# UNIVERSIDAD DE INVESTIGACIÓN DE TECNOLOGÍA EXPERIMENTAL YACHAY

**Escuela de Ciencias Biológicas e Ingeniería**

## TÍTULO:

Magnetic Resonance Imaging: Analysis of the patient risk, evaluation of the internal regulations and generation of national normative of security

Trabajo de integración curricular presentado como requisito para la obtención del título de Ingeniería Biomédica

**Autor:**

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Urcuquí, Febrero 2020

Urcuquí, 2 de julio de 2020

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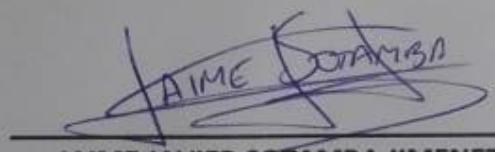

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# Dedicatoria

*Dedico este trabajo a mi Madre, mi Mamita, mis hermanos, primos y a toda mi familia en general. Gracias por guiarme, apoyarme y forjarme como la persona que soy en la actualidad. Me formaron con reglas y con algunas libertades, pero a fin de cuentas siempre me motivaron a alcanzar mis metas.*

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*Este nuevo logro se los dedico a ustedes.*

Jaime Javier Sotamba Jimenez

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**ABSTRACT**

Magnetic resonance imaging represents a great tool in the area of imaging. Its use in the health sector has had a growing reception; due to its characteristics, it is considered a reasonably safe technique. Magnetic Resonances (MRI) implies the use of large magnets to generate a powerful magnetic field to which the patient is exposed and, in many cases, the medical staff. Other aspects to consider in MRIs are the radiofrequency pulses and the high noise to which the patient is subjected. This exposure to magnetism and radiofrequency pulses generates certain risks that can reduce with an adequate procedure in the MRI rooms.

The main hazard is due to the presence of ferromagnetic material objects (missile effect), tissue heating due to RF pulses, and the involvement of the peripheral system. Also, there are other directly related risks such as hearing impairment or adverse reactions due to the means of contrasts. International organizations such as WHO, FDA, ICNIRP, ASTM, among others, have prepared several studies about the risks of MRI and have made recommendations for each country to adopt these recommendations and generate their safety regulations adapting them to the situation of each country.

In Ecuador, there is currently no regulation that regulates the use and operation of MRI equipment in the health sector. This work brings together the different recommendations of international organizations, guides, and safety limits. It adapts them to the national health system, thus delivering a National Security Normative in Magnetic Resonance Rooms. This safety regulation can be adopted and implemented by all health centers that provide magnetic resonance imaging.

**Keywords**: Magnetic Resonance, Magnetic Field, Radiofrequency Pulse, Ferromagnetic, Implants, Health, Risk.

**RESUMEN**

Las imágenes por resonancia magnética representan una gran herramienta en el área de imagenologia. Su uso en el sector de salud ha tenido una creciente acogida, debido a sus características se considera una técnica bastante segura. Las Resonancias Magnéticas (RM) implica el uso de grandes imanes para generar un potente campo magnético a la cual es expuesto el paciente y en muchos casos el personal médico. Otros aspectos que se deben considerar en las RM son los pulsos de radiofrecuencia y el alto ruido al que es sometido el paciente. Esta exposición al magnetismo y pulsos de radiofrecuencia genera ciertos riesgos los cuales se reducirían con un adecuado procedimiento en las salas de RM.

Los principales riesgos se dan debido a la presencia de objetos de materiales ferromagnéticos (efecto misil), calentamiento de tejidos debido a los pulsos de RF y la afectación al sistema periférico. Además, existen otros riesgos relacionados directamente como la afectación auditiva o reacciones adveras debido a los medios de contrastes. Organismos internacionales como la OMS, FDA, ICNINRP, ASTM entre otras; han elaborado varios estudios acerca de los riesgos de las RM y han hecho recomendaciones para que cada país adopte estas recomendaciones y genere sus propios normativos de seguridad adaptándolos a la situación de cada país.

En el ecuador actualmente no se cuenta con un normativo que regule el uso y funcionamiento de los equipos de RM en el sector de salud. Este trabajo reúne las diferentes recomendaciones de los organismos internacionales, guías y límites de seguridad y los adapta al sistema de salud nacional entregando así un Normativo Nacional de Seguridad en las Salas de Resonancia Magnética. Este normativo de seguridad puede ser adoptado y puesto en marcha por todos los centros de salud que brinden el servicio de imágenes por resonancia magnética.

**Palabras Claves:** Resonancia Magnética, Campo Magnético, Pulso de Radiofrecuencia, Ferromagnético, Implantes, Salud, Riesgo.

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## 1. INTRODUCTION

Nuclear magnetic resonance is undoubtedly one of the most widely used techniques in the area of imaging for the diagnosis of diseases. Due to various characteristics such as no use of ionizing radiation and high affinity with contrast agents to improve the quality of the image. In 1939, Isidor Isaac Rabi designed a device with which he evidenced how an atom behaved in a magnetic field when applying radio waves. This technique and all the knowledge about this phenomenon were progressing. In 1984, it was possible to carry out the first imaging studies using magnetic resonance imaging (MRI) in humans. At present, magnetic resonance is known and used in different areas, especially in medical diagnosis.

In the images for medical diagnostic, the atom that is precessing is mainly atoms of hydrogen due to its abundance in the human body, especially in the soft tissues. When the hydrogen atoms are subjected to a strong magnetic field, they leave their normal alignment and align with the external magnetic field. Then, magnets of gradients of MRI equipment change the magnetic field and thus have different precession frequencies. Finally, the emission of the radiofrequency pulse gives energy to the atoms, which causes them to enter resonance and subsequently release energy that is measured with the antennas in the resonator and then analyzed and digitized to obtain images. Magnetic resonance images need RF in the range from approximately 10 to 300 MHz and the conventional Resonator machine.

Although MRI does not use ionizing energy, it can not assure with complete confidence that there are no risks for people, whether patients or users. Several studies have reported on the different dangers of MRI, mainly due to the lack of protocols and security measures (Buendía et al., 2010; Grainger, 2015; Schaefer, Bourland, & Nyenhuis, 2000a). The contrast agents used and the magnetic field cause risks that can cause serious effects (Hasebroock & Serkova, 2009; H. S. Kim et al., 2010; Raynaud, Darmon-Kern, Lancelot, & Desché, 2018).

The International Commission Non-Ionizing Radiation Protection (ICNIRP), published an article in which they reviewed the biological responses to the application of static magnetic fields. Live tests were performed in vitro to establish limits to occupational and general public exposures. After the revision, several values were standardized, such as: for the occupational exposure of the trunk and the head a total of 2T, for the occupational exposure of the extremities a total of

8T and, for the general public exposure 400mT ( International Commission Non-Ionizing Radiation Protection [ICNIRP], 2009).

According to a study in mice that were subjected to 4T magnetic fields, they showed that there is a decrease in sperm production, postpartum death, and delay in the development of motor skills in the offspring (Magin, Lee, Klintsova, Carnes, & Dunn, 2000). To date, many studies have been conducted focusing on the biological effects of the Magnetic Field in humans, many of which co-exist in effects such as nausea, vertigo, and a slightly metallic taste; however direct alterations to the tissues have not been established (Schenck, 2000) (Franco, Perduri, & Murolo, 2008) Although there is an increase in temperature during MRI studies, studies show that these values do not exceed the values recommended by the FDA (De Vocht, Van Drooge, Engels, & Kromhout, 2006).

Imaging techniques that use magnetic resonance increasingly use contrast agents to improve the quality of the image. One of the most used agents is Gadolinium (Gd), which has severe side effects in certain patients. Recent studies have shown that there is a relationship between the use of Gd and the development of NSF (Hasebroock & Serkova, 2009).

After a severe legal demand for the adverse effects of the use of Gadolinium in a person, FDA issued a new statement on the use of this contrast agent. According to the report, after a review on the retention of Gadolinium, health professionals are advised to take more precautions in the use of this type of contrast agent in patients with kidney problems to control a chronic condition( Food and Drug Administration [FDA], 2017).

The evidence so far has shown that if there is long-term retention of this contrast agent in tissues; however, its potential risk is something that is not established. Therefore, the Radiological Society of North America suggests that more research should be done to determine if gadolinium retention affects the function of human tissues. Even if this retention is associated with clinical manifestations of the disease in the short or long term, and if vulnerable patients have a higher risk of developing chronic conditions (McDonald et al., 2018).

An important issue to consider is when patients have metallic or electronic implants. For these cases, magnetic resonance is practically prohibited. Given the paramagnetic components of the devices, a magnetic resonance study could be harmful. The FDA has requested a careful

examination to determine if the devices are compatible with magnetic resonance. The images by magnetic resonance in patients with cochlear implants represent a big challenge for radiologists. Studies have shown significant adverse effects for this type of patient, inversion in polarity, pain, magnetic displacement (B. G. Kim et al., 2015).

The work of Buendia et al., with 38 patients with cardiac implants, did not show significant adverse effects after practicing an MRI. Although several devices indeed presented slight defects, this was momentary, which led them to conclude that these alterations are minimal and are within the limits of international regulations. Also, there are cases in which the MRI could be safe for patients with electronic implants (Buendía et al., 2010).

Studies indicate that adequate management of these devices would make feasible the realization of an MRI, for which users should be fully trained, so as not to deny an image of vital importance for the patient (Muthalaly, Nerlekar, Ge, Kwong, & Nasis, 2018; Nazarian, Beinart, & Halperin, 2013). Following this advice, the institutions must do everything possible to create safe verification protocols and monitor the adverse events of the MRI.

Organizations such as the International Commission on Non-Ionizing Radiation Protection (ICNIR) and the World Health Organization (WHO) have analyzed MRI and its possible risks. They have issued several safety reports and protocols. In 2006, WHO made recommendations in terms of exposure to magnetic fields, indicating that each country should adopt these measures and even generate its protocols to protect the safety of people in the process of obtaining MRI.

Currently, in Ecuador, there are no national safety protocols in Magnetic Resonance. Users are based on international information or their own experiences to take imagines with Magnetic Resonators. Just a few hospitals have a security protocol for MRI; however, these are not complete and lack several essential aspects of biological issues. This background is necessary for a comprehensive study of the risks of the patient and operator, revision of internationals normative, and the creation of a national normative that provides total security in MRI.

# 2 THEORETICAL BACKGROUND

Magnetic resonance is undoubtedly one of the most used techniques in the area of imaging for the diagnosis of diseases. Magnetic resonance imaging or MRI, has various characteristics, such as the absence of the use of ionizing radiation and high affinity with contrast agents, to improve image quality. It was in 1939 when Isidor Isaac Rabi designed a device that showed how an atom behaved in a magnetic field when applying radio waves.

This technique and all the knowledge about this phenomenon progressed until in 1984 it was possible to carry out the first imaging studies employing magnetic resonance imaging (MRI) in humans, and today this field is widely known and used in different research areas, especially in the area of health for medical diagnosis.

During an MRI study, patients and people that operate the equipment (users) can be exposed simultaneously to three variants of magnetic fields: the static magnetic field (B0), time-varying magnetic field gradients (dB / dt) and radiofrequency pulses (B1).

## 2.1 Principal Components

### 2.1.1 Main Magnet

It is one of the principals and heavy elements of the RM system. This component produces the static magnetic field Bo and its power is measured in Tesla (T) (1T = 10000Gauss). This main magnet is an electromagnet made with superconducting wire. A superconducting wire has a resistance approximately equal to zero when cooled to a temperature close to absolute zero, by immersion in liquid helium. The magnetic field is produced when the electric current passes through the circuit of wires cooled by the liquid helium that surrounds them. Once the system has been charged and operates at the desired field strength, the electrical power is disconnected. However, some losses occur over time due to an infinitely small resistance of the coil.

The length of the superconducting wire in the magnet is about several thousand meters. The wire coil is maintained at a temperature of 4.2 K, by immersion in liquid helium. The coil and liquid helium are located in a large receptacle that provides thermal insulation. The characteristic volume of liquid helium in an MRI magnet is 1700 liters.

An advance in magnet technology is the armored magnet. This magnet has a smaller range. The power of the field falls to 0.5 mT four meters away from the magnet. This is important for security reasons and facilitates the location of the magnet. The shielding is achieved with a second set of superconducting wires, outside the main wires and where current flows in the opposite direction, thus reducing the range of the field.

### 2.1.2 Gradient Coils

To create images using MRI, the existence of magnetic field gradients is necessary. The gradient coils produce the gradients in the magnetic field, Bo. They are coils that operate at room temperature and, by their configuration, generate the desired gradient. Since the central opening of the superconducting magnet is generally horizontal, the gradient system will be described for this magnet configuration.

To be able to create a weak magnetic field in any direction of space, three sets of gradient coils are necessary. In systems with a medium and high-intensity field, the intensity created by the gradient coils is approximately 100 times lower than that of the main field. The performance of the gradient coils is measured in the form of maximum amplitudes (mT/m). The most common maximum amplitudes are 10 mT/m, and high-performance systems require up to 30 mT/m. A second valuable property of gradients is their rise time, rise time (ms), or response time, slew rate (mT/m/ms) (The Round Table Foundation, 2016).

The faster the upload time or faster response speed, the system performance will be better; that is, the image data can be acquired more quickly. The technology of the gradient coils has also evolved considerably since the introduction of the first generation equipment. Modern equipment can reach a maximum power of 100 mT/m and a higher rate of change of 150 mT/ms. These values allow the system to obtain cuts of 0.7 mm thickness for 2D acquisitions and 0.1 in 3D RF Coils.

### 2.1.3 RF Coils

The RF coils produce the B1 field that rotates the net magnetization in a sequence of pulses. They also detect transverse magnetization while precessing in the XY plane. RF

coils can be divided into three general categories; 1) transmission and reception coils, 2) reception coils only, and 3) transmission coils only. The transmission and reception coils function as transmitters of the B1 fields, and receivers of the RF energy of the object studied. The transmission coil is used to create field B1, and together, a reception coil is used to detect or receive the signal from the spins of the object under study. There are several varieties of coils. A coil must resonate, or store energy efficiently, at the Larmor frequency. All coils of a resonance device are composed of a set of capacitive elements and inductive elements, and  The resonant frequency of an RF coil is determined by the inductance (L) and capacitance (C) of the inductor and capacitor circuit (Hornak, 2019).

$$\nu = \frac{1}{2\pi\sqrt{LC}}$$

The other requirement of the coil of a resonance device is that the field B1 must be perpendicular to the magnetic field Bo. There are many types of coils for resonance equipment. The volume coils surround the object to be examined while the surface coils are placed on top of the object to be examined. Some coils are designed only to receive the RF signal. When a receiver coil is used, a larger coil must be used to transmit the RF energy that produces the 90º or 180º pulses. Figure 1 shows the schematic of parts of MRI equipment.

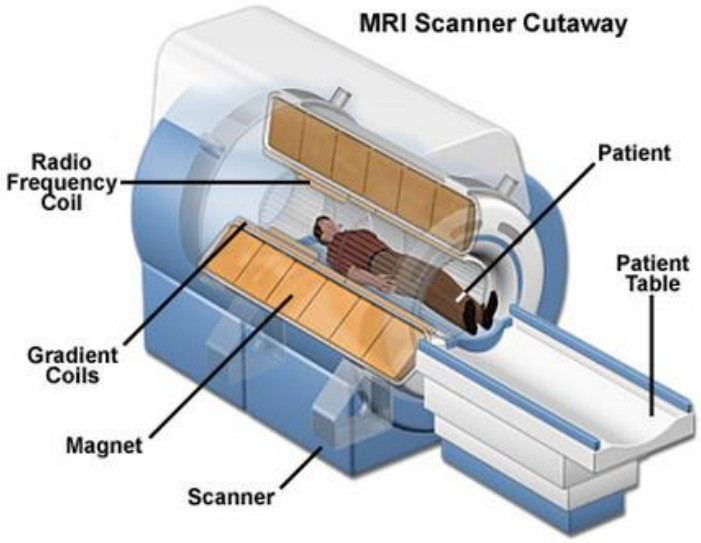



*Figure1. Conventional MRI Scanner.* (Al-Tamimi, Mohammed & Sulong, 2014)

### 2.1.4 Faraday cage

Faraday cages are an essential and essential part of an MRI team. The cage is a cover that surrounds the resonator and prevents electromagnetic waves from entering or leaving. In this way, the cage prevents electromagnetic signals from the environment from distorting the weak magnetic resonance signal.

It owes its name to physicist Michael Faraday, who built one in 1836. The operation of the Faraday cage is based on the properties of an electrostatic equilibrium conductor. When the metal box is placed in the presence of an external electric field, the positive charges remain in the network positions; electrons, however, which on metal are free, begin to move since a force given by:

$$\vec{F} = e\vec{E}_{ext}$$

Where e is the charge of the electron. As the charge of the electron is negative, the electrons move in the opposite direction to the electric field and, although the total charge of the conductor is zero, one of the sides of the box (in which the electrons accumulate) is left with an excess negative charge, while the other side is left with an electron defect (positive charge). This displacement of the charges causes an electric field to be created inside the box in the opposite direction to the external field. The resulting electric field inside the conductor is, therefore, zero. Since there is no field inside the box, no cargo can pass through it; therefore, it is used to protect devices from electric charges. The phenomenon is called electrical shielding.

## 2.2 Working principles

The magnetic resonator is a device with many components that are integrated to obtain images of the human body using the MRI phenomenon. Its main component is a big magnet in which a high magnetic field is generated. Magnetic resonance imaging (MRI) is based on the precession of the nuclei of atoms due to a magnetic field (Peters & Cleary, 2008). In the images for medical diagnosis, the atoms that make the precession movement are mainly hydrogen atoms. Its importance lies in its abundance in the human body, especially in soft tissues.

The hydrogen nucleus has a magnetic moment, with a ½ spin, which means that it is observed in one of the two states, referred to as "up" and "down." Thus, the rotation of the hydrogen core assumes an "up" or "down" orientation concerning an externally applied magnetic field. A property of the hydrogen atom that makes it ideal for MRIs is its weak magnetic movement. As is known, electronic spins are what create magnetism in magnetic materials, such as iron. However, the magnetic moment of hydrogen is approximately 2000 times weaker than that of the electron and, therefore, hydrogenated materials do not adhere to magnets.

When the body is placed in a strong magnetic field, the magnetic moments of the nuclei of the atoms are aligned in two directions, parallel and antiparallel (Bushberg, Seibert, Leidholdt, & Boone, 2013). Figure 2 shows the different movements of the protons.

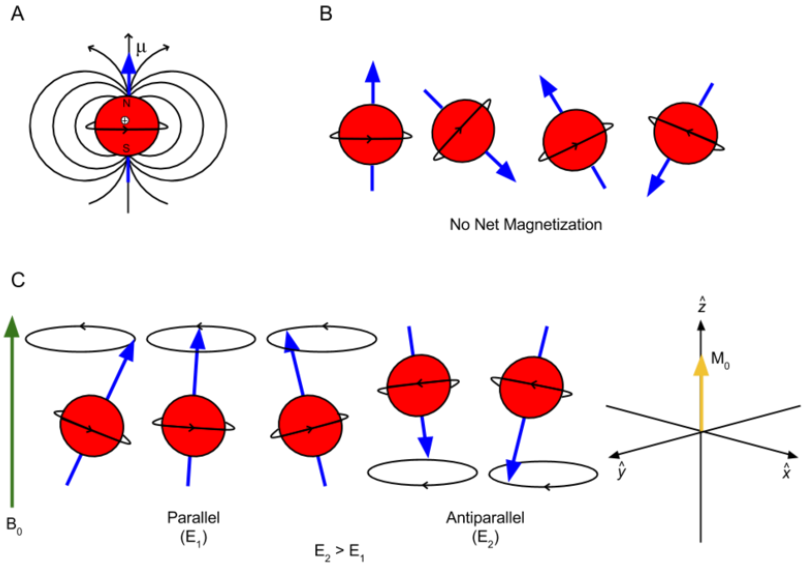



*Figure 2. (A) Protons possess a quantum property called spin. (B) Each proton is oriented in all directions and has no net magnetization. (C) Protons orient their spins either parallel or antiparallel to $B_0$. The parallel spin state has a lower energy state, and therefore a few more protons will spin parallel to $B_0$ compared to antiparallel. Figure adapted from* (Bushberg et al., 2013)

This uniform alignment creates a magnetic vector oriented along the axis of the MRI equipment. Protons do not just align, but also begin to rotate on their axis; this movement is known as precession. This rotating movement has a spin speed called the precession frequency. The precession frequency is determined by the Larmor equation:

$$\omega = B_0 * \gamma$$

Where “ω” is the precession frequency (MHz), $B_0$ is the static magnetic field (in Tesla) y “γ” is a gyromagnetic constant (MHz/T) that depends on the atom, in this case, hydrogen. This equation is fundamental because its calculation allows knowing the frequency that must be applied to the atoms so that they enter into resonance. In the case of hydrogen whose gyromagnetic constant is 42.58 MHz / T, it will have a Larmor frequency of 63.87 MHz if it is subjected to a magnetic field of 1.5 T. The intensity of the magnetic field and gyromagnetic constant of the nucleus are who determine the resonance frequency of the hydrogen nuclei (Möller & Reif, 2012). MRI scanners can have different field strengths, usually between 0.5 and 3 Tesla.

Magnetic resonance occurs when an applied radiofrequency pulse is the same as that precession frequency of the hydrogen, changing them in direction. Due to the status of the cores, some of those in the parallel or low energy state will turn to the antiparallel or high energy state and, after a short period, will return to their previous low energy parallel state, losing (in the form of photons) the energy they had gained. Figure 3 shows the effects of a radiofrequency pulse application. This process is known as relaxation and occurs in the longitudinal and transverse axis simultaneously.

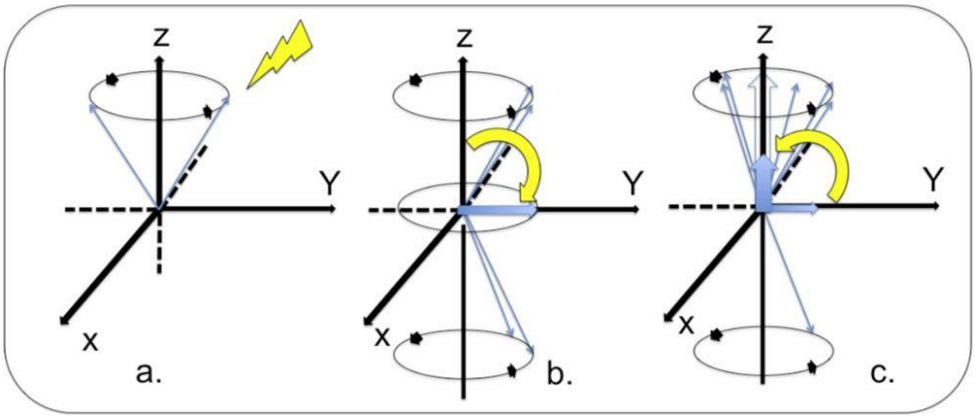



*Figure 3. Radiofrequency pulse application. The figure was taken from* (SEIC, 2015)

In MRI, two different relaxation times T1 and T2 are differentiated with which the tissues can be characterized. Both T1 and T2 are characteristic of each tissue, and their duration is expressed in milliseconds (ms). T1 (longitudinal relaxation time) determines the rate at which excited protons return to equilibrium. By consensus, the T1 of a tissue is the time it takes to recover 63% of the longitudinal magnetization. This is the time that the rotating protons need to realign with the external magnetic field. T2 (transverse relaxation time) determines the rate at which excited

protons reach equilibrium or offset each other. The T2 of a tissue is the time it takes to lose 63% of its transverse magnetization. It is the necessary time taken for spinning protons to lose phase coherence among the nuclei spinning perpendicular to the main field. Figure 4 shows the Longitudinal and Transversal relaxation curves of fat and water.

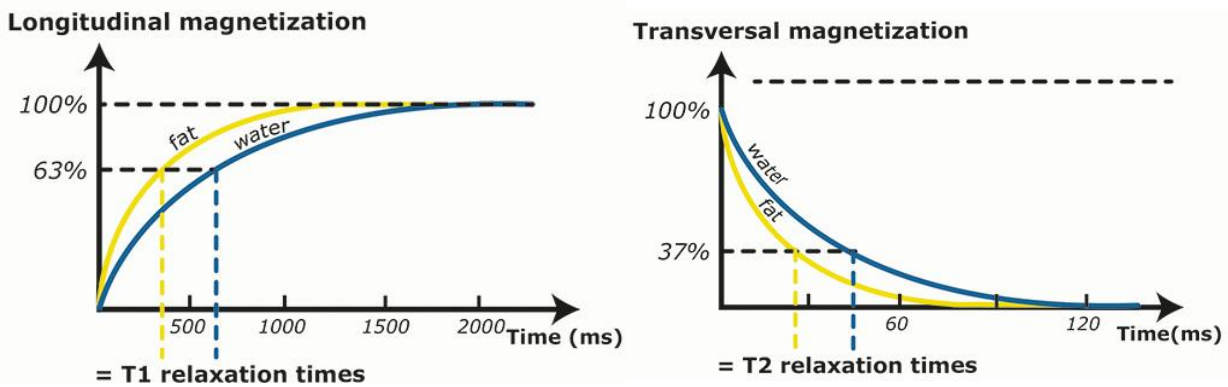



*Figure 4. T1 and T2 relaxation times of fat and water. The figure was taken from*(Van Der Plas, 2016)

These photons can be detected by a coil that acts as an antenna, receiver, and transmitter, an amplifier, and an RF synthesizer (McRobbie, Moore, Graves, & Prince, 2006). The receiver coils are used to act as antennas to improve the detection of the emitted signal. Anatomic structures from tissues are distinguished due to the different signal intensities generated from hydrogen; these signals differ in magnitude and duration. Fourier transformation is used to convert the received signal from each location to corresponding intensity levels. The intensity of the received signal is plotted on grayscale after a mathematical treatment, and cross-sectional images are created (Berger, 2002).

Imaging can also be performed while infusing Gadolinium (Gad). When injected during the scan, Gad changes signal intensities by shortening T1. Thus, Gad is very bright on T1 relaxation time images. Gad enhanced images are especially useful in looking at vascular structures and breakdown in the blood-brain barrier (Preston, 2006).

The intensity of the magnetic field can be altered using a series of gradient coils and, by changing the local magnetic field by small increments, different cuts of the body will resonate at different frequencies. Each of the coils generates a magnetic field of a certain intensity with a controlled frequency. These magnetic fields alter the magnetic field already present and, therefore, the resonance frequency of the nuclei. Using three orthogonal coils is possible to

assign a different resonance frequency to each region of the space so that when resonance occurs at a specific frequency, it will be possible to determine the area of the space from which it comes.

Although MRI does not use ionizing energy, it cannot be assured with complete confidence that there are no risks to people, whether they are patients or users. Several studies have reported on the different dangers of MRI, mainly due to the lack of protocols and security measures (Buendía et al., 2010; Grainger, 2015; Schaefer et al., 2000a). The contrast agents used and the magnetic field cause risks that can cause serious effects (Hasebroock & Serkova, 2009; H. S. Kim et al., 2010; Raynaud et al., 2018).

During an MRI study, patients and people that operate the equipment (users) are exposed simultaneously to two variants of the magnetic field, the static magnetic field ($B_0$) and time-varying magnetic field gradients (dB / dt) and radiofrequency pulses (B1). MRI images are made with RF in the range of approximately 10 to 300 MHz. In Ecuador, the clinical resonators generate a magnetic field that goes from 0.3 T to 3 T. To get a rough idea, the minimum power of the resonator's magnetic field is 10,000 times the earth's gravity.

### 2.3 Biological effects of MRI

The biological effects come from the use of magnetic fields and radiofrequency pulses. One of the most important phenomena to consider is the induction of Faraday, due to the low frequencies (below 100kHz) of the current that is induced. This effect can produce stimulation in nerve and muscle cells (Ham, Engels, Van de Wiel, & Machielsen, 1997).

Long-term exposure to the static magnetic field has deleterious effects on the male reproductive system. Exposure of mice to EMF at 1.5 Tesla induces slight changes in the testicular tissue (Rostamzadeh, Anjamrooz, Rezaie, Fathi, & Mohammadi, 2019). Another effect of the magnetic fields is the sensation of nausea, vertigo, and a sensation of a metallic taste in the mouth (ICNIRP, 2009a). Brief exposures to static magnetic fields do not have any significant biological effects on mammals. Healthy tissue does not interact with static fields, and therefore, the tissue is essentially imperceptible to static fields.

Time-varying magnetic field gradients are much weaker in magnitude than the static magnetic field. However, in terms of biological effects, the important property of the imaging gradients is

that they are switched on and off very rapidly (in milliseconds or tens of milliseconds) during the MRI acquisition sequence. The switching frequency of the gradients (of order 100–1000 Hz) results in two main effects in humans exposed to MRI: peripheral nerve stimulation and loud audible noise.

Peripheral nerve stimulation and audible noise are perceived as being more unpleasant for some patients than others; however, under normal circumstances, neither of these biological effects of gradient switching is life-threatening or results in any lasting harm to patients.

When applying the radiofrequency pulses, there is a release of energy that is used to obtain images. However, part of this released energy is absorbed by the human body, which causes the body temperature to increase in general to a degree centigrade (Shellock, 2000). A study by Machata et al. showed an increase in body temperature of children who underwent resonators of 1.5 and 3 tesla (Machata, Willschke, Kabon, Prayer, & Marhofer, 2009).

### 2.4 Risks of magnetic resonance imaging

The principal risks of magnetic resonance imaging have been classified into two groups, those produced due to the magnetic field and those produced by contrast media. In the case of static magnetic fields, biological effects, incompatibility with implants, projectile risks, and compatibility of peripheral equipment are the principal risks.

Peripheral nerve stimulation, acoustic noise, and muscle stimulation are the principal risks in the case of variable gradient magnetic fields (Schaefer et al., 2000a). The projectile effect is considered a high risk for patients or staff who are inside the MRI room. The force generated in the MRI scanners strongly attracts the objects of ferromagnetic material towards the magnet, that is, in the center of the MRI equipment. The potential danger of ferromagnetic material objects increases with an increasing magnetic field (in Tesla unit).

Ferromagnetic materials are characterized by the presence of iron in their composition. These interact strongly with the magnetic fields; however, not all iron-containing materials or substances are ferromagnetic. For example, hemoglobin, which contains iron, exhibits a very weak magnetism and is not significantly affected by the magnetic fields of MRI.

Radiofrequency pulses are linked with energy absorption; some of this released energy is absorbed by the human body, which causes that the body temperature to increase generally to a degree centigrade (Shellock, 2000). Heating effects due to radio frequencies predominate at frequencies greater than 0.1 MHz (Grainger, 2015). Some medical devices and implants can also concentrate some of this energy, which causes an increase in temperature. In devices made with conductive materials, this concentration of energy is significant.

Finally, some MRI procedures involve the use of intravenously injected contrast agents to improve the diagnostic accuracy of the MRI scan. The most used agents are gadolinium-based contrast agents (GBCAs) Gadolinium (Gd), which is better tolerated and gives rise to fewer side effects and allergic reactions compared with the iodinated contrast agents used in X-ray imaging.

The gadolinium has odd electrons, giving it a high paramagnetic power; that is, it increases the intensity of the magnetic field in the vicinity of its molecule. This is a property that facilitates the longitudinal relaxation of nearby protons, shortening the relaxation times T1, so we will see signal hyperintensity in the sequences weighted in T1.

The commercially available gadolinium contrast concentrations vary between 0.5 and 1 M. The standard dose of intravenous gadolinium administration is 0.1 mmol/kg in weight, which is equivalent to 0.2 ml/kg when the contrast is 0.5 molar. In patients with normal kidney function, over 90% of the gadolinium contrast medium injected is passed out in the urine within 24 hours (Ferris & Georgen, 2017). However, there is a severe complication of gadolinium contrast that occurs in patients with compromised renal function. The condition is known as nephrogenic systemic fibrosis (NSF). A recent study has shown that there is a relationship between the use of Gd and the development of nephrogenic systemic fibrosis (Hasebroock & Serkova, 2009).

There are two classes of GBCA according to their chemical structure: linear and macrocyclic agents. Linear agents have greater retention in the brain than macrocyclic agents (Ranga, Agarwal, & Garg, 2017). Figure 5 shows the different structures of gadolinium-based contrast agents.

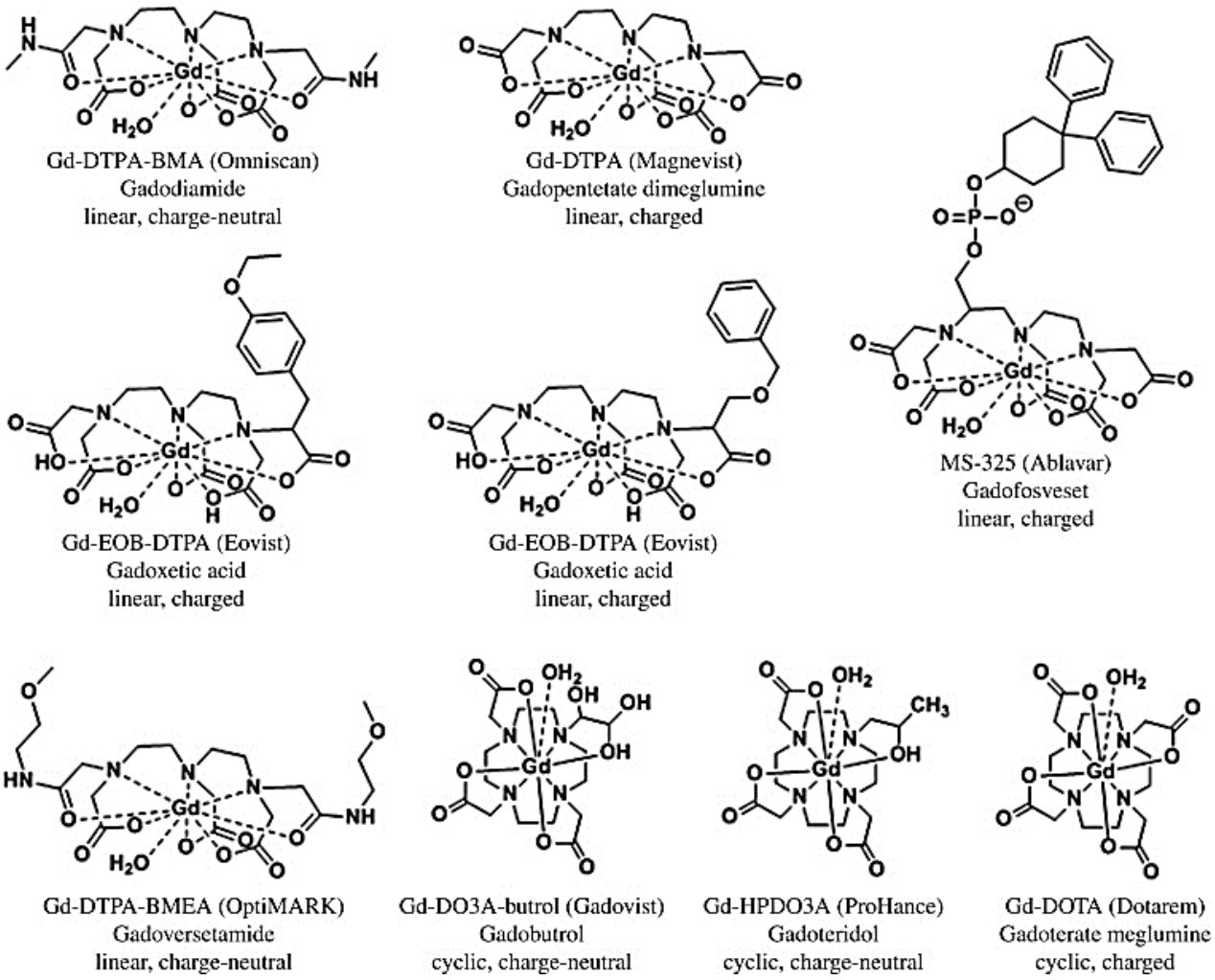



*Figure 5. Chemical structures and chemical identification of gadolinium-based contrast agents. The figure was taken from (Garcia, 2017)*

### 2.5 National and international guidelines

At the moment, there is no safety regulation for IRM rooms in Ecuador. In 2005, the National Government, together with the National Telecommunications Council, established a regulation for the protection of non-ionizing radiation emissions (CONATEL, 2005). However, this regulation is mainly aimed at radio stations and communication antennas, so there is a lack of regulations for the use of magnetic resonance imaging in medical imaging.

Organizations such as the World Health Organization (WHO), the Pan American Health Organization and the International Commission for the Protection of Non-Ionizing Radiation are the ones that have most recommended doing a specific study in each country and thus generate

their regulations to prevent accident and reduce risks for both patients and NMR equipment operators (Clauson, 2012; ICNIRP, 2009; WHO, 2016).

Below is a list of the main international organizations that work on the generation of norms and recommendations in terms of security.

- World Health Organization (WHO)
- Pan American Health Organization (PAHO)
- Food and Drug Administration (FDA)
- American Society for Testing and Materials (ASTM)
- American College of Radiologists (ACR)
- International Commission Non-Ionizing Radiation Protection (ICNIRP)
- Medicines and Healthcare Products *Regulatory* Agency (MHPRA)
- The Royal Australian and New Zealand College of Radiologists (RANZCR)
- Radiological Society of Netherland (RSN)
- International Society for Magnetic Resonance in Medicine (ISMRM)

## 3 PROBLEM STATEMENT

Magnetic Resonance Imaging (MRI) is considered a safe technology since it cannot alter the structure or properties of atoms. Non-ionizing radiation only has the ability to change the position of atoms. However, as with any health intervention, some risks must be known and taken into consideration. MRI is one of the most used imaging techniques in the health system. The non-use of ionizing radiation and the excellent image resolution in soft tissues make it eligible by medical personnel for the diagnosis of diseases.

One of the main risks is the strong electromagnetic field to which the patient is subjected, objects of ferromagnetic material become missiles due to strong magnetization. Medical devices implanted in the patient run the risk of being misadjusted or even detached and moving towards the magnetic center. Radiofrequency waves also present risks in the patient; the increase in temperature in the tissues is one of the main ones.

International organizations such as ICNIRP, WHO, and FDA have joined forces to reduce the risks associated with the use of magnetic resonance in the health sector. F2503 regulation results as a work between the FDA and the ASTM who, at the request of the WHO, carried out this work providing guidelines to the proper management of MRI rooms and devices that it encompasses. This regulation, together with guidance from ICNIRP, is the primary source of advice for the prevention of incidents in the MRI rooms.

In Ecuador, there is no national regulation that gives the necessary guidelines to prevent incidents in MRI rooms. Control and regulation entities are limited to inspecting the useful life of the equipment but not its proper handling. Despite the few reported incidents, it is necessary to have a normative that regulates and give the guidelines required to ensure both patients, medical staff, and the equipment.

# 4 OBJECTIVES

## 4.1 General objective:

To elaborate a National Security Normative to apply in the public and private health system of Ecuador based on a review of International Standards and Protocols about the security of Magnetic Resonance Imaging.

## 4.2 Specifics objectives:

- To review the safety regulations of other countries, which serve as a guide for the elaboration of the national normative.
- To analyze the international institution's safety recommendations such as WHO, ICNIRP, FDA, ASTM, among others.
- To identify the possible risks of magnetic, static, gradient, and radiofrequency fields.
- To adjust international protocols and standards to the reality of the country.

# 5 METHODOLOGY

This final grade project is of a select type in which it is intended to develop a Safety Normative for the Magnetic Resonant rooms in Ecuador, based on international papers, protocols, and Regulations. In this work, three main processes are distinguished: bibliographic search and information analysis, information synthesis, and as a result, the development of the Normative.

## 5.1 Bibliographic search and information analysis

The bibliographic search was made manually, reviewing relevant information from both Ecuador and all the world. Academic search engines were used, with the following keywords: resonances, risks, normative, magnetism, and health. The sources of information varied from indexed journals, databases, publications of international organizations to interviews with professionals in this field.

The numbers of articles reviewed within each database were: Academia (2), Google Scholar (3), Latindex (4), PubMed (7), SciELO (9), Science Direct (5), and Scopus (2). Also, articles and publications of international institutions such as the World Health Organization (WHO), International Commission No Ionization Radiation Protection (ICNIRP), American Society for Testing and Materials (ASTM), Food and Drug Administration (FDA) and International Society for Magnetic Resonance in Medicine (ISMRM) were reviewed.

Public information was collected through the National Institute of Statistics and Census (INEC), as well as Ecuadorian articles about resonances. Also, I had several interviews with various Ecuadorian control agencies such as the Health Regulation and Control Agency, Undersecretary of Control and Nuclear Applications, Agency for Quality Assurance of Health Services, and Ministry of Public Health. With the help of the Mendeley Program, analysis and classification were carried out with the obtained information. It should be noted that the collected data in both English and Spanish, due to the scope of the regulations.

## 5.2 Synthesis

In this step, the collected documents are reviewed one by one, extracting the essential information for the Normative, taking care that there is no unnecessary accumulation of knowledge.

Also, a comparative evaluation of the information from the different sources was carried out. Specific differences between the sources were analyzed and resolved based on the knowledge of the body or author of higher hierarchical weight. At this stage, the information was organized to comply with all the necessary aspects to elaborate on the normative.

### 5.3 Development of Normative

In this step, a script that establishes the necessary guidelines, and the topics that will be covered within the regulations was prepared.

**Normative Script**

1. Introduction
2. Objectives
3. Concepts and definitions
4. How the MRI works
    - History
    - Principle of work
    - Its use in Ecuador
5. MRI risks
    - Static Magnetic Field
    - Variable Gradient Magnetic Field
    - Radio Frequency Pulses
6. International Protocols and Regulations
    - World Health Organization (WHO)
    - International Commission for the Protection of Non-Ionizing Radiation (ICNIRP)
    - American Society for Testing and Materials (ASTM)
    - Food and Drug Administration (FDA)
7. Exposure limits and guidance
    - Patients
    - Personnel (employees/freelancers)
    - The general public (visitors)
8. Handles of the MRI units
    - RM rooms
    - Controlled Areas
    - Area and equipment labeling
9. Annexes

After having established the normative script, it is reviewed that the information is relevant to the topics present in the text. The use of applications such as Mendeley was necessary to accelerate the drafting of the Regulation and ensure excellent preparation.

# SAFETY NORMATIVE FOR THE USE OF MAGNETIC RESONANCE EQUIPMENT IN THE HOSPITAL SYSTEM

2020

# SAFETY NORMATIVE FOR THE USE OF MAGNETIC RESONANCE EQUIPMENT IN THE HOSPITAL SYSTEM

**Index**

## 1. INTRODUCTION

Magnetic resonance imaging (MRI) is a technique widely used in medicine for medical diagnosis. One of its main characteristics is that it does not use ionizing radiation, such as tomography or X-rays. Its extensive use is because it uses non-ionizing radiation, which is part of the electromagnetic spectrum whose wavelength is very wide and, therefore, their interaction with the tissue does not cause the creation of even ions. Consequently, it does not represent damage due to radiation. MRI procedures are considered safe; however, there are several risks at the magnetic field level, radiofrequency pulse, and contrast media that cannot be overlooked.

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) has carried out different studies and has made recommendations about the limits of exposure to non-ionizing radiation (ICNIRP, 2009a). The ICNIRP concluded that there is no scientific evidence to associate the levels of non-ionizing radiation and possible carcinogenic effects. In this way, the recommendations are based on short-term effects, such as burns, the induction of magneto phosphenes, muscle stimulation, stimulation of peripheral nerves, and the increase in body temperature (Ziegelberger, 2014).

This regulation refers to the exposure limits defined by the ICNIRP and its possible biological effects. Also, the risks involved in MRI studies are shown, and the different safety aspects that must be taken into account in this diagnostic technique are analyzed. A review of the different international standards is made, and a summary of the issues that regulators must take into account when regulating the operation of the RM rooms is made.

This regulation tries to give the necessary guidelines in terms of safety when conducting a study by Magnetic Resonance Imaging. Thus, preventing possible accidents or adverse biological effects due to the absence of a safety protocol that provides the necessary guidelines to ensure both the patient and the users.

## 2. PURPOSE

To give guidelines to improve safety and avoid risks in the areas of MR through the explanation about the real risks/dangers of the effect of magnetization to which so many users, patients, and the general public are exposed.

## 3. QUANTITIES AND UNITS

Table 1 shows the main units used in the MRI environment. In addition to the units presented in this table, other commonly used units are mentioned, such as meter (m) and centimeter (cm). Magnetic flux density units such as Maxwell (Mx) and Webber (Wb) and area units such as square meter (m2) and square centimeter (cm2) are also presented.

| Unit | Unit Symbol | Quantity | Unit Dimension(s) |
|---|---|---|---|
| Tesla | **T** | **Magnetic Flux Density** | **Wb/m²** |
| Hertz | **Hz** | **Frequency** | **1/s** |
| *Gauss | **G** | **Magnetic Flux Density** | **Mx/cm²** |
| Kilogram | **Kg** | **Mass** | |
| Second | **s** | **Time** | |

*Table 1. Quantities and Units used in this work.*

** This magnitude is given by the CGS system*

## 4. HOW THE MRI WORKS

### 4.1 History

Magnetic resonance imaging is undoubtedly one of the most used techniques in the area of imaging for the diagnosis of diseases. MRI has various characteristics, such as the absence of the use of ionizing radiation and high affinity with contrast agents, to improve image quality.

It was in 1939 when Isidor Isaac Rabi designed a device that showed how an atom behaved in a magnetic field when applying radio waves. This technique and the knowledge about this phenomenon progressed until in 1984 when it was possible to carry out the first imaging studies employing magnetic resonance imaging (MRI) in humans, and today this field is widely known and used in different research areas, especially in the area of health for medical diagnosis.

Although MRI does not use ionizing energy, it cannot be assured with complete confidence that there are no risks to people, whether they are patients or users. Several studies have reported on the different risks of MRI, mainly due to the lack of protocols and security measures (Buendía et al., 2010; Grainger, 2015; Schaefer et al., 2000a). The contrast agents used and the magnetic field cause risks that can cause serious effects (Hasebroock & Serkova, 2009; H. S. Kim et al., 2010; Raynaud et al., 2018).

### 4.2 Working principle

Magnetic resonance imaging (MRI) is based on the precession of the nuclei of atoms due to an external magnetic field (Peters & Cleary, 2008). In the images for medical diagnosis, the atoms that have a precession movement are mainly hydrogen atoms. For this application, the hydrogen atoms are very important due to their abundance in the human body, especially in soft tissues.

After the hydrogen atoms are subjected to a strong magnetic field, they leave their normal alignment and align with the external magnetic moment. Then, the magnetic field is varied by gradient magnets and, therefore, have different frequencies. Finally, emitted radiofrequency pulses cause that the atom enters in resonance and releases energy. This energy is measured with the antennas in the resonator, and then the energy is analyzed and digitized to obtain images. MRI images are made with RF in the range of approximately 10 to 300 MHz.

During an MRI study, patients and people that operate the equipment (users) can be exposed simultaneously to three variants of magnetic fields: the static magnetic field (B0), time-varying magnetic field gradients (dB / dt) and radiofrequency pulses (B1).

The static magnetic field, also known as the main magnetic field, is created by a large magnet. The clinical resonators generate magnetic fields that go from 0.3 T to 8 T. It is known as a static magnetic field because its magnitude and direction do not change over time. In almost all MRI systems, this static magnetic field is continuously present, that is, 24 hours a day. The magnetic field strength of the MRI systems varies from 0.2 to 1.0 T for open systems with a vertical static magnetic field, and from 0.5 to 3.0 T for classic cylindrical systems with a horizontal field. To get a rough idea, the minimum power of the resonator's magnetic field is 10,000 times the earth's gravity.

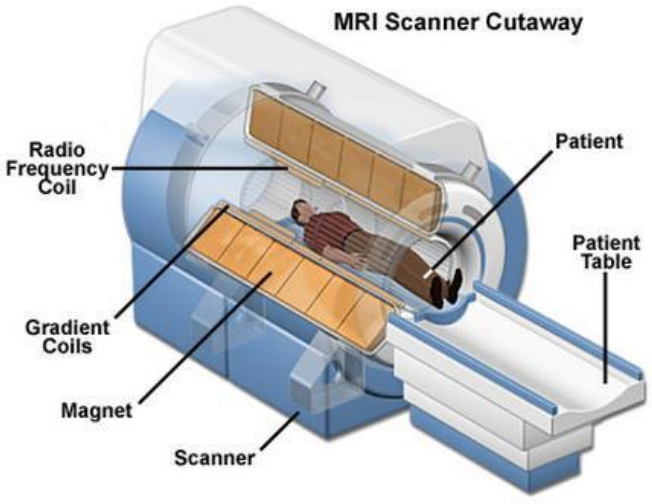



*Illustration 1. Conventional MRI Scanner* (Al-Tamimi, Mohammed & Sulong, 2014).

### 4.3 Use in Ecuador

Magnetic resonance imaging in Ecuador has very little history. It was in the year of 1992 when a Magnetic Resonance device was imported for the first time, which was used in the Pichincha Old Clinic (Jara., 2017). According to INEC data, in 2016 in Ecuador had 50 resonators (INEC, 2016), whose magnetic power varies from 0.2T and 3T. At present, Ecuador has resonators in almost all its provinces, with Quito and Guayaquil being the cities where most of these teams are concentrated.

## 5. RISKS OF MRI

The risks of magnetic resonance imaging have been classified into two groups: those produced due to the magnetic field and those produced by contrast media. In general, the following risks have been considered in this study: Static Magnetic Fields (Main Magnet), Variable Magnetic Fields, or Gradient (Produced upon graduation of the magnetic field) and Radiofrequency pulses.

### 5.1 Static magnetic fields.

The main safety risks presented by static magnetic fields in a Magnetic Resonance study are related to biological effects, incompatibility with implants, projectile risks, and compatibility of peripheral equipment. Currently, resonators in the health system in Ecuador vary from 0.2T to 3T.

MRI magnets can be represented as a superconducting solenoid, which is immersed in liquid helium (at a temperature of −269 ° C) to

maintain the superconductive state. The magnetic field is maintained indefinitely without a constant input of electrical energy due to superconductivity (the flow of electrical current without resistance). Once the resonator is magnetized, the magnetic field is maintained at a constant value over time, ideally throughout the life of the scanner (hence the term "static" field) (Radiology Key, 2016).

**• Biological effects**

The creation of electrical potentials and the resulting currents are the main interactions of a static magnetic field, $B_0$, with the body. Several studies have been conducted to determine the effect of magnetic fields on biological cells and tissues. Despite the many reports of potentially harmful biological effects, none of them have been able to be verified and firmly established as a scientific fact.

The absence of serious harmful effects of magnetic fields is attributed to the very weak diamagnetic susceptibility of these tissues (Schenck, 2000). What most of these studies converge on is the mild sensory effects such as vertigo, dizziness, metallic taste. However, there is no evidence that these effects are harmful.

Another important aspect to consider is the effect of accumulated exposure to high magnetic fields. Although there is no evidence of a negative effect, subsequent studies of the exposed populations will be useful to establish rational guidelines for occupational exposure to magnetic fields.

The World Health Organization, in 2016, published about the possible effects of exposure to static magnetic fields on health and noted the following:

'It is reported that physical movement within a static field gradient induces feelings of vertigo and nausea, and sometimes phosphenes and a metallic taste in the mouth, for static fields about of 2 to 4 T. Although only transient, such effects they can negatively affect people. Together with the possible effects on eye-hand coordination, the optimal performance of workers performing delicate procedures could be reduced ... Effects on other physiological responses have been reported, but it is difficult to reach a firm conclusion without independent replication'. (World Health Organization [WHO], 2016).

On the other hand, the ICNIRP statements in reference to the static field are:

'The current information does not indicate any serious health effects as a result of acute exposure to static magnetic fields of up to 8 T. However; it should be borne in mind that such exposures can lead to unpleasant sensory effects such as vertigo during the movement of the head or body' (ICNIRP, 2009b)(ICNIRP, 2009a).

**• Projectile Risk**

The projectile effect is the ability of the static magnetic field to attract a ferromagnetic object towards the center of the resonator with great force and speed. It is one of the risks that worry most in Magnetic Resonance rooms, and this is due to the strong magnetic field that is generated in this area. The potential danger of ferromagnetic material

objects increases with an increasing magnetic field (in Tesla unit).

The force generated in the MRI scanners reaches its highest threshold just inside the opening of the magnet, which is to say in the center of the MRI equipment. This effect could consider a great risk for patients or staff who are inside the MRI room. Also, the impact of objects can cause serious damage to the resonator or the magnet.

The resonators most used in the equator have a force of between 1.5T to 3T, which corresponds up to 60,000 times the magnetic field of the earth. This risk can be minimized by strictly and carefully following the guidelines framed in this regulation.

### 5.2 Magnetic fields of variable gradient

The main safety risks presented by variable magnetic fields in a Magnetic Resonance study are peripheral nerve stimulation, acoustic noise, and muscle stimulation. In MR imaging processes, time-varying gradient magnetic fields (dB/dt) can stimulate nerves or muscles by inducing electric fields in patients (Schaefer et al., 2000a) (Schaefer, Bourland, & Nyenhuis, 2000b)

**• Biological effects**

Subjecting the human body to electromagnetic fields that vary over time can lead to induced electric fields and circulating currents in conductive tissues. In any particular location, the induced currents will be determined by the rate of change of the magnetic field and the local distribution of the impedance of the body, which is mainly resistive at frequencies below approximately 1 MHz.

The field gradients variable in the time taken in MRI scanners are relatively low frequency compared, for example, with radiofrequency and microwave fields. Magnetic fields of varying gradient over time induce electrical currents that potentially interfere with the normal function of nerve cells and muscle fibers. An example of this is peripheral nerve stimulation (SNP).

The tingling sensations of nerve stimulation are perceptible to a certain extent. The magnetic fields of simultaneous gradient axes combine almost like a vector sum to produce stimulation. According to a study by Schaefer, patients may present slight discomfort at amplitudes of 50% to 100% above the perception thresholds (Schaefer et al., 2000b).

**• Muscle and peripheral nervous system stimulation**

One of the most important phenomena to consider is the induction of Faraday, due to the low frequencies (below 100 kHz) of the current that is induced. This effect can produce stimulation in nerve and muscle cells (Ham et al., 1997). As a result, this stimulation could be large enough to cause discomfort and, in certain cases, ventricular fibrillation, which could lead to serious problems for the patient.

In 2008, the United Kingdom Health Protection Agency published a document detailing:

'Exposure to switched gradient fields induces electric fields and currents that vary over time in biological

tissues. These can cause stimulation of excitable tissues if they are of sufficient intensity and appropriate frequency. The rapidly changing fields induced by the high gradient field change rates used in magnetic resonance systems will preferably stimulate the peripheral nerves. These thresholds are well below those of ventricular fibrillation for pulse widths of the induced current of less than 3 msec. Therefore, limiting the exposure of patients and volunteers to switched gradient fields may be based on minimizing the uncomfortable or painful sensation caused by the field (Health Protection Agency, 2008).

rise in body temperature in a short time, cardiovascular tension is increased (Shellock, 2000). Some tips to keep the patient safe and burn-free are presented in illustration 4.

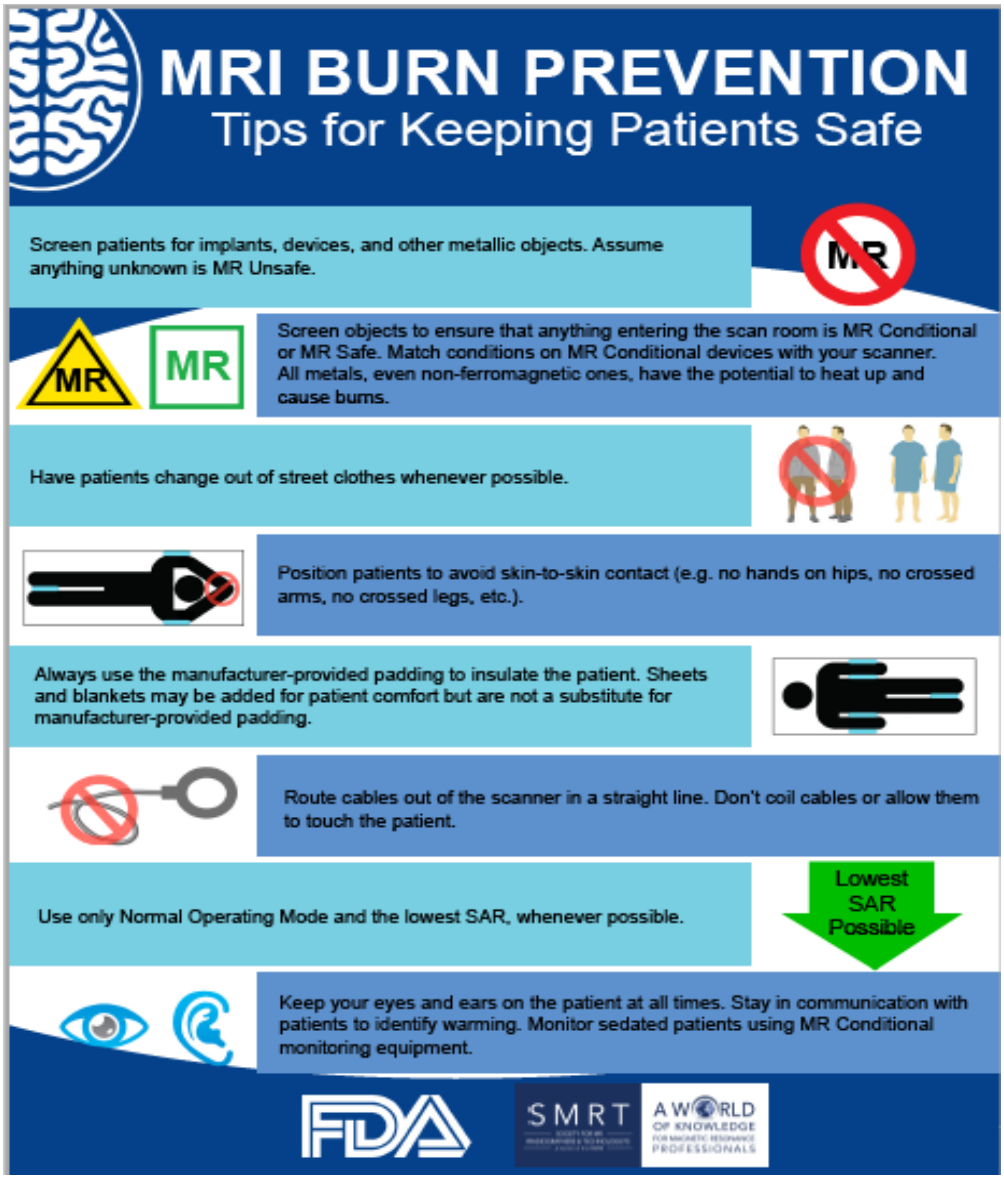



*Illustration 2. MRI burn prevention tips. Taken from (Food and Drug Administration, 2019)*

### 5.3 Radiofrequency pulses

Radiofrequency pulses play a very important role in MRI studies for imaging. Some of this released energy is absorbed by the human body, which cause the body temperature to increase generally to a degree centigrade (Shellock, 2000). Another study conducted by Machata et al. has shown an increase in body temperature of children who underwent resonators of 1.5T and 3T (Machata et al., 2009). Burns due to thermal heating is part of the risks that the patient faces when subjected to radiofrequency (RF) fields.

Heating effects due to radio frequencies predominate at frequencies greater than 0.1 MHz (Grainger, 2015). Some medical devices and implants can also concentrate some of this energy, which causes an increase in temperature. In devices made with conductive materials, this concentration of energy is significant.

**• Heat stress**

Stress due to temperature rise is another problem to which attention should be paid. Patients suffering from hypertension, pregnant women, or those taking medications such as diuretics or vasodilators may be

### 5.4 Contrast Agent

A contrast agent is used to improve the quality of the image; it is introduced into the body intravenously just before entering the MRI scanner. One of the most widely used contrast agents is Gadolinium (Gd) because it alters the magnetic properties of hydrogen atoms. Once the body absorbs the contrast agent, it will accelerate the speed at which tissues respond to the magnetic field and radiofrequency pulses.

As a result, the signals produce higher quality images. In healthy patients, an adverse effect is unlikely, and the probability of an allergic reaction is very rare. However, contrasts with Gadolinium should not be used if the patient has renal function problems since, in these cases, the possibility of a severe risk has been described.

Studies have shown that presence of allergies to the contrast agent is relatively minimal (from 0.0016% to 0.019% for severe reactions and from 0.015% to 0.91% in general), but if these data tend to rise it could be a critical effect (Raynaud et al., 2018). Recent studies have shown that there is a relationship between the use of Gd and the development of nephrogenic systemic fibrosis (Hasebroock & Serkova, 2009). Another study showed that there is a toxic effect on mitochondrial respiratory function and cell viability by MRI contrast agents containing Gadolinium (Bower, Richter, von Tengg-Kobligk, Heverhagen, & Runge, 2019). For this reason, the FDA recommends that Gadolinium be used just if it is strictly necessary.

# 6 INTERNATIONAL RECOMMENDATIONS

The study of Magnetic Resonance Imaging has generated some interest in international organizations; however, there are few studies on the effects of magnetic fields on people and possible risks. Organizations such as the World Health Organization (WHO), American Society for Testing and Materials (ASTM) and the International Commission on Non-Ionizing Radiation Protection (ICNIRP) are the ones that have most recommended and did a specific study in each country and thus generated their regulations in order to prevent accident and reduce risks for both patients and MRI equipment operators.

## 6.1 World Health Organization

In 2006, WHO made recommendations in terms of times and the dose of exposure to magnetic fields and indicated that each country must adopt these recommendations and generate its protocols to protect the safety of people in the process of MRI (WHO, 2016).

## 6.2 American Society for Testing and Materials

Due to the increasing use of Magnetic Resonance technologies in the health system, this institution saw the need to generate a standard called F2503 (Clauson, 2012). This standard assesses the possible risks that patients face when undergoing an MRI study. Table 4 shows a summary of the F2503 standard proposed by the ASTM.

## 6.3 International Commission for the Protection of Non-Ionizing Radiation

In 2009, ICNIRP published procedures for patient protection in MRI processes (ICNIRP, 2009b). This study shows how the static magnetic field can biologically and physiologically affect people who are subjected to a high magnetic field. Also, this agency in 2014 made another publication that establishes guidelines for the protection of people who are subjected to static magnetic fields or with a frequency of less than 1Hz (Ziegelberger, 2014).

# 7 EXPOSURE LIMITS AND GUIDANCE

MRI is a diagnostic medical technique that, although it is considered harmless for not using ionizing radiation, has some aspects that pose a risk to the patient's health. The magnitude of greatest importance in this regard is the specific absorption rate (or SAR) that is related to the deposition of energy per unit of mass and time in the patient due to the effect of radiofrequency (RF) pulses. The impossibility of measuring this magnitude directly in the patient implies that the MRI system calculates this value based on the weight and type of imaging

sequences to which the patient is going to be subjected.

Peripheral nerve stimulation (or PNS) to which field gradients give rise does not represent a danger to the patient's health, but it can lead to discomfort or pain sensation that can make the MRI study impossible.

Both SAR and PNS depend on parameters that are directly involved in the quality of the final image, and its modification to protect the patient can lead to a loss of the diagnostic image quality. The MRI equipment has established different modes of operation in which ICNIRP propose different limits of exposure to SAR:

| Operation | $B_0$ limit | Effects on the patient | Requires medical supervision? |
|---|---|---|---|
| Normal | < 2 T | No | No |
| Controlled | < 4 T | Possible discomfort / Stress | Yes |
| Experimental | > 4 T | Possible risk | Yes. Also, it requires a SCAN-approved license |

*Table 2. Static magnetic field exposure limits established by the ICNIRP.*

| Characteristics | Frequency Range | SAR (W/kg) | | |
|---|---|---|---|---|
| | | Whole body | Head/Trunk | Limbs |
| Occupational | 100 kHz - 6 GHz | 0.4 | 10 | 20 |
| | > 6 GHz - 300 GHz | 0.4 | --- | --- |
| General Public | 100 kHz - 6 GHz | 0.8 | 2 | 4 |
| | > 6 GHz - 300 GHz | 0.8 | --- | --- |

*Table 3. Limits of SAR at different frequencies.*

## 8 MRI UNIT MANAGEMENTS

One of the most important aspects to the care of patients within the MRI units is to analyze the risks that the use of implants, accessories, or other objects of ferromagnetic material or non-MRI compatible can bring. It is necessary to constantly update information on the existence of these objects, as well as a review and identification protocol in the patient.

Patient Screening is a fundamental step before the MRI study because most incidents occur due to a lack of control of access to the resonator. At this point, it is really necessary to follow the procedure to prevent some incidents that may occur. The patient must be properly screened before entering the resonator, and if there is any doubt, consult with the Doctor. Also, it is necessary to request written authorizations, and in case of doubt, refrain from taking the exam.

### Controlled Areas

All resonance rooms must be built under strict control and review of regulatory agencies in the field of non-ionizing radiation. To prevent accidents and to avoid damage caused by magnetic fields, radiofrequency pulses, and noise, the World Health Organization, together with the American College of Radiology have recommended that the rooms of MRI be divided into four zones (Kanal et al., 2013), which are described below.

**Zone 1.** This area is free to the general public; the influence of the magnetic field of the MRI equipment is very low: it is less than 5 Gauss (0.5 mT). This area is usually the one that surrounds the MRI rooms.

**Zone 2.** This zone is the connection between zone 1, which is not controlled, and zone 3, which is controlled. In this area, patients are usually received and prepared for the MRI process. Also, the patient is asked about safety questions to ensure that he or she is ready to move into the area. This zone, like zone 1, is open to the public; however, only those involved in the MRI study can enter. The magnetic field in this area remains low, the same that should not exceed 0.5 mT.

**Zone 3.** In this zone, the magnetic field is strong enough to be considered risky and cause injuries to both patients and operational personnel. It can cause injuries when moving ferromagnetic objects or cause damage to electronic equipment. The magnetic field in this area can have an intensity of between 0.5 mT and 3 mT. In this area, it is advisable to be careful with objects of ferromagnetic material, and in most cases, avoid their presence.

**Zone 4.** This zone is exclusive for the MRI equipment. The general public must enter through zone 3. This zone must have a shield or shield of electromagnetic waves because a high magnetic field is generated. This shield must ensure that external frequencies do not enter, interfere with, or alter the results of the images.

Also, this shield must reduce the magnetic field of the MRI equipment that is transmitted to the other areas. To achieve this, shielding is recommended to manufacture a Faraday cage, whose construction characteristics are detailed in the shielding segment. In this area, the presence of ferromagnetic material objects is strictly prohibited. It should be taken into account that the presence of any metal is highly dangerous due to the missile phenomenon that these generate when entering a high magnetic field. The magnetic field in this area will have an intensity of between 0.3 and 3 T.

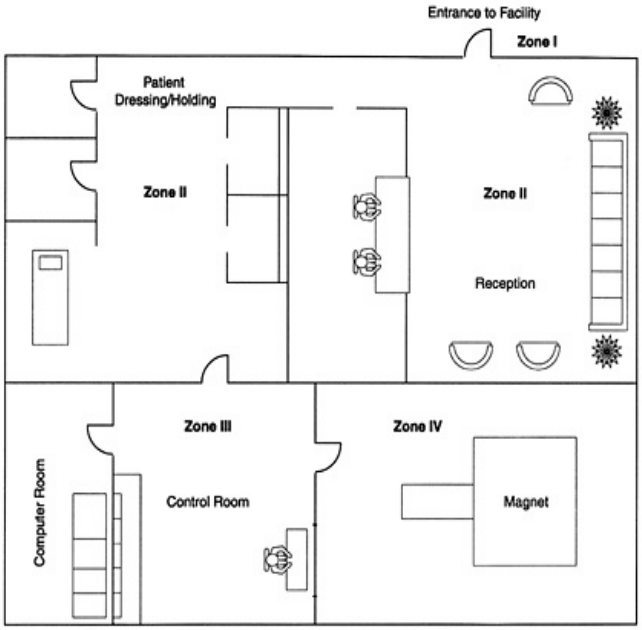



*Illustration 3. Design and distribution of the areas of an MRI room. It was taken from ACR Guidance on MR Safe Practices, 2013* (Kanal et al., 2013).

## Shielding

Zone 4 must be isolated from the outside to reduce the propagation of the magnetic field and the external radiofrequency pulses. This protection is known as shielding, and it is essential both to reduce the intensity of the magnetic field that leaves the room and to keep radio waves away from the resonator. For this type of shielding, it is necessary to cover the entire zone 4 with a metal layer, usually copper sheets about 2 mm of thick (Barbosa, Agulles-Pedrós, Daza, & Lozano, 2013).

For maximum protection of the static magnetic field, zone 4 must be fully protected, including walls, ceiling, and floor. In a study conducted by Koppel et al., it was possible to demonstrate that rooms that are partially armored allow ten times more magnetic field passage than those that are fully armored (Koppel, Ross, & Vilcane, 2017).

**Area and equipment labeling**

The risks and potential dangers in the areas of magnetic resonance are important aspects in which it is necessary to act. These risks endanger patients, technicians, and other medical professionals. External ferromagnetic material objects, as well as metal implants or pacemakers, can interact with magnets and cause serious damage to both people and equipment.

In response to the increasing use of magnetic resonance imaging for medical studies and the number of safety incidents that have been reported, the Food and Drug Administration (FDA) has found that it is necessary to address safety issues related to MRI.

The World Health Organization, together with the FDA, has requested that a complete study of the potential risks of MRIs be carried out. Thus, these institutions, together with the international ASTM, they generated the F2503 standard (Clauson, 2012). This regulation seeks to reach a consensus between manufacturers, health institutions, doctors, and patients.

The F2503 standard regulates a uniform labeling system to indicate the level of risk of a device within a magnetic field, in addition to establishing the level of security of each area in the RM rooms. This standard offers several terms and graphic images for the labeling of RM equipment and rooms to reduce the risks when using the RM equipment. The F2503 classifies medical devices and other elements in the MRI room into three groups: MR Safe, MR Conditional, and MR Unsafe.

## 9 BASIC SECURITY PROTOCOL

Magnetic resonance imaging is carried out in hospitals or Imaging centers. These must have the operating permission and advice of the regulatory agencies. To prevent accidents, the immediate areas around the MRI system must be delimited and marked with an appropriate warning or danger signs and secured by personnel trained in the appropriate safety procedures at MRI facilities.

To start an MRI study is necessary for the patient to present a study order from their attending doctor. The patient's medical history should be reviewed to know about previous incidents (if there was).

Before entering the MRI system room, patient screening is realized using a form with safety questions (see Appendix 2) to avoid accidents and potential damage related to the missile effect. Screening patients for ferromagnetic objects before entering the MR suite is the single most important safety precaution in the MR environment.

If a patient who is inside the MRI scanner requires emergency medical treatment, the recommendation is to remove the patient from the MR scanner room. Because emergency treatment typically involves personnel and equipment that have not been screened for MR safety. It is faster and safer to move the patient to an area with low magnetic field than it is to either shut down the magnet (emergency shutdown requires minutes) or to attempt to screen all of the personnel and crash cart equipment.

If the patient has kidney problems, allergies due to contrast, or another verifiable risk such as the use of active implants or metal implants, it is necessary to consult with the attending doctor. Table 5 shows the principal devices and its level of security. In case of doubt, it is essential to refrain from performing the magnetic resonance study.

Then, the patient should be asked to remove all metal objects, such as jewelry, watches, or other such objects (see Illustration 6). Also, you should be provided with a gown, clothing with which the study will proceed. The safety classification of the main items is detailed in the table

The scanner room (zone 4) must be easily recognizable by using warning labels (see Illustration 4). In addition, a spotlight with red light should be located, indicating that the scanner is turned on. MRI personnel need to be trained and certified to provide medical support in case of cardiac or respiratory co-complications. As a precaution, people should also be advised not to stay longer than strictly necessary in the scanner room. Besides, additional measures must be taken to reduce exposure and raise awareness of possible risks.

Because the noise inside the resonator is greater than tolerable, it is necessary to use headphones or earplugs for patients. It is recommended that the technicians operating the resonance equipment be auditioned periodically (for example, once a year).

MRI rooms must have a director to ensure the application and monitoring of safety guidelines. Also, it is necessary to create a database in which adverse effects and/or safety problems are documented at the RM work site.

| Security Level | Detail | Symbol |
|---|---|---|
| MR Safe | It is used for objects that are non-conductive, non-magnetic, non-metallic, or present no risk of exposure to any MRI environment. Its presence within the MR area does not represent any risk for both the people and the equipment. |  |
| MR Conditional | It is used for objects that do not represent danger in MRI rooms under defined conditions. These conditions include the strength of the static magnetic field, variable gradient field, radiofrequency fields, the specific absorption rate, among other factors. The elements classified as conditional for the MRI guarantee that you have had enough evidence to ensure controllable behavior within the MRI room. |  |
| MR Unsafe | It is used for objects that are highly dangerous within the RM room. These objects can be metallic, conductive, and ferromagnetic. The presence of these objects must be strictly prohibited. |  |

*Table 4. Labeling proposal on the F2503 norm by the ASTM.*

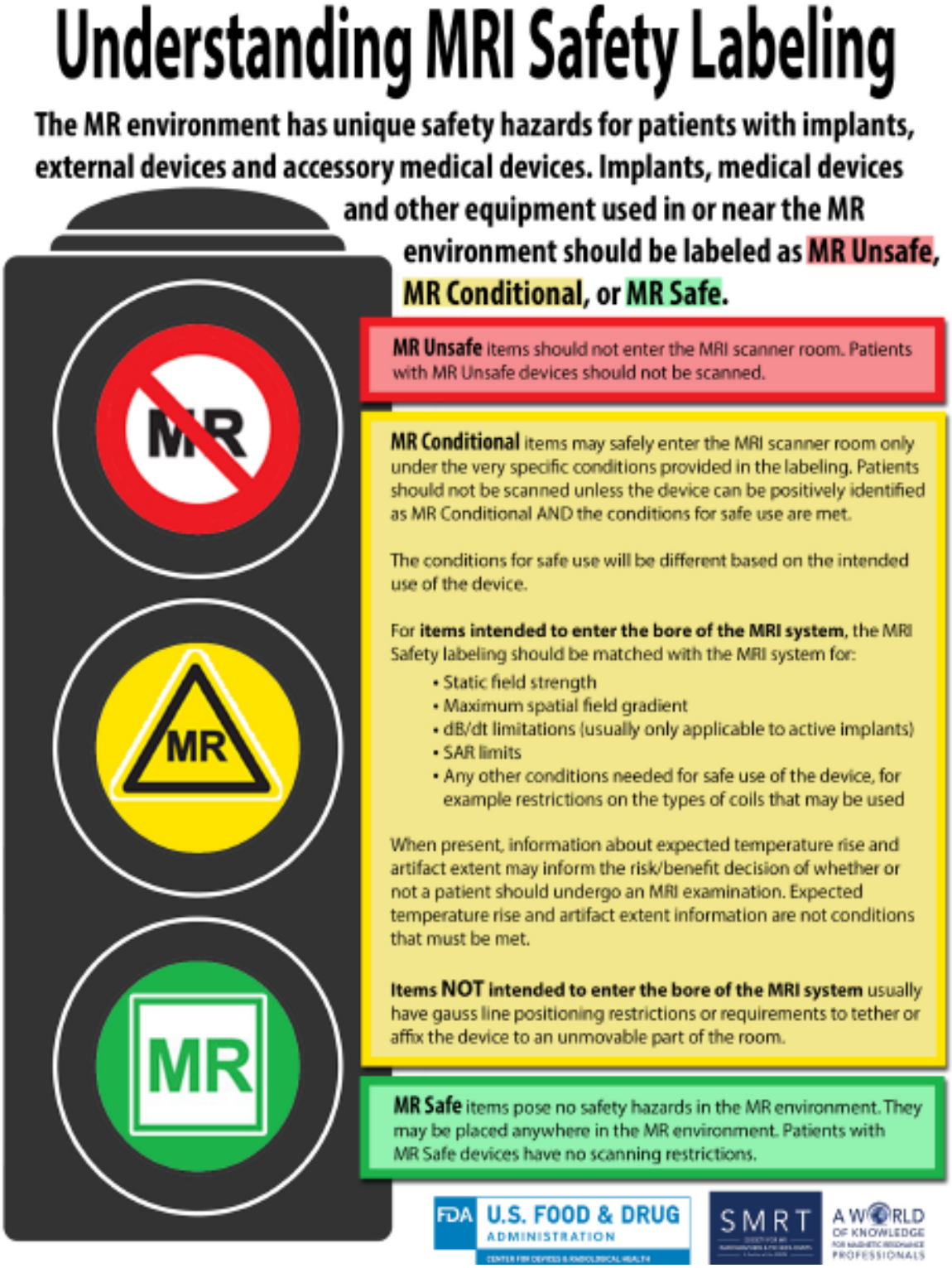



*Illustration 4. Understanding MRI Safety Labeling. Taken from* (Food and Drug Administration, 2019)

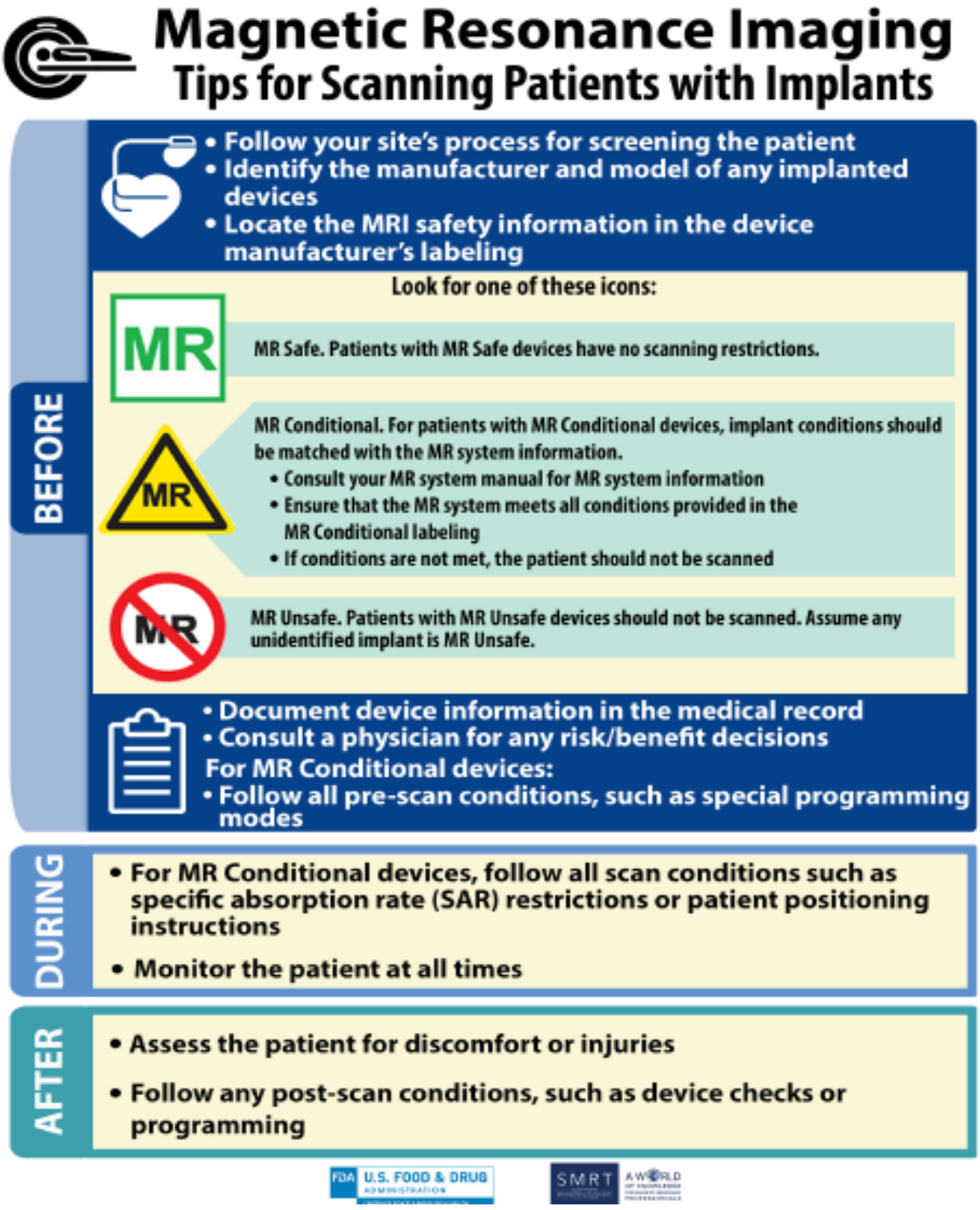



*Illustration 5. Tips for Scanning Patients with Implants. Taken from* (Food and Drug Administration, 2019)

| | |
|---|---|
| **ATTENTION<br>HIGH MAGNETIC FIELD** |  |
| **ATTENTION<br>NON-IONIZING RADIATION** |  |
| **PROTECT EARS WHEN THE SCANNER IS OPERATING** |  |
| **THE USE OF WATCHES AND JEWELRY IS PROHIBITED** |  |
| **RESTRICTED INCOME WITH MARCAPASOS OR COCHLEAR IMPLANTS** |  |
| **THE USE OF THE CELLPHONE IS PROHIBITED** |  |
| **NO METAL OBJECTS** |  |

*Illustration 6. Labeling proposal in the RM rooms.*

| Safe | Conditional | Unsafe |
|---|---|---|
| Heart valves | Pacemakers | ECG Electrodes |
| Annuloplasty Rings | Self-Implantable Defibrillators | |
| Hemostatic clips | Cardiovascular catheters and accessories | |
| Coronary stents | | |
| LCR bypass valves | Deep brain stimulation systems | Cochlear implants |
| Intraspinal dural catheter | Glaucoma drainage implant | Orbital metal bodies |
| Retinal implant | Brain aneurysm clips | |
| Implant of auditory conduction | | |
| Dental implants | Endoscopic Marking Clips | Continuous infusion pumps |
| Intrauterine devices | Surgical staples | Insulin pumps |
| Orthopedic external fixation devices | Breast Expanders | O2 pumps |
| Cranial bone flap fixation plates | Penile implants | Biopsy needles and devices |

*Table 5. Classification of the main devices according to their level of security.* (Mut Pons et al., 2017)

# 10 APPENDICES

## 10.3 Appendix 1

| Risk | Causal Agent | Effect | Latent Error / Condition | Preventive Measures |
|---|---|---|---|---|
| Missile effect | Magnetic field | * Impact injuries.<br>* Person trapped between the magnet and the missil.<br>* Damage to the magnet. | * Failure to control access to the restricted area<br>* Non compatble material | * Access control and correct signaling of the access area restricted.<br>* Identification of emergency switches<br>*Obligatory to perform examination in gown and shims<br>*Use and identification of compatible material (chair, stretcher, carrier, extinguisher) |
| Introduction in the magnet of a patient with contraindications | *Magnetic field<br>*Radiofrequency | *Injury due to heating, displacement or failure of the device.<br>*Device failure | Patient screening failure | *Access control and correct signaling of the restricted access area.<br>*Posters information on contraindications in reception and waiting room.<br>*Registration in the medical history of a patient, for subsequent RM. |
| Quench | Helium leak | If helium flows into the room: asphyxiation, freezing, fire | Helium loading by the technical service: little experience, accidents | *Know consequences of pressing the stop switch.<br>*Correct installation and operation of the evacuation duct of gases.<br>*Periodic record of helium levels and temporary power outages. |
| Thermal injury | Radio frequency | Burn | Contact with coil / coil in poor condition.<br>*Skin-to-skin contacts.<br>*Tattoos, metal bodies.<br>*Electrodes, pulse oximeter | Careful placement of patient coils, cables and limbs.<br>*Avoid direct contacts with coils and inside of the tunnel.<br>*Alert on the risk to patients with tattoos.<br>*Place cold serum bags / wet packs on the tattoo. |
| Hearing injury | Gradients | Transient hearing loss | | Use of acoustic protection (earplugs, helmets) |
| Traumatic injury | Table movement | Catching clothes, limbs, hair | Automated table movement | *Careful placement of the patient on the table before starting the movement.<br>*Switching the switch to stop the automated table movement. |

*Ilustration 7 Identified risks and preventive measures.* (Capelastegui, Fernández-Cantón, & Fernández-Ruanova, 2006)

## 10.4 Appendix 2

**Formulario de detección de seguridad para procedimientos de resonancia magnética (MR)**

Fecha_____ Nombre_____

Hombre [ ] Mujer [ ] Edad____ Fecha de Nacimiento__/__/____ Altura____cm
Peso_____

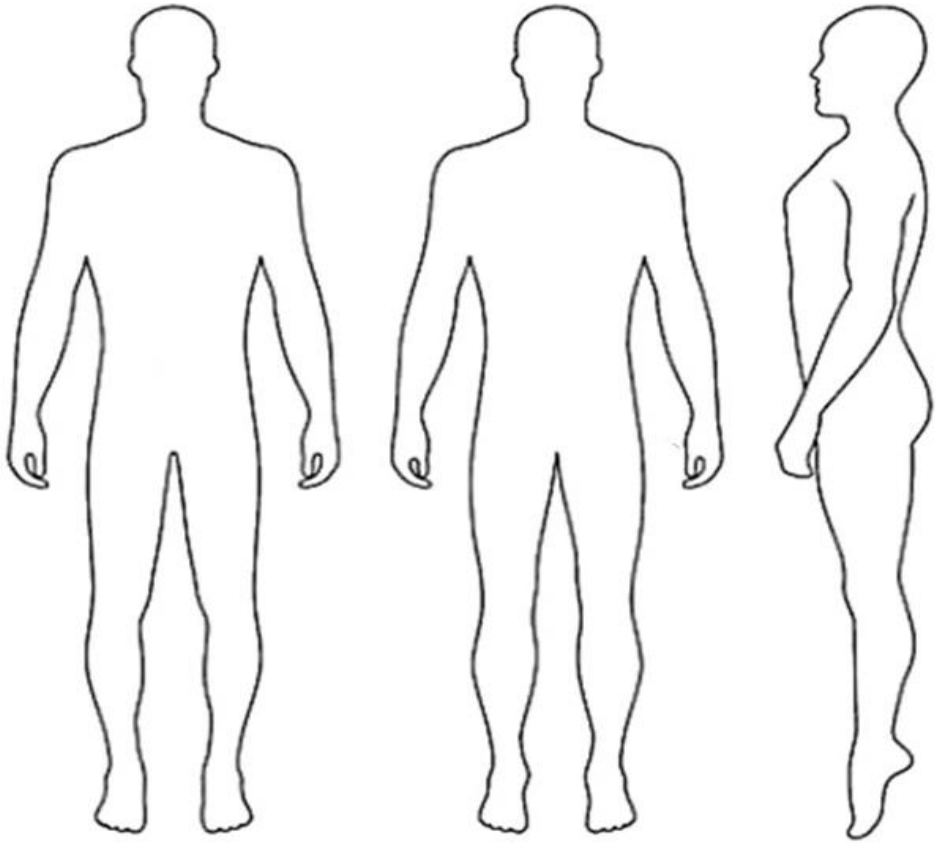
Por qué se realiza este análisis (Problema médico) ?_____

_____

| | SÍ | NO |
|---|---|---|
| ¿Alguna vez ha tenido un examen de resonancia magnética y tuvo un problema? | [ ] | [ ] |
| Por favor describa_____ | | |
| ¿Alguna vez ha tenido alguna operación quirúrgica o procedimiento de algún tipo? | [ ] | [ ] |
| En caso afirmativo, enumere todas las cirugías anteriores y las fechas aproximadas: | | |
| _____ | | |
| ¿Alguna vez ha resultado lesionado por un objeto metálico o un cuerpo extraño (por ejemplo, bala, metralla BB)? | [ ] | [ ] |
| ¿Alguna vez se lesionó con un objeto de metal en el ojo (astillas de metal, virutas de metal, otro objeto de metal)? | [ ] | [ ] |
| En caso afirmativo, ¿buscó atención médica? | [ ] | [ ] |
| En caso afirmativo, describa lo que se encontró_____ | | |
| ¿Tiene antecedentes de enfermedad renal, asma u otra enfermedad respiratoria alérgica? | [ ] | [ ] |
| ¿Tiene alguna alergia a medicamentos? | [ ] | [ ] |
| En caso afirmativo, indique los medicamentos _____ | | |
| ¿Alguna vez ha recibido un agente de contraste o un tinte de rayos X utilizado para resonancia magnética, tomografía computarizada u otra radiografía o estudio? | [ ] | [ ] |
| ¿Alguna vez ha tenido una reacción alérgica a un tinte de rayos X o una a un agente de contraste de imágenes de resonancia magnética (IRM)? | [ ] | [ ] |
| En caso afirmativo, describa_____ | | |
| ¿Está embarazada o sospecha que puede estar embarazada? | [ ] | [ ] |
| ¿Está amamantando? | [ ] | [ ] |
| Fecha del último período menstrual _____Postmenopáusica? | | |

**Lista de verificación de riesgos de MR**

Marque en los dibujos la ubicación de cualquier metal dentro de su cuerpo o sitio de operación quirúrgica.




Los siguientes elementos pueden ser perjudiciales para usted durante su examen de RM o pueden interferir con el examen de RM. Debe proporcionar un "sí" o "no" para cada elemento. Indique si tiene o ha tenido alguno de los siguientes:

SÍ NO

[ ] [ ] Cualquier tipo de implante electrónico, mecánico o magnético
Tipo _____

[ ] [ ] Marcapasos cardíaco

[ ] [ ] Pinza de aneurisma

[ ] [ ] Desfibrilador cardíaco implantado

[ ] [ ] Neuroestimulador

[ ] [ ] Bioestimulador
Tipo_____

[ ] [ ] Cualquier tipo de electrodos internos o cables

[ ] [ ] Implante coclear

[ ] [ ] Audífono

[ ] [ ] Bomba de medicina implantadas (p. Ej., Insulina, baclofeno, quimioterapia, medicina para el dolor)
[ ] [ ] Dispositivo de fijación espinal
[ ] [ ] Procedimiento de fusión vertebral

[ ] [ ] Cualquier tipo de bobina, filtro o stent
Tipo_____

[ ] [ ] Cualquier tipo de objeto metálico (p. Ej., Metralla, bala, BB

[ ] [ ] Válvula cardíaca artificial

[ ] [ ] Cualquier tipo de implante de oído

[ ] [ ] Implante de pene

[ ] [ ] Ojo artificial

[ ] [ ] Muelle del párpado

[ ] [ ] Cualquier tipo de implante sostenido en su lugar por un imán
Tipo _____
[ ] [ ] Cualquier tipo de grapa quirúrgica o grapa
[ ] [ ] Cualquier puerto de acceso IV (p. ej., Broviac, Port-a-Cath, Hickman, línea Picc)

[ ] [ ] Parche de medicación (p. ej., nitroglicerina, nicotina)

[ ] [ ] Miembro o articulación artificial
Qué y dónde _____
[ ] [ ] Expansor de tejidos (p. ej., seno)

[ ] [ ] Dentaduras removibles, dientes postizos o placa parcial

[ ] [ ] Diafragma, DIU, Pesario
Tipo _____
[ ] [ ] Malla quirúrgica
Ubicación _____
[ ] [ ] Perforación del cuerpo
Ubicación _____
[ ] [ ] Peluca, implantes capilares

[ ] [ ] Tatuajes o delineador tatuado

[ ] [ ] Semillas de radiación (p. Ej., Tratamiento contra el cáncer)

[ ] [ ] Cualquier artículo implantado (p. Ej. Alfileres, varillas, tornillos, clavos, placas, alambres)

[ ] [ ] Cualquier cabello accesorios (por ejemplo, horquillas, pasadores, clips)

[ ] [ ] Joyas

[ ] [ ] Cualquier otro tipo de artículo implantado
Tipo _____

Appendix 3. Photograph of the current labeling of the resonance area of the IESS Hospital in Quito.


*Appendix 3. Photograph of the current labeling of the resonance area of the IESS Hospital in Quito.*

# 7 CONCLUSIONS

- Although magnetic resonance imaging is considered a safe method of imaging for medical diagnosis, exist certain risks that we can prevent.
- The investigations carried out in this field have determined Risks due to the static magnetic field, the radio frequency pulses, magnetic fields of a variable gradient, due to contrast agents, and even due to incorrect management within the MRI rooms.
- Besides, even though the biological hazards are low, attention should be paid to them, mainly to the risks associated with contrast agents.
- This work focused on the safety recommendations made by international organizations such as the WHO, ICNIRP, FDA, ASTM. The result of this research is a Normative that sets forth certain guidelines that reduce the risk of accidents for both patients and medical personnel.
- The normative developed compile the international protocols, adjusting them to the national reality. Analysis of the type and quantity of resonance equipment at the Ecuador was decisive.

# 8 RECOMMENDATIONS

- It is essential that clinics and hospitals that have MRI services adhere to an effective security protocol. The regulations presented in this work are shown as the best tool to ensure the health of both patients and medical personnel.
- Training of all staff involved in MRI areas is necessary to improve the safety of this important imaging technique. It is recommended to periodically evaluate the technicians who operate the resonance equipment (for example, once a year).
- MRI rooms must have a director to ensure the application and monitoring of security guidelines.
- It is recommended to create a database documenting adverse effects and / or safety issues on the RM workplace.
- Greater control by the Ecuadorian control agencies is necessary, because currently, no agency monitors the correct procedure within the areas of Magnetic Resonance.
- Finally, it is recommended that more research work be done on MRI at the national level. Thus developing statistical data that can be used for analysis and decision-making by the control authorities.

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