radiological protection and quality control as a crucial factor to ensure an improvement in the quality of imaging services provided to patients and population; regarding being aware or signing the dosimetry, 40% of the private sign or know, however in the public only 16% are aware or subscribe. One reason for this difference may be the absence of a more active radiation protection supervisor, as the Occupationally Exposed Individual (IOE) must know and be aware of their dose limit.

Among the facts mentioned, the lack of implementation of Ordinance 453/98, the current economic situation of the state and the bureaucratic and financial difficulties inherent in most public and private hospitals, reflect the need for agile adaptation that can ensure an improvement in quality of imaging services and quality control of radiodiagnostic equipment, promoting the safety of patients in the population and workers exposed to ionizing radiation.

In addition, with technological advances, it was evident that Ordinance 453 of 1998 should be
updated (the process is in the public consultation phase). Many items in this new document are being questioned by experts in the field concerned with getting a standard that is in line with current international recommendations.

Despite the importance of regulatory standards as well as an effective monitoring system, without a broad change in health policy that includes restructuring professional training programs and raising awareness of the importance of radiation protection, the current scenario will not only change with the publication of a new Ordinance.

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Annex 1 – Questionnaire Applied to Radiology Technicians of Public and Private Hospitals
Dear Technician. Regard to the radiological protection in our area, this questionnaire aims to verify the level of knowledge of some basic topics of Ordinance 453/98. In this way, your answer will be very important. Thank you!

1. Do you use your dosimeter during your workday? ( )Y ( )N
2. Do you know or sign the dosimetry monthly? ( )Y ( )N
3. Do you know Ordinance 453/98? ( )Y ( )N
4. Do you perform periodic exams for individual monitoring? ( )Y ( )N
5. Have you received training regarding Ordinance No. 453? ( )Y ( )N
6. Are there dismal clothing in the industry for patients and/or accompanying? ( )Y ( )N
7. Is the exterior of the exam room properly marked? ( )Y ( )N
8. Is the interior of the exam room properly marked? ( )Y ( )N
9. Is the X-rays service digital or conventional? ( )Digital ( )Conventional
10. Is the image development system analog? ( )Y ( )N
11. Is there a PACS system in the imaging sector? ( )Y ( )N
12. The images are printed on film, paper or media (DVD, CD)? ( )Y ( )N
13. What is your professional background? ( )Technician ( )Technologist
14. Do you have a specialization course? ( )Y ( )N