2021 International Nuclear Atlantic Conference – INAC 2021
Virtual meeting, Brazil, November 29 – December 2, 2021

ISBN: 978-65-594-1256-3

Magnetic Resonance Safety in the view of new Brazilian regulations

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1. Introduction

Magnetic Resonance (MR) is a sophisticated technique which uses high magnetic fields electromagnets and radiofrequency waves to obtain medical images. Its first use on humans in history dates back to 1976 and its first Latin America clinical application was in 1986, in Brazil [1]. The method currently is part of a group of technologies which make imaging diagnostics possible, however, differently from other imaging technologies that use x-rays, magnetic resonance does not use ionization radiation. This difference excludes the MR method from specific legislations on imaging diagnosis and radiation uses on clinical setting. In this context, the use of magnetic resonance for medical applications in Brazil had been guided until 2018 by good practice guides published by international bodies, with no national regulation available for the equivalent purpose. In the same year, the state of Minas Gerais published the first ever Brazilian resolution about safety and protection on MR, named SES 6234 from its State Health Department [2], defining the basic requirements for protection and safety in magnetic resonance, with state validity, followed in 2019 by normative instruction number 59 (IN 59) of the National Health Surveillance Agency [3], which defines the sanitary requirements for quality assurance and safety in nuclear magnetic resonance imaging systems, which apply throughout the country. The purpose of this study is to analyze the main differences between these two Brazilian regulations regarding MRI safety, especially in relation to the physical structure of the MRI clinic, patient safety and equipment safety, with the aim of elucidating the recommendations and agreements of both publications and its impact on MRI safety in the country.

2. Methodology

For this study, data related to magnetic resonance safety from the original texts published by the Secretaria Estadual de Saúde de Minas Gerais and the Agência Nacional de Vigilância Sanitária were collected, analyzed in relation to its content and then divided into 4 major groups: physical structure of the MRI clinic; staff qualifications and administrative demands; patient and public safety and equipment and device safety.
Later, the subjects selected were evaluated for their presence or absence in the text of each publication, focused on differentiating the content of the resolutions and highlighting the issues addressed by both. Additionally, the coverage of each publication was studied, in an attempt to demonstrate major areas and subjects addressed individually by them.

3. Results and Discussion

The subjects grouped as categories are shown below divided into major areas: physical structure of the MRI clinic, staff qualifications and administrative demands, patient and public safety and equipment and device safety. Each category registered 15, 14, 5 and 2 subjects identified, respectively, summing up 36 main subjects. They are displayed into the following tables, with the columns "IN 59" and "SES 6234" demonstrating the adherence of the subject in question to the text of each publication. A brief description is provided for better understanding the context of the subject itself.

Table 1: Category “Physical structure of the MRI clinic” of subjects related to magnetic resonance safety covered by the SES-MG 6234 and IN59

Category	Subject	Description	IN 59	SES 6234
Physical structure of the MRI clinic	Magnetic shielding	Restrict the magnetic field to the interior of the MR exam room accordingly to recommendations of the manufacturer	x	
	5 Gauss line	Perimeter around the equipment where the value of the magnetic field is less than 5 gauss, considered safe for public (or 0,5mT)		x
	Attenuation of mechanical vibrations	Attenuation of mechanical vibrations from the RM equipment	x	
	Soundproofing	Isolating the equipment noise produced in the exam room	x	
	Gas massive evacuation	System responsible for gas forced evacuation from the exam room	x	
	Radiofrequency shielding	Shield the exam room from radiofrequencies generated outside of it		x
	Signalled exam room	Exam room identified as a RM room through signs and cards, indicating the risks and prohibitions such as implants and other incompatibles devices.	x	x
	Metal detector	Metal detector device to identify risk potential objects in the patient. Mandatory between zones III and IV.	x	x
	Zoning	Separation of the service in zones evaluated by access and risk.	x	x
	Table stop button	A button located inside the exam room dedicated to stop the MR table		x
	Magnet stop button	A button located inside the exam room dedicated to stop the magneto of the MR machine		x
	Temperature and humidity control	Temperature and humidity control inside the exam room		x
	Fire protection	Requirement of fire protection in the exam room		x
	Observation room	Room allocated for patient observation and follow-up after the exam		x
	Exclusive control room	Control room dedicated only to MR modality, which can operate up to 2 devices at the same time.		x

On table 1, from 15 subjects, IN59 quoted 7 of them (46,7%) and SES 6234, 10 (66,7%). They agreed only 3 times, with SES 6234 covering more subjects exclusively (7 of them) and bringing more structural requirements, such as observation room, exclusive control room and radiofrequency shielding, for example. Furthermore, the resolution delivers exclusive demands related to the quality and maintenance of the MRI machine besides the acceptance tests, like controlling the temperature and humidity of the room, which are recommended by the manufactures [4] and decisive in maintaining the quality of the equipment.
The IN 59 quoted the need of restricting the magnetic field following the manufacturer’ appointments, when SES 6234 defines a magnetic field limit value of 5G, adding that any value below the limit is safe for public. The IN 59 in addiction it does not address any subject related to emergency stop of the MRI systems, items required by most of manufactures [4] [5].

Table 2: Category “Patient and public safety” of subjects related to magnetic resonance safety covered by the SES-MG 6234 and IN59

Category	Subject	Description	IN 59	SES 6234
Patient and public safety	Audio-visual contact	Audio-visual contact with the patient throughout the exam session	x	x
	No-entrance of Incompatible medical devices	Prohibition of entry of patients using incompatible medical devices in zones III or IV	x	x
	Companion restriction	Companions not allowed in the room during the MR exam, except when strictly necessary and authorized		x
	Ear protection for the patient	Device for ear protection for the patient during the exam	x	x
	Weight scale	Device located on zone III focused on measuring the patient weight and determining its suitability for the MRI machine		x

The category “Patient and public safety” is the one with the highest compatibility registered between the publications, with 60% of its content being shared by them. Furthermore, it is the only category where all the topics were quoted by any of the texts, in this case, the state SES 6234, addressing again concerns related to machine safety, such as the requirement of a weight scale, since the MRI equipment has a patient weight limit that must not be surpassed because it leads to malfunctioning, and public safety, quoting the restriction of

companions.

Table 3: Category “Staff qualifications and administrative demands” of subjects related to magnetic resonance safety covered by the SES-MG 6234 and IN59

Category	Subject	Description	IN 59	SES 6234
Staff qualifications and administrative demands	Magnetic Resonance Safety Supervisor	Individual with higher-level technological training and specific capacitation to respond to the safety and quality requirements in MR.		x
	Permanent education	Program focused on providing permanent education for those related directly or indirectly to RM practices	x	x
	Patient Safety Nucleus	The instance of the health service created to promote and support the implementation of actions focused at patient safety on MR applications		x
	Quality assurance program	Set of systematic and planned actions to ensure the reliability of the MR sector, in accordance with quality standards, ensuring safety for patients and technical staff;		x
	Descriptive memorial	Description of the procedures and activities developed in the service and its facilities, including the protection and safety program, quality assurance and facility acceptance reports		x
	Acceptance tests	Tests performed prior to use to verify the system against its original requirements	x	x
	Justification-driven execution	Exams executed only when a justification is provided.	x	
	Safety and criteria-based execution	Exams executed only when the patient fits the safety and criteria of the RM method.	x	
	Risk mitigation	Execution focused on reducing or zeroing risk	x	x
	Pregnancy relative contraindication	Evaluation of contraindications for MR examinations in pregnant women, especially in the first 3 months of pregnancy		x
	Screening and anamnesis	Step prior to admission, responsible for identifying possible risks and sensitive conditions of the patient in relation to the MR method		x
	Urgency and emergency arrangements	Protocols’ definition about MR practice in case of urgency and/or emergency		x
	Risk factor evaluation	Responsible to identify and measure possible risks and create an emergency protocol to be executed outside the exam room		x
	Patient removal procedure	Protocol that defines how a patient must be removed from the exam room in case of urgency/emergency		x

From 14 subjects in category “Staff qualifications and administrative demands”, only 3 of them were quoted by both of resolutions. It is the lower participation category by IN59, with only 5 topics, nevertheless the instruction alone addressed concerns related to exam execution directly, demanding a justification and the adoption of MRI’s criteria and safety for the procedure to be performed. The approach suggested by SES 6234 is different, demanding protocols and several evaluations done previously, with more general content. The SES 6234 alone approaches the Patient Safety Nucleus concept, requiring a group of professionals responsible for the safety maintenance in an MRI service, the descriptive memorial, focused on evaluating every and each process and objects daily related to the MRI practice, and the quality assurance program, performed simultaneously to MRI’s routine to assure its adherence with quality standards.

Table 4: Category “Equipment and device safety” of subjects related to magnetic resonance safety covered by the SES-MG 6234 and IN59

Category	Subject	Description	IN 59	SES 6234
Equipment and device safety	Electromagnetic compatibility report	Reports the compatibility between medical devices and the RM machine	x	
	Electromagnetic compatibility manual	Manual describing compatibilities between medical devices and the RM machine (medical devices must be labelled accordingly to their compatibility)		x

On table 4 is possible to see that there was no adherence in the category shown. The two subjects registered were quoted alone by each publication and despite the name, they have no similarity. The electromagnetic compatibility report required by IN 59 is provided by the manufacturer of the equipment in question or a

specialized consultant. On the other hand, the electromagnetic compatibility manual quoted by SES 6234 is the American College of Radiology Manual on MR Safety [6], developed by the ACR MR Safety committee. In addition, the state publication requires every object on an MRI service to be labelled following the compatibility criteria, described in the publication as MR Safe and MR Unsafe items.

4. Conclusions

In conclusion, from the 36 subjects addressed, none of the regulations discussed their totality, showing a non-conformity between the publications. Of all the topics, 29 (80,5%) of them were quoted by SES 6234 and 16 (44,4%) by IN 59. In comparison, only 9 (25%) subjects were in both regulations ("Permanent education", "Acceptance tests", "Risk mitigation", "Signalled exam room ", "Metal detector", "Zoning", "Audio-visual contact", "No-entrance of incompatible medical devices" and "Ear protection for the patient"), when the SES 6234 resolution included exclusive subjects 19 times, against only 7 in IN 59, demonstrating that the state one has a greater coverage alone in all categories analyzed, mostly in "Patient and public safety" and "Staff qualifications and administrative demands". There is no apparent reason for that difference of approach based on the texts, only the distinctive organs responsible of each publication and their appliance. Other important note is that IN 59 was published more than one year later the SES 6234, pointing out the awareness of all the subjects addressed by the state regulation and the choice of National Health Surveillance Agency to address MRI safety on different basis. It is essential also to highlight that, as IN 59 is a national regulation, all the exclusive matters addressed by it will be practiced by all the Brazilian states, including Minas Gerais.

Lastly, none of the regulations reports conditional evaluation of the patient, topic that is quoted by American College of Radiology [6] and also by the user's manuals provided by manufactures [4][5], responsible to recognize techniques and conditions of the patient that separately does not present risk, but when combined, could cause harm.

With MR Safety finally on the spotlight in Brazil, it is expected to see further developments on the subject in the near future.

Acknowledgements

We thank the Instituto de Pesquisas Energéticas e Nucleares for providing the support and resources needed to develop this project.

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