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RDC 330 IN PRACTICE: ANALYSIS OF THE CHALLENGES OF IMPLEMENTING NORMATIVE INSTRUCTION 97 IN THE PRIVATE MAGNETIC RESONANCE CLINICS OF THE CITY OF FORTALEZA-CE.

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ABSTRACT

Medical radiology has social and academic relevance because it is a specialty that uses different types of radiation for diagnostic and therapeutic purposes. It requires a multidisciplinary team that is attentive to the changing guidelines imposed by the government. The rules are presented and enforced by the National Health Surveillance Agency (ANVISA) and the State and Municipal Health Surveillance (VISA). Currently, the ANVISA standard that regulates radiodiagnostic clinics is Collegiate Board Resolution 330 (RDC) and Normative Instructions (INs) 90, 91, 92, 93, 94, 95, 96 and 97, which dictate the rules of operation of the clinic in general and each equipment in particular. In this work, we evaluated the implementation of this new resolution, through a qualitative study, with the following procedures: interviews, analysis, comparison of results, and direct observation in 05 magnetic resonance centers of the private hospital network of the metropolitan region of Fortaleza. A question that the work intends to try to answer: Given the data collected, what will be the possible initial, medium and long-term impacts of the implementation of these Ins.

Keywords: **ANVISA RDC 330, magnetic resonance, SOP, radiodiagnosis, radiology.**

1. INTRODUCTION

Many illnesses, such as cancer, require high-precision imaging equipment for diagnosis and treatment planning. Magnetic Resonance Imaging (MRI) is one of the alternatives yielding results with great detail and resolution. Because of its high accuracy in cancer diagnosis and screening, magnetic resonance imaging is increasingly being re-evaluated and applied in disease and injury screening, and in pre-operative preparation [1]. MRI is one of the most flexible tools in medical research and diagnostic imaging, with more than 35,000 devices currently in use worldwide and an annual turnover rate of about 3,000 units [2,3].

Based on the Nobel-worthy work of Paul Lauterbur and Sir Peter Mansfield (2003) the technique use strong magnetic fields, magnetic field gradients, radio waves, and powerful computational tools to generate images of the organs in the body. It requires a multidisciplinary team that, besides the knowledge and training, is attentive to the changing guidelines imposed by the government. In Brazil, the rules are presented and enforced by the National Health Surveillance Agency (ANVISA) and the State and Municipal Health Surveillance (VISA). Currently, the ANVISA standard that regulates radiodiagnostic clinics is Collegiate Board Resolution 330 (RDC) and Normative Instructions (INs) 90, 91, 92, 93, 94, 95, 96, and 97, which dictate the rules of operation. The full implementation of these guidelines requires planning, being a complex activity for a service that is in operation.

This work will present an evaluation of the implementation of this new resolution by performing interviews with the staff, analysis, comparison, and direct observation in 5 magnetic resonance centers of the private hospital network of the metropolitan region of Fortaleza. At the end, a Standard Operating Procedure (SOP) will be created than can be used to assist other clinics to safely implement the guidelines.

2. THEORY

MRI devices produce strong electromagnetic fields. A strong static magnetic field changes magnetization vectors in the human body, which is a measure of proton density. Radio frequency (RF) fields are used to energize the magnetization vector. When the vector returns to the original state it emits a signal that is detected by the MRI scanner. Each tissue has a different signal density and this information is used in the conversion of high-resolution images [2].

From a non-ionizing radiation protection point of view, the guidance regarding MRI equipment focuses on the patients being diagnosed and on the supporting personnel that are operating, cleaning, or manufacturing the machines. The general public is less of a concern as they are installed within access-restricted wings.

As with all radiation involving medical procedures, general exposure limits do not apply to patients. The physician and physicists will always have to make a balanced judgment between the expected benefits of the treatment/diagnosis and the potential adverse effects. However, International Commission Non-Ionizing Radiation Protection (ICNIRP) recommends that account be taken of a patient's tolerance to body temperature elevation and of the need to avoid nerve stimulation. Special attention should also be given to pregnant patients, with a recommendation that the duration of exposure is kept to the minimum [4].

The main issue is with accidents regarding the strong magnetic field. The magnet of the MRI apparatus can cause accidents if metal objects are in the range of field. Cases in which patients brough to the exam room with metal wheelchair, for example, have resulted in catastrophic results, not only damaging the machine, but also trapping and injuring the patient. The safety requirements have an important role in guaranteeing the diagnostics accuracy, protecting patients and staff, and diminish possible down times.

In relation to personnel working near MRI devices, the main protection issue also relates to the static magnetic fields. These can cause sensory effects such as vertigo and nausea as a result of the generation of small electrical currents inside the balance organ. This, in turn, transmits signals to the brain, providing different information to that obtained through vision, resulting in the unwelcome adverse effects. These transient effects may be bothersome and impair normal functioning. Thus, for workers, such as doctors, nurses, and other health care staff, the recommendation is in some cases to limit the strength of the field so that transient effects such as vertigo and nausea do not occur, and in other cases to provide for a set of site-specific work procedures. In particular, the speed of movement within a static magnetic field should be limited, as body movement induces electric fields and reinforces the sensory effects described above [4].

There are few epidemiological data on long-term health in persons exposed to static fields, and none on potentially high exposure groups such as MRI operators. The available studies, on workers exposed up to several tens of mT in work in aluminum smelters, chloralkali plants, or as welders have had methodological limitations, but do not indicate strong effects from exposure of the above levels on cancer incidence, reproductive outcomes, or the other outcomes studied [7]. Table 1 shows the guidelines established by ICNIRP on occupational and general public exposure limits to static magnetic fields.

Table 1: Limits of exposure to static magnetic fields.

Exposure characteristics	Magnetic flux density
Occupational	
Exposure of head and of trunk	2 T
Exposure of limbs	8 T
General Public	
Exposure of any part of the body	400 mT

In December 2019, the Brazilian National Health Surveillance Agency (ANVISA) published in the Official Gazette (DOU), RESOLUTION - RDC No. 330 of December 20, 2019. RDC No. 330 repeals Ordinance SVS/MS No. 453 of June 1, 1998 and Resolution No. 1016 of April 3, 2006. It discusses the basic guidelines for radiological protection in medical and dental radiodiagnosis, and about the use of diagnostic x-rays throughout Brazil.

RDC 330 is a standard that brings the standards on the use of x-rays for diagnosis throughout the national territory and the basic guidelines of radiological protection in the field of medicine and dentistry. The main objective of 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 centers.

The main differences from RDC 330 to Ordinance 453 are that the new document adopts basic radioprotection guidelines and eight Normative Instructions - one for each technology in imaging diagnosis. In addition to reviewing issues related to radiation protection and radiological image quality, the updated versions of the resolution began to cover magnetic resonance (Normative Instruction 97) and ultrasound (Normative Instruction 96) equipment, which represents a major advance to obtain good diagnoses [5].

Normative Instruction IN 97 establishes sanitary requirements for ensuring quality and safety in MRI imaging systems, as well as the minimum ratio of acceptance and quality control tests that must be performed by health services, determining their periodicities and tolerances.

The IN 97 is divided into two chapters, the first is divided into two sessions, session I dealing with environments and equipment and session II that is about the working processes, the second chapter is about the final provisions and the annex with the acceptance and quality control tests for MRI.

Before this legislation there was no other legislation that legislated on the use of MRI in Brazil. As a result, the state of Minas Gerais has taken the initial steps developing a Technical Regulation for Magnetic Resonance Safety, SES/MG No. 6234, of May 10, 2018, establishing that these standards should be followed in its territory [6]. On 2 June 2021, this resolution was repealed by No. 7533.

In this scenario, a SOP created based on experience can greatly help hospitals and clinics to implement the new requirements.

The city of Fortaleza has a growing number of imaging diagnostic clinics that use MRI, but many of these providers have difficulty in adapting to the new legislation. According to DataSus [7], the availability of MRI equipment in use in the northeast region of Brazil in 2008 was 0.15 equipment per 100,000 inhabitants. In 2012, 0.52 equipment per 100,000 inhabitants was registered in Fortaleza/CE.

Providing a guide in order to standardize and facilitate the implementation of RDC 330 based on experience will allow to access the current state and to quantify the necessary changes. This will help ensure a higher level of safety for patients and workers in magnetic resonance centers.

A survey was made of the adequacy of five MRI services in the state of Ceará, and it is pointed out what are the main adequacy difficulties faced by the institution and employees. Some changes are suggested for the best suitability and compliance to the standard and later a full POP will be made available free of charge, divided into three parts Pre-installation, installation and Equipment already in use.

3. MATERIALS AND METHODS

This work will analyze the topics necessary for the implementation of the new Resolution of the Collegiate Board of ANVISA (RDC) 330, with normative instruction (IN) 97. It will consider the current situation of in 5 magnetic resonance centers located in Fortaleza. The information of the machines evaluated in the centers is described in Table 2.

Table 2: Information on magnetic resonance imaging equipment of the five centers analyzed.

	Magnectic Field(T)	Manufacturer	Model	ANVISA registry
Location 1	1.5	GE	Optima MR 360	10295030061
Location 2	0.4	Esaote	O-Scan	80372000006
Location 3	3.0	Philips	Achieva	10216710205
Location 4	1.5	GE	HDxt	80071260103
Location 5	1.5	GE	HDxt	80071260103

The analysis mechanisms will be done by:

- Direct observation of the physical structure around the MRI facility, which security and update protocols were adopted;
- Interviews with the staff (doctors, nurses, technologists, reception staff and general clinics) to survey the main demands that the center required;
- Analysis and comparison of results through spreadsheets in EXCEL;
- Application of a Standard Operating Program.

With all the information, a SOP will be created that aims to ensure a higher level of safety for patients and workers in magnetic resonance centers. The SOP comprises the following topics:

1. responsibilities and competencies at each stage;
2. contrast media and adverse events that it can cause;
3. care involving the Static Magnetic Field and radiofrequency;
4. cryogenic fluid care;
5. signaling and demarcation of the areas;

6. access restriction and anamnesis;
7. mode of operation with pregnant patients or employees;
8. emergency situations involving persons or only equipment;
9. dates of the periodicity of employee training by the Radiology Radioprotection Supervisor.

Of the items above, the absence of zoning in a center will generate an immediate financial impact. This is a mandatory action, meaning if the centers are reluctant to make the necessary adjustments and are not working in accordance with the new legislation, ANVISA can notify or close the MRI diagnostic center until the company adapts to the changes. IN 97 mentions that the facility has to be separated into:

- Zone I: Free access environment for public individuals;
- Zone II: environments externally adjacent to zone III, where the procedures of reception, anamnesis and preparation of the patient and evaluation of compatibility of objects are performed, for example;
- Zone III: environments adjacent to zone IV where there is a restriction on the movement of people and equipment due to the risk of adverse events caused by the interaction of individuals or objects with electromagnetic fields produced by nuclear magnetic resonance equipment; and
- Zone IV: ward where magnetic resonance equipment is located [8].

4. RESULTS AND DISCUSSION

Table 3 will show the result of the physical evaluation of the centers. The information is the result of direct observation of the 9 items in the RDC normative. Information was confirmed by interviews with the staff. Information was organized through spreadsheets in EXCEL. Each center has access to its own spreadsheet, serving as a checkpoint and a general view of the current state of the facility.

Table 3: Evaluation of the five centers regarding the total or partial presence of the items request in the SOP.

	Location 1	**Location 2**	**Location 3**	**Location 4**	**Location 5**
1- Responsibilities and competencies			X	X	
2- Contrast media and adverse events	X	X	X	X	X
3- Care involving the Static Magnetic Field			X	X	
4- Cryogenic fluid care	X	X	X	X	X

5-Signaling and demarcation				X	
6- Access restriction and anamnesis	X	X	X	X	X
7- Mode of operation with pregnant woman					
8- Emergency situations					
9- Employee training					

From the data collected, the following information was obtained:

1- Location 3 and location 4 had a booklet detailing those responsible for each stage of the MRI routine, assigning functions to technologists, physicians, and nurses. Other clinics did not have well-defined attributions.
2- All centers had an emergency manual for adverse effects of contrast.
3- Location 3 and 4 placed warnings on the door bringing attention to the presence of the static magnetic field and trained their staff with radiofrequency care. Locations 2, 3, and 5 did not any specific instruction or internal regulations for such care.
4- All centers hire third party companies to take care of what involves cryogenic liquids.
5- Only location 4 is in an isolated and demarcated area, but still without zone signaling. All other centers do not have well-defined signs.
6- All clinics have anamnesis place for patients before the exam. Also, they all have restricted access to the equipment.
7- There are no proper operating directives for pregnant workers, but location 3 and 4 have a specific protocol for pregnant patients.
8- None of the centers analyzed have specific protocols for emergency situations in case of equipment failure or accidents.
9- None of the location conduct periodic training with their employees.

There is a lot of issues that need addressing. There will be an immediate impact, mainly financial, because none of the centers analyzed are in accordance with the zoning regulations of MRI areas. Besides that, annual periodic training was not done. The normative claims that all employees, from doctors, nurses, technologists to reception, and general clinics need specific periodical training.

We can observe in Figure 1A the blue print of location 1, we can analyze that the resonance door already opens to an area of free movement, having an absence of zone 3, and there may be accidents due to this failure, with this was elaborated a projection of how the service could demarcatise these zones as we can see in Figure 1B, also the use of a metal detector was not detected at the entrance of the equipment room.

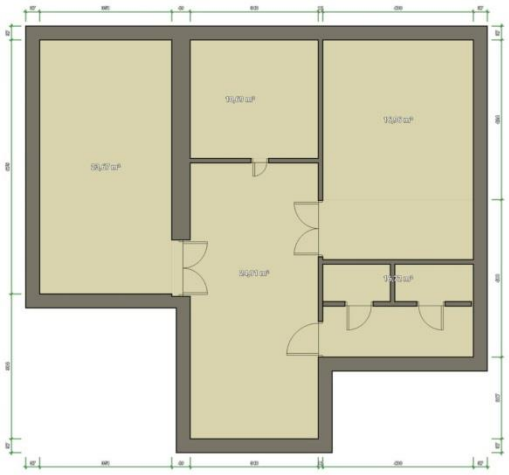

Figure 1A: Blue Print Location 1

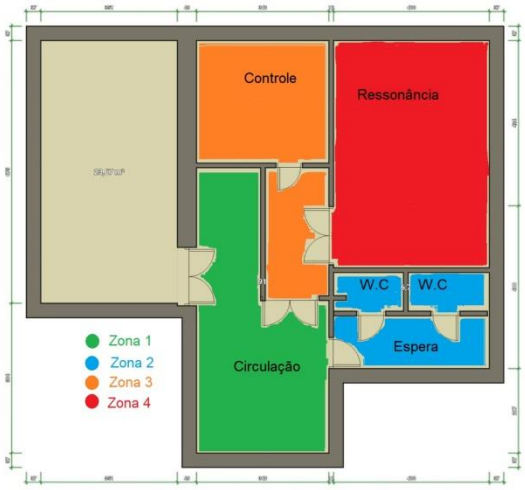

Figure 1B: Blue Print Location 1

Source: Author

Location 2 resonance equipment has a lower magnetic field than the others, not requiring such a large room, but as we can analyze in Figure 2A the zoning system is not obeyed, besides there is no metal detector in the clinic. Once the necessary observations were made, a blue print was prepared with the zoning system well defined as requested by IN 97.

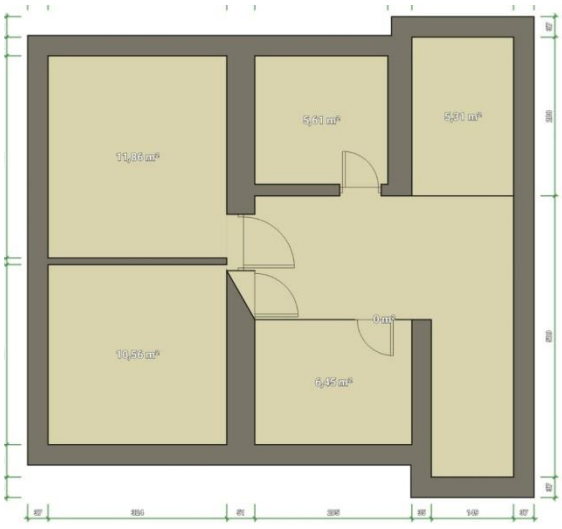

Figure 2A: Blue Print Location 2

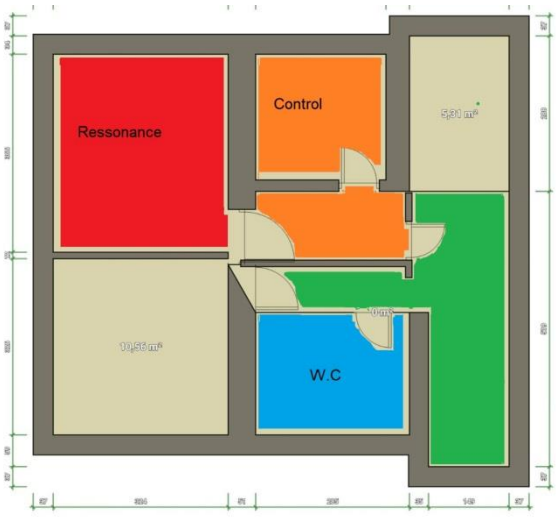

Figure 2B: Blue Print Location 2

Source : Author

This center is the one that is in agreement with the regulations, in Figure 3A has the first blue print, after going through a consulting with a radiological protection supervisor, they adapted their installation by purchasing the metal detector and elaborating a zoning according to Figure 3B.

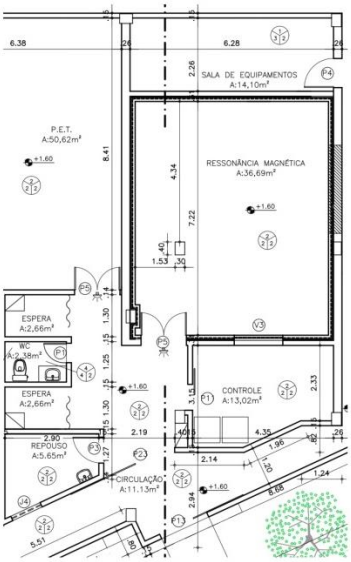

Figure 3A: Blue Print Location 3

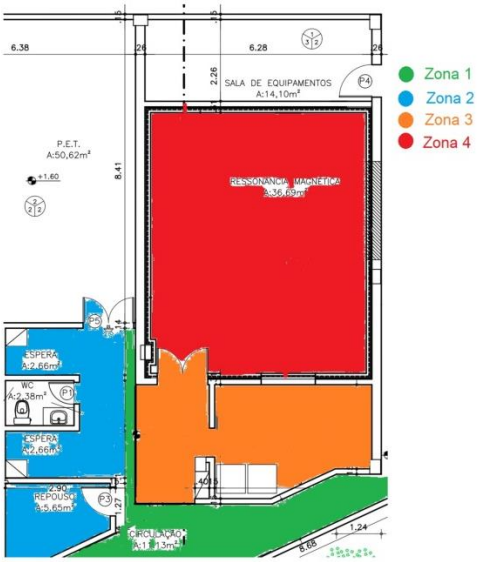

Figure 3B: Blue Print Location 3

Source : Location 3

In Figure 4A we can observe the blue print of the Location 4 analyzed in this work. As we analyze the resonance centers divides its space with other hospital services, we have the medical residency that access passes through the resonance center, in addition to other administrative services. It is also perceptive in the center that there is no zoning according to the rules of health surveillance, we do not have a well-defined zone 3 this is in accordance with normative instruction number 97 that states "Art. 9º The health service must have a system of detection of metals for monitoring the access of people and objects to zones III and IV in quantity compatible with the number of examination rooms." (Normative Instruction 97 of 05/27/2021 of ANVISA), thus generating the impossibility of having a control using metal detector as requested. No metal detection devices were also found at the scene.

Analyzing the blue print, it is perceptive the need for some structural changes, a new plant was made with these changes and suggesting where each service zone would be, as we can see in Figure 4B.

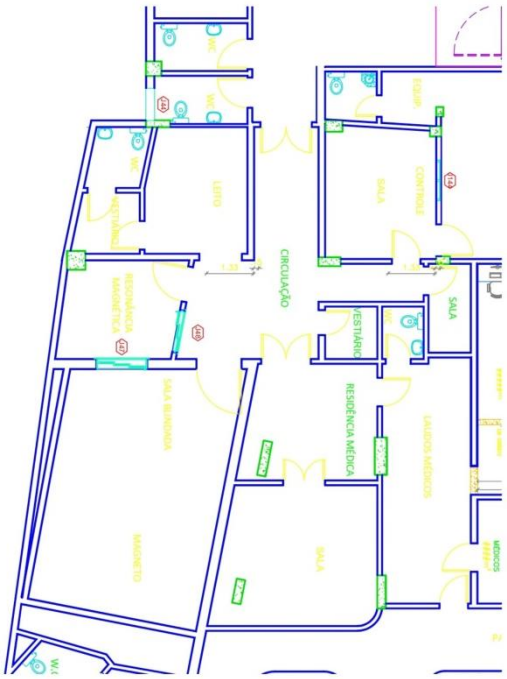

Figure 4A: Blue Print Location 4 **Figure 4B:** Blue Print Location 4
Source: Location 4

In location 5, its entire structure was already ready for zoning, just needed to make clear where each zone was and acquire a metal detector as we can see in Figure 5A. With this was elaborated from your blue print how would the service zones system look, as we can analyze in the Figure 5B.

Figure 5A: Blue Print Location 5 **Figure 5B:** Blue Print Location 5
Source: Author

As a result of this evaluation, 2 documents are being created. The first contains specific recommendations for each center. The second is the SOP document, containing all information necessary for the correct implementation of the new normative.

5. CONCLUSION

The IN 97 has not yet been actually implemented in all institutions and it is up to the radiological protection supervisor to ensure its execution. In the centers analyzed in this work, adequacy requires changes in the center infrastructure. With the observations done in this study, a targeted Standard Operational Program based on the Normative Instruction 97 can now be elaborated, in order to assist these and other centers of the State of Ceará in the best implementation of the new protocols, aiming on the known difficulties and current state. The goal is to facilitate the implementation of these new regulations, and enumerate the immediate steps necessary.

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