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RDC 330 in practice: analysis of the challenges of implementing normative instruction 97 in the private magnetic resonance services of the city of Fortaleza-ce.

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1. Introduction

There is a growing demand for imaging tests for the early diagnosis of diseases such as cancer, aneurysm, tumors, among others. As the use of these equipment increases, greater control is required by the inspection agencies to ensure that the equipment is generating reliable and efficient diagnostics.

Treatments such as oncology 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 evaluated and applied in local and preoperative preparation. [1] Magnetic resonance imaging 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]

Magnetic resonance imaging devices produce magnetic and electromagnetic fields during imaging. 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]

The magnetic resonance security protocol must exist to ensure the protection of providers and patients. The magnet of the MRI apparatus can cause accidents if metal objects are in the area of operation of the magnetic field. These safety requirements assist in the accuracy of diagnostics and diminish possible down times.

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.

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) equipments, which represents a major advance to obtain good diagnoses. [4]

Before this legislation there was no other legislation that legislated on the use of MRI in Brazil. As a result of this lack, 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. [5] On 2 June 2021, this resolution was repealed to No. 7533.

The city of Fortaleza has a growing number of imaging diagnostic companies that use MRI, but many of these providers have difficulty in adapting to the new legislation. According to DataSus[6], the availability of MRI equipment in use in the northeast region in 2008 was 0.15 equipment per 100,000 inhabitants. In 2012, 0.52 equipment per 100,000 inhabitants was registered in Fortaleza/CE.

In order to standardize and facilitate the implementation of RDC 330, IN 97, this work suggests the evaluation of the current state of 5 magnetic resonance centers of the private health care network in the city of Fortaleza, State of Ceará. This situational analysis will allow to access the current state and point to the necessary changes. This will help ensure a higher level of safety for patients and workers in magnetic resonance centers.

2. Methodology

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 1.

Table 1: 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 services) to survey the main demands that the center required;
- Analysis and comparison of results through spreadsheets in EXCEL;
- Application of a Standard Operating Program.

The standard operational procedure (SOP) 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 nuclear magnetic resonance equipment is located. [7]

3. Results and discussion

Table 2 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 2: 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					
8- Emergency situations					
9- Employee training					

From the data gathered, 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. The others did not have well-defined attributions.
2- All centers had an emergency manual for adverse contrast effects.
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 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 make use of anamnesis 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 services need specific periodical training.
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.

4. 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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