Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

ADMINISTRATIVE ORDER
No. 2023 - _____

SUBJECT: **Rules and Regulations for Establishment and Operation of Medical Magnetic Resonance Imaging (MRI) Facilities in the Philippines**

I. RATIONALE

Pursuant to Presidential Decree (P.D.) No. 480 "Creating the Radiation Health Office in the Department of Health" dated 06 June 1974, as amended by P.D. 1372, and under the Republic Act 9711, known as the Food and Drug Administration (FDA) Act of 2009, and its Implementing Rules and Regulation (IRR), the Center for Device Regulation, Radiation Health and Research (CDRRHR), is mandated to regulate the use of non-ionizing radiation (NIR) devices.

Magnetic Resonance Imaging (MRI) is potentially one of the best imaging modalities used in the diagnosis of diseases as it utilizes non-ionizing radiation. However, MRI systems employ high-field strength magnets, radiofrequency (RF), and time-varying gradient pulses to create detailed images of organs and tissues in the body. MRI techniques (pulse sequences) involve exposure of the patient to static and time-varying magnetic fields, radiofrequency electromagnetic fields, and acoustic noise. Exposures to the components of the MRI system during MRI procedures may pose risks and hazards to patients, workers, and members of the public.

MRI has been used clinically for about three decades with apparently few serious side effects aside from well-documented acute injuries resulting from effects on implanted electronic devices or acceleration of ferromagnetic materials towards the scanner by the magnetic field, or from RF-induced burns due to poor positioning of the patient to the scanner (ICNIRP 2017). Guidelines were published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) for limiting exposure to time-varying electric, magnetic and electromagnetic fields (EMF). These guidelines were based on short term, immediate health such as stimulation of peripheral nerves and muscles, shocks and burns caused by touching conducting objects, and elevated tissue temperatures resulting from absorption of energy during exposure to EMF.

In the Philippines, incidents such as magnet quench and projectile effects were noted with the use of superconducting magnets. These incidents can lead to accidents if these safety issues will not be addressed. In 2022, the Center for Device Regulation. Radiation Health, and Regulation, has issued Certificates of Registration to one hundred twenty-three (123) MRI facilities in the Philippines. Almost eighty percent (80%) of MRI installations utilize superconducting magnets, because of its superior image quality. With the use of these MRI systems, safety issues may rise due to the effects of the components of these systems on workers, patients, and members of the public having access to these MRI facilities.

Thus, this administrative order has to be issued to provide specific guidelines and safety requirements for the operation and establishment of MRI facilities, so as to limit the exposure of workers and the public to EMF and provide protection to patients during MRI procedures.

II. OBJECTIVES

This Administrative Order (AO) is promulgated to specify requirements on the use of MRI and operation of facilities utilizing MRI through the provision of safety guidelines, qualification of personnel, and institutional quality assurance program.

III. SCOPE

A. This AO shall apply to any person, manufacturers, suppliers, testing service providers, firm, corporation, establishment or entity, whether government or private using MRI devices, operating and maintaining MRI facility and to the health professional or individuals involved in the practice.

B. This AO shall not apply on the use of MRI devices for non-medical application

IV. DEFINITION OF TERMS

For the purposes of this issuance, the terms used shall be defined and understood as follows:

A. Acceptance Testing is the initial inspection performed on a piece of medical equipment prior to it being put in place. When the device first arrives in the healthcare facility, it is checked to ensure it matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly (WHO definition, 2011).

B. Certified Medical Physicist-Diagnostic Radiology Medical Physicist (CMP-DRMP) is a Clinically Qualified Medical Physicist, who, under certification by appropriate boards or societies, has professional licenses or academic qualifications, and experience duly recognized as having expertise in diagnostic and interventional radiology medical physics and is charged with specific duties and responsibilities indicated herein and in Annex H of this AO

C. Digital Imaging and Communications in Medicine (DICOM) is an international standard protocol for medical device intercommunication and for the storage and transmission of medical images.

D. Electromagnetic Field (EMF*)* is a physical field produced by moving electrically charged objects. It affects the behavior of non-comoving charged objects at any distance of the field. The electromagnetic field extends indefinitely throughout space and describes the electromagnetic interaction.

E. Gauss is the unit of measurement of magnetic flux density. One (1) *Gauss* is equal to $1x10^{-4}$ *Tesla* (100 μT), 1 *Tesla* = 10,000 *Gauss*.

F. Homogeneity is the uniformity of the main magnetic field strength (B_o) over a specified volume. It is usually specified in parts per million of a magnetic field strength over a spherical volume (d,s,v = diameter of spherical volume).

G. International Electrotechnical Commission (IEC) is an independent organization that prepares and publishes International Standards for all electrical, electronic and related technologies, collectively known as "electrotechnology".

H. International Organization for Standardization (ISO) is an independent, non-governmental international organization of national standards bodies from different countries. The members develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

I. Level 1 MR-Personnel are personnel designated in Zones I and II of an MR environment with at least Level 1 MR Safety Training as stated in Section C of Annex F of this AO. Hospital personnel that may be categorized as Level 1 MR-personnel are nurses, anesthetists, and other personnel who may be present during scanning.

J. Level 2 MR-Personnel are personnel with education and training in MR safety. These personnel shall have Level 2 MR Safety Training as stated Section C of Annex F of this AO

K. Licensee is the holder of the current license. The licensee is the person or organization having overall responsibility for a facility.

L. Licensing is the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

M. Magnetic Resonance Imaging (MRI) is an imaging technique used to form pictures of the anatomy and the physiological processes of the body. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body.

N. Medical Physicist pertains to a health professional, with specialist education and training in the concepts and techniques of applying physics in medicine, and competent to practice independently in one or more of the subfields (specialists) of medical physics.

O. MR Environment is the three-dimensional space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 Gauss line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.

P. Radiological Medical Practitioner (RMP) is a physician, with qualifications specified in Section VI. B. of this AO, who is responsible for the overall conduct of the procedures involving the exposure of the patient to ionizing and non-ionizing radiation.

Q. MR Safety Expert (MRSE) is a designated professional with expertise in MR equipment, its uses, and associated requirements. He or She can be a third-party expert or a medical physicist with expertise in MRI.

R. MR Safety Officer (MRSO) is an individual technically competent on MR Safety matters who is designated by an authorized officer.

S. MR Safety Zones are delineated areas in an MRI facility where respective levels of restrictions are implemented in different zones for safety. Some zones may extend into other areas or floors of the facility due to the three-dimensional extent of the magnetic field.

T. Non-MR Personnel are personnel designated in an MR environment with MR safety awareness training. Hospital personnel that may be categorized as Non-MR personnel are the cleaning staff, maintenance staff, and other staff who may be required to enter the MR environment.

U. Passive shielding is the placement of heavy ferromagnetic plating in the walls or floor of the magnet room or even the magnet itself. This concentrates magnetic flux lines, reducing the fringe field beyond the shielding.

V. Performance Testing is the testing of radiologic equipment for compliance with the national radiation protection regulations and with other standards that have been adopted by the FDA.

W. Permanent magnet is a material that produces a magnetic field. They are made from ferromagnetic materials, such as iron, and are created when the material is placed inside of a magnetic field. When the magnetic field is removed, the object remains magnetized.

X. Phantom is a specially designed object that is scanned or imaged in the field of medical imaging to evaluate, analyze, and tune the performance of various imaging devices. It can also be called as imaging phantom.

Y. Philippine National Standards (PNS) is a set of documents established through a consensus of a technical committee and approved by the Bureau of Product Standards, which provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Z. Picture Archiving and Communication System (PACS) is a medical imaging technology that provides economical storage and convenient access to images from multiple modalities. It consists of four components: imaging systems, a secured network for the transmission of patient information, workstations for reviewing and interpreting images, and archives for the storage and retrieval of images and reports.

aa. Preventive Maintenance are the actions that detect, preclude, or mitigate degradation of functional structure, system or component to sustain or extend its useful life by controlling degradation and failures to an acceptable level.

bb. Quality Assurance is a comprehensive concept that comprises all of the management practices instituted by MR imaging physicians to ensure that systematic arrangement which is aimed at providing adequate consideration of MR safety.

cc. Reconditioned/Refurbished Equipment [1] is a medical device restored to the OEM's original specifications or to be "like new". The device may be brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications, or intended use. These activities include repair components, installation of software/hardware updates that do not change the intended use of the original device, and replacement of worn parts.

dd. Repair[1] is a type of servicing that returns a component to its original specifications. Including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

ee. Remanufacture[1] is the process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

ff. Remarket[1] is the act of facilitating the transfer of previously owned device from one party to another by sale, donation, gift, or lease.

V. GENERAL GUIDELINES

A. All MRI facilities shall secure authorization from the FDA. The MRI facility shall **NOT** be allowed to operate without a valid authorization issued by the FDA.

B. Any authorized officer or organization applying for authorization shall:

1. Submit to the FDA the relevant information necessary to support the application for authorization as required in the current rules and regulations on the licensing of radiation facilities.
2. Refrain from carrying out any actions/activities pertaining to the use of the MRI equipment until authorization is issued.

C. The licensee shall ensure that all personnel involved in the operation of the MRI facility are appropriately trained and qualified.

D. The licensee shall ensure conformance to the Center for Device Regulation, Radiation Health, and Research's (CDRRHR) safety requirements associated with the use of the MRI system.

E. The licensee shall allow the CDRRHR personnel to conduct pre and post-licensing inspection of the MRI facility.

F. The licensee shall be responsible for the implementation and maintenance of procedures to ensure the safety of the patient, personnel, and the general public.

[1] *Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices*. (2018). USA: Food and Drug Administration. p.2-3

VI. SPECIFIC GUIDELINES

A. ADMINISTRATIVE REQUIREMENTS

1. The licensee shall submit an authorization application and safety assessment plan of his/her facility and activity, through current rules and regulations on the licensing and registration of radiation facilities. The licensee shall abide to the two-stage process of authorization as follows:

a. **Stage 1: Pre-operational permit (POP)** – is an authorization prior to the construction of an MRI facility. This facility shall fulfill the requirements stated in Annex B of this AO before a pre-operational permit is issued.

i. The licensee shall ensure that the shielding is compliant with the appropriate requirement during the construction of the MRI facility and the construction engineer and architect had sought the approval of a certified medical physicist – diagnostic radiology medical physicist during the construction phase.

ii. The construction phase shall be inspected and supervised by an MR Safety Expert and MR Safety Officer in coordination with the architect and/or engineer. The MR Safety Officer shall document and submit to the CDRRHR a report (with photos, if possible) of the said inspection and supervision.

iii. The licensee shall ensure that the selection and purchase of appropriate quality control test tools have undergone review and approval of an MR Safety Expert and are made available during the conduct of quality control procedures.

iv. The licensee shall ensure that the selection and purchase of appropriate ancillary equipment have undergone review and approval of the MR Safety Committee.

v. For any renovation plan that may compromise the shielding of the facility, the licensee shall secure a POP prior to construction due to renovation.

b. **Stage 2: License to Operate (LTO)** – is the authorization prior to the clinical operation of an MRI facility. The facility shall fulfill the requirements stated in Annex B of this AO before a license to operate is issued.

i. The initial license to operate shall be valid for the period of five (5) years, and shall be renewed based on the criteria and guidelines established by CDRRHR in its current rules and regulations on the licensing of radiation facilities.

ii. Any plans or modification of the MRI facility which may affect the conditions of the LTO shall be reported and approved by CDRRHR. The CDRRHR may conduct verification of compliance and may warrant amendment or revocation of the LTO.

2. The licensee shall establish the following:

a. MRI Policies relating to the equipment, patient and MR hazards management

b. Institutional MRI safety policies and procedures (including practice drills for emergency responses)

c. Review and analysis of lessons learned from incidents and accidents that have occurred in the facility or elsewhere
d. Use and operation of the equipment and other support devices
e. Instruction procedures to patients, caregivers and comforters
f. Policy that provides continuing education and professional development of personnel.

B. MANPOWER REQUIREMENTS

1. LEVEL 2 MR-PERSONNEL

All MRI facilities shall have the following authorized personnel:

a. Head of the Facility (MR Responsible Person)

The head is the person who assumes technical and administrative supervision and control of the activities in the MRI facility. He/She shall be a full-time employee of the facility and shall perform his/her roles and responsibilities as stated in Annex C of this AO

b. Radiological Medical Practitioner (RMP)

i. The licensee shall appoint a radiological medical practitioner (RMP), duly licensed by the Professional Regulation Commission (PRC).
ii. The licensee shall designate a Chief RMP who is a Fellow of CT-MRI Society of the Philippines.
iii. The RMP shall be board certified by the Philippine College of Radiology.
iv. The number of RMP shall be reviewed as to the adequacy requirement and shall be hired as the workload increases.

c. Radiologic Technologist (RT)

i. The licensee shall ensure that at least two (2) full-time radiologic technologist per MRI machine is present at all times during operating hours in adherence to the normal working hours as required by the Labor Code of the Philippines[3]. The ratio of full-time radiologic technologists per MRI machine shall be at least 2:1.
ii. The licensee shall designate a chief radiologic technologist.
iii. The radiologic technologist shall be duly licensed by the Professional Regulation Commission (PRC).
iv. The RT shall have undergone training in the operation of the appropriate MRI machine for at least three (3) months under a senior MR RT and MR safety education conducted by the MR safety officer.
v. For initial facilities and/or any upgrades in the equipment, the radiologic technologist shall undergo at least two (2) weeks of appropriate hands-on training provided by the MR equipment supplier.

[3] Art. 83 Chapter 1 Book III of *The Labor Code of the Philippines*, as amended.

d. Certified Medical Physicist -Diagnostic Radiology Medical Physicist (CMP-DRMP)

i. The licensee shall ensure that the services of a CMP-DRMP are made available.

ii. The CMP-DRMP shall be certified by the Philippine Board of Medical Physics (PBMP) Section of Diagnostic Radiology Medical Physics.

iii. The CMP-DRMP shall perform his/her duties and responsibilities as specified in Annex H of this AO

e. MR Safety Expert (MRSE)

i. The licensee shall ensure that the services of an MR safety expert are made available.

ii. The designated MRSE may be a part-time consultant of the facility.

iii. The MRSE shall perform his/her duties and responsibilities as specified in Annex C of this AO.

f. MR Safety Officer (MRSO)

The licensee shall designate a qualified MR safety officer who is responsible for the practice of MR safety of the facility and compliance with relevant regulatory requirements. The qualified MRSO shall be a fulltime employee of the facility

i. The MRSO shall either be a diagnostic radiology medical physicist or a radiologic technologist.

ii. The MRSO shall have completed appropriate training in MR Safety by an organization recognized by the FDA.

iii. The MRSO shall perform his/her duties and responsibilities as specified in Annex C of this AO

2. LEVEL 1 MR-PERSONNEL

The licensee may designate Level 1 MR-personnel to be stationed at Zones I and II. He/She shall have completed at least Level 1 MR Training as stated in Annex F (basic training course on MR safety).

3. NON-MR PERSONNEL

The licensee should designate Non-MR personnel to be allowed access to the Safety Zones of an MRI environment. He/She shall have completed the MR Safety Awareness training as stated in Annex F.

C. MACHINE REQUIREMENTS

1. The licensee in specific cooperation with suppliers shall ensure that, with regard to the MRI machine:

a. Whether imported into or manufactured in the Philippines where it is used, the equipment shall conform to applicable and updated standards of the

IEC and ISO or to equivalent national standards. Evidence of such compliance shall be provided such as type tests, or acceptance tests in the absence of type tests.

b. Performance specifications and operating and maintenance instructions, including protection and safety instructions, shall be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents".

c. Where practicable, the operating terminology (or its abbreviations) and operating values shall be displayed on operating consoles in a major language acceptable to the user.

d. Preventive and corrective maintenance shall be performed to ensure that the equipment retains their designed specification for image quality, radiation protection and safety for their useful lives.

e. The operating terminology (or its abbreviations) and operating values shall be displayed on operating consoles in English language.

f. The MRI machine shall be equipped with protection and safety system capable of preventing its utilization by unauthorized personnel.

g. The MRI machine shall conform to the minimum performance criteria of an MRI unit as specified in Annex E of this AO. Minimum performance criteria should be done once a year.

2. The licensee shall ensure that:

a. Maintenance (preventive and corrective) shall be performed as necessary to ensure that the equipment retain their designed specification for image quality, protection and safety for their useful lives.

b. The licensee shall ensure that the preventive and corrective maintenance of the equipment shall be performed only by qualified maintenance/service personnel.

c. Records of preventive and corrective maintenance program shall be kept for reference.

D. ACCESSORIES

A. The MRI facility shall be provided with the appropriate equipment/devices and accessories necessary in the conduct of MRI procedures as stated in Annex A of this AO.

B. The licensee shall perform a physical inventory of all equipment and accessories to confirm that they are present and secure in their assigned location.

E. Other specific requirements relative to physical plant requirements, management of safety, quality assurance program and safety assessment program, and the requirements in performing MRI examinations can be found in the Annex A of this AO.

F. Other types of MR systems in medical imaging where provisions herein are not applicable shall be considered new devices requiring appropriate evaluation by the CDRRHR wherein safety standards and guidelines shall be covered in another issuance.

VIII. TRANSITORY PROVISIONS

A. All existing MRI facilities shall be given *three (3) years* from the effectivity date of this AO to comply with the quality assurance program requirements, MRI safety program, and safety assessment plan/program.

B. All existing MRI Facilities not consistent with MR zoning requirements shall be allowed to operate provided that they comply with all the safety requirements specified in this AO.

IX. SEPARABILITY CLAUSE

If any clause, sentence, or provisions of this Order shall be declared invalid or unconditional, the other provisions unaffected thereby shall remain valid and effective.

X. REPEALING CLAUSE

Provisions from Annex C Section C.3 of the DOH Administrative Order No. 2020-0035 are hereby amended or modified accordingly.

XI. PENALTY CLAUSE

Any person or establishment found to violate any of the rules and regulations set herein shall be imposed with the penalty prescribed in the Republic Act 9711 and its Implementing Rules and Regulation.

XII. EFFECTIVITY

This Order shall take effect fifteen (15) days following its publication in one (1) newspaper of general circulation and filing of three (3) certified copies to the Office of the National Administrative Register (ONAR), University of the Philippines.

TEODORO J. HERBOSA, MD
Secretary of Health

Office	*Food and Drug Administration*	*Office of the Secretary*
Initial	**DR. SAMUEL A. ZACATE** Director General	**ATTY. FAITH LAPERAL** Head Executive Assistant
Date:		

Keywords	*magnetic resonance imaging, magnetic resonance safety, superconducting magnets*
Related issuances, laws, directives	RA 9711, DOH AO 2020-0035,

ANNEX A

OTHER SPECIFIC REQUIREMENTS

I. PHYSICAL PLANT REQUIREMENTS

A. MRI Facility Layout

1. MRI Safety Zoning

a. The licensee shall implement site access restriction. A visible sign shall be made available to distinguish each Zone. Standard size of signage per zone shall be 21 cm x 29.70 cm. Refer to Annex K of this AO

b. The MR facility shall have the following zones:

i. Zone I

(1) Zone I is the entrance to the MR facility freely accessible to the general public and shall not pose any magnetic field hazards.

(2) Zone I is typically outside the MRI environment and the area where which patients and their companions can stay.

(3) This zone includes the reception and waiting area.

ii. Zone II

(1) Zone II are all areas between Zone I and the more restrictive Zone III.

(2) In Zone II, patients are under general supervision of MR personnel.

(3) Zone II shall be distinguished with blue demarcation line and shall be visible throughout the perimeter of the zone.

(4) A **ferromagnetic detection system** with the following specification shall be installed in between Zone II and Zone III (entrance to Zone III):

(a) The detection system shall conform to international standards (i.e. IEC, ISO)

(b) Capable of differentiating between ferromagnetic and non-ferromagnetic materials (100% specificity).

(c) The detection system shall be capable of automatic sensing and detection of locating ferrous hazard.

(d) The detection system shall be able to detect 2x5 mm ferromagnetic material and able to suppress false warning.

(5) This zone may include the following:

(1) Screening room / area.

(2) Changing room

(3) Cabinets / lockers dedicated for patient's use

(4) Interview area

(5) Toilet room

For MRI facilities performing contrast procedures and/or sedations, the following are recommended in addition to the above-mentioned:

(1) Insertion room
(2) Recovery room / area

iii. Zone III

(1) All areas that are access-restricted by physical barriers such as doors with security access.
(2) Only screened MR personnel and patients for ferromagnetic materials shall be allowed to enter the zone. The MR personnel shall ensure that the patient was properly screened prior to entering Zone IV.
(3) Zone III shall be distinguished with yellow demarcation line and shall be visible throughout the perimeter of the zone.
(4) Additional partition shall be installed to restrict access between Zone II and Zone III.
(5) This zone shall consist the location of the MR control and equipment rooms and shall be equipped with the following fixtures and accessories:
   (a) RF shielded window between Zone III and Zone IV
   (b) Viewing monitor to observe the patient inside the MR examination room.
   (c) MR-compatible fire extinguisher
   (d) MR-compatible patient monitors
   (e) MR-compatible emergency resuscitation equipment

iv. Zone IV

(1) Zone IV is the restricted area where the MR examination room is located.
(2) Access to Zone IV shall only be possible by passing through Zone III.
(3) Zone IV shall be distinguished with red demarcation line and shall be visible throughout the perimeter of the zone.
(4) This zone shall be equipped with following fixtures:
   (a) MR-compatible fire extinguisher
   (b) Cabinets for storage of all the coils inside the MRI examination room

c. Level 1 MR-Personnel and Non-MR personnel shall not be allowed to enter Zone III and IV unaccompanied by an MR-Personnel.
d. Zones II to III shall be classified as controlled MR access area.

2. MRI Examination Room

a. MRI Siting

The licensee shall ensure proper siting of the MRI unit considering the three-dimensional magnetic fringe that could affect the operation of a variety of the medical facility instruments and devices.

i. Physical access should be provided to the room for placement of the magnet, service / maintenance and other installation requirements.

ii. Exit from the magnet room should allow for rapid patient removal from the magnetic field to an area where patient monitoring and life support equipment will operate satisfactorily in case a medical emergency occurs.

b. MRI Examination Room Size

i. The minimum room size shall be 5 m x 7 m after appropriate shielding is installed.

ii. The height from ceiling to floor after the appropriate shielding installed shall follow the MRI manufacturer's specifications.

c. MRI Examination Room Design

i. RF & Magnet Shielding

(1) The floor, walls, ceiling, and partitions shall be properly shielded from radiofrequency interferences from outside RF sources.

(2) The walls shall be shielded from ferromagnetic interferences to ensure the containment of the five (5) Gauss line magnetic fringe field inside the MRI examination room.

(3) The standard MRI door shall be constructed in such a way that the door leaf shall be constructed utilizing a 2" and 3" stainless steel tube around the perimeter.

ii. Plumbing and Electrical Fixtures

(1) All ductwork, fasteners, hangers and appurtenances within the radio frequency (RF) shield shall be non-ferrous. Ductwork penetrations shall utilize RF wave guides at the shielding feed-through points.

(2) All electrical conduits shall be non-ferromagnetic. Electrical conduit within 25 ft. of magnet isocenter shall be PVC or Aluminum.

(3) Final cable requirements and associated ducts shall be specific to the particular type of system installed.

(4) All plumbing pipes and drains shall be non-ferromagnetic. Pipes and drains within 25 ft. Of magnet isocenter shall be PVC or Aluminum.

(5) Heating, Ventilation and Air Conditioning (HVAC) equipment shall not be located in the area inside the 10 Gauss line.

(6) Electrical distribution transformers shall not be located inside the 3 Gauss line.

(7) For superconducting magnets:

(a) Venting for cryogen exhaust which is electrically isolated at the penetration points shall be aluminum ducting suitable for the MRI system installed.

(b) The quench pipe shall be within the limits of the quench pipes pressure capability and the maximum pressure specified by the manufacturer of the MRI scanner.

(c) The size of the quench pipe shall be based on the MRI manufacturers' recommendations and design calculations.

3. Control Room

i. The minimum room size requirement shall be 5 m x 2.5 m.
ii. The viewing window:
3.ii.2. shall be shielded from RF interferences.
3.ii.3. shall be at least 0.8 m x 1 m.

4. Equipment Room

i. The minimum room size requirement shall be 6 m x 2.5 m.
ii. The equipment room shall be situated near the MRI examination room.

5. Image Interpretation Area / Room

i. A separate image interpretation room/area shall be provided.
ii. Digital display devices used for interpretation of digital images shall have a resolution of at least 2 megapixels.
iii. MRI Facilities utilizing the practice of teleradiology, the communication protocols, file formats, and image data compression shall conform to Digital Imaging and Communication in Medicine (DICOM) standards.
(1) There shall be no reduction of clinically diagnostic image quality whenever the image is compressed and transmitted for image interpretation. Means to ensure that the image is properly identified and delivered in a timely manner to the patient shall be provided.
(2) Integration of Picture Archiving and Communication System (PACS) in the departmental workflow should be provided. If PACS is available, the use of an electronic source of identity, ordering and scheduling information, and the integration of disparate sources of information shall be provided
(3) The official interpretation of clinical images, emergency examinations in on call situations and additional opinions by external consultation shall be done by a radiological medical practitioner.
(4) The MRI facility shall notify the FDA all qualified physicians or organization interpreting MR images through teleradiology.

II. MANAGEMENT OF SAFETY

The licensee has responsibility at all times for all aspects of safety with respect to the equipment, its location, its use, the subjects scanned, and all personnel who have access to the equipment location. An MRI safety program shall be established as specified in Annex D of this AO

A. MR ENVIRONMENT

1. Before installation of MRI equipment, the licensee shall ensure that the design of the facility and installations are within the specifications and guidance of the MRI system manufacturer.
2. Loading dock platforms shall be made accessible.
3. Special warning signs and notices on the strong magnetic field and its associated hazards shall be set up in the MRI facility.
a. For superconducting magnets, a warning sign shall be sighted at the vent outlet.

b. Respective warning notices shall be posted outside the entrance door of each MR Zones and on the floor entrances for Zones III and IV. Standard warning notices are specified in Annex K of this AO

4. Fringe field plots showing at least the 0.5 mT and 3 mT contours shall be on display in MRI departments. These should be shown to staff and explained clearly.
   a. MR staff moving from one type of scanner to another shall be aware of the scanner fringe fields

B. EQUIPMENT SAFETY

1. All equipment brought into the scan room, from wheelchairs, stretchers and emergency trolleys to cleaning equipment, shall not contain significant amounts of ferromagnetic material in order to avoid the projectile effect from the static magnetic field.
2. All devices that may be taken into the MR examination room shall be labelled using markings and where possible, the appropriate descriptive texts. (See Annex K)
3. No equipment shall be brought to the MR examination room, unless it has been identified and labelled as either MR-SAFE or MR-CONDITIONAL.
4. For superconducting magnets, protocols for quenching the magnet shall be established, maintained, and reviewed periodically.

C. PATIENT SAFETY

1. Risk Assessment

   Written protocols of risk assessment and communication between the MR Personnel and patient shall be established.

   a. The risk assessment and protective measures shall specifically consider the following issues:
      i. Static magnetic fields:
         (1) Prevention of interactions between ferromagnetic material and the static field.
         (2) Prevention of motion induced effects such as vertigo, dizziness or nausea that may lead to danger.
      ii. Time-varying magnetic field gradients:
         Prevention of Peripheral Nerve Stimulation (PNS).
      iii. Specific absorption rate:
         Prevention of heat related disorders.
      iv. Acoustic noise
         When the noise level exceeds 80dB(A), the MR personnel remaining in the scan room shall wear non-metallic earplugs and or ear defenders.

2. Patient screening[1]

[1] *MRI Safety Guidelines* (2nd ed.). (2017). Sydney, Australia: The Royal Australian and New Zealand College of Radiologists (RANZCR).

The licensee shall establish a written protocol for patient screening which shall be periodically reviewed by the MR Safety Committee. The following shall be required for patient screening:

a. Pre-screening
   i. The referring physicians shall be required to confirm that no major contraindication to MRI is present.
   ii. There shall be a specific MRI request form listing contra-indications and patient preparations.
   iii. There shall be a written policy for implant acceptance/rejection. This should include provision for written documentation of the acceptance/exclusion of patients with implants, the reasons for this, and the name of the relevant supervising radiologist.

b. Actual / On-site Screening
   The licensee shall ensure the veracity of the information declared by the patients prior to granting entry to MR Zone III.

c. Final Screening
   Final screening shall be performed to confirm the satisfactory completion of MR safety screening for the patient, support equipment, and personnel immediately prior to crossing from Zone III to Zone IV. The purpose of this final screening is to confirm the patient's identification, ensure that all screening has been appropriately performed, and ensure that there has been no change in patient and/or equipment status while in Zone III.

3. Patient Protection

a. The use of MR safe plugs, ear defenders, or other means of hearing protection shall be in place. Staff training in the use and selection of ear protection is also necessary.
b. Staff shall carefully instruct any person remaining in the MR scanner room during the MR exam on the proper use of hearing protection, and shall verify the fitting and the functionality of hearing protection in place prior to initiation of the MR exam.
c. Foam pads, 1–2 cm thick, should be used to insulate the patient from cables, the bore and between limbs shall be provided.
d. Patient monitoring devices or peripherals such as patient squeeze bulb, respiratory bellows, ECG and peripheral gating shall be made available.
e. There shall be MR-compatible emergency resuscitation equipment available at all times and preferably stationed at Zone III.
f. Clinical protocols (use of MR exposure Modes) shall be strictly observed for pregnant, pediatric, and hypertensive patients.

D. OCCUPATIONAL SAFETY

1. Written protocols of occupational safety shall be established.

a. Static magnetic fields

i. Prevention of interactions between ferromagnetic material and the static field. Prevention of motion induced effects such as vertigo, dizziness or nausea that may lead to danger.

b. Time-varying magnetic field gradients
   i. Prevention of Peripheral Nerve Stimulation (PNS).
   ii. PNS is unlikely to occur in staff outside the imaging volume.

c. RF pulse
   i. Specific absorption rate
      Prevention of heat related disorders. Heating is unlikely to occur in staff outside the imaging volume.
   ii. Acoustic noise
      Exposure to noise should be within the specified limit.

d. Screening of MR Personnel
   i. Staff with implants
      Any ferromagnetic component within an implantable medical device may experience both an attractive force and/or a torque force (Both of these effects can cause tissue damage and/or damage to the implantable medical device.
   ii. Pregnant Staff
      The pregnant staff should not remain in the MRI examination room during scanning.

e. The MRI facility shall maintain safety screening information of all MR and Non-MR personnel who enter the MRI Zones III and IV. This shall be updated annually.

2. For MRI machines with more than 3.0 Tesla, occupational exposures (SAR) shall be kept below the limits as stated in Annex I.

E. PUBLIC SAFETY

The general public shall not have access to the MR environment and it is unlikely that they will be exposed to above risks for correctly installed units.

1. The exposure for general public shall not exceed the limits as stated Annex I of this AO

III. QUALITY ASSURANCE PROGRAM (QAP)

A. A comprehensive Quality Assurance Program (QAP) shall be established and maintained to ensure adequate assurance that the specified requirements, quality control mechanisms and procedures relating to the diagnostic uses and image quality from the use of magnetic resonance imaging equipment is achieved. Guidelines for the establishment of a QAP is provided in Annex J of this AO

B. A quality manual has to be prepared which shall be feasible and regularly reviewed for relevance to existing practices. This shall be made available during the conduct of inspection.

C. Written safety procedures, work instructions, emergency procedures and operating instructions, are issued to all concerned after full consultation with the MR Safety Expert and all MR workers who have access to the equipment.
D. Local rules shall be established, reviewed and updated at regular intervals and after any significant changes to the MR equipment.
E. Written methods for the acceptance, commissioning, use, maintenance, quality control shall be developed.
F. The visual and audio warning of the detection system shall be functional at all times
G. For superconducting magnets, the vent piping shall be inspected annually and it shall include at least visual inspection of the external piping as recommended by MR manufacturers.
H. The licensee shall have access to appropriate and calibrated instrumentations, QA phantoms with inserts and other testing equipment.

IV. SAFETY ASSESSMENT PROGRAM (SAP)

A. A safety assessment shall be conducted in all stages of operation of the MRI facility. A safety assessment plan shall be submitted to the FDA prior to the issuance of authorization.
B. Format for the formulation of the safety assessment is provided in Annex G of this AO

V. REQUIREMENTS IN PERFORMING MRI EXAMINATIONS:

A. All MRI examination request shall be made by a qualified medical practitioner or referring physician in consultation with the RMP. Referrals for MRI examinations shall not be accepted from anyone other than the qualified medical practitioner.
B. All patients or individuals together with their accompanying carer or comforter scheduled for MRI examinations shall be screened for safety hazards by the attending Radiologic Technologist (RT) before being allowed to enter the designated MRI Zone. The attending RMP shall be consulted in the event of any doubt as to patient safety
C. Complete documentation and filing of data on all MRI examinations shall be made by the attending RT with regards to:
    1. patient identification data
    2. referring medical practitioner and department
    3. date and type of MRI examinations
    4. MRI protocol and sequences
    5. attending RT and RMP
D. The above-mentioned data should be recorded and maintained in accordance with the hospital / facility's records and archiving policy or applicable national guidelines.
E. Each MRI scanning facility shall have documented procedures and technical expertise and appropriate equipment to examine each anatomic site. Clinical applications of MRI continue to expand and the MR Head in coordination with the MR Safety Committee should review and update the procedures at appropriate intervals
F. The MRI scan data should be recorded and retained for a minimum period commensurate with the facility's records and archiving policy or applicable national guidelines

ANNEX B

TWO-STAGE PROCESS OF AUTHORIZATIONS FOR PRACTICES INVOLVING THE USE OF MAGNETIC RESONANCE IMAGING

I. Requirements for the issuance of **pre-operational permit:**

A. Complete and correct submission of application details for the issuance of a Pre-operational permit as prescribed in the current rules and regulations on the licensing and registration of radiation facilities

B. Uploading of regulatory requirements as shown below:

1. A certified true copy of SEC/DTI registration.

2. The design of magnetic resonance imaging facility describing its building materials, shielding materials, delineation of MRI Safety Zones, magnetic fringe field mapping duly evaluated, verified and signed by a CMP-DRMP.

3. Technical description / specifications of the Magnetic Resonance Imaging

4. Certification issued by the equipment manufacturer that the magnetic resonance imaging in its present conditions is compliant with the performance and safety requirements of the relevant International Commission on Non-Ionizing Radiation Protection and the International Organization for Standardization / International Electrotechnical Commission (ISO/IEC)

5. Notarized contract of employment between the facility and

a. Radiological Medical Practitioner;
b. Radiologic Technologist;
c. Certified Medical Physicist – Diagnostic Radiology Medical Physicist;
d. MR Safety Officer

6. Quality Assurance Program

7. Emergency procedures during testing, commissioning and during clinical operation, including a system of reporting a medical accident/incident

8. Emergency preparedness and response plan in the event of medical emergencies such as accident medical exposure of a patient, accident exposure of a worker or a member of the public

C. Payment of corresponding fee

II. Requirements for the issuance of initial **license to operate:**

A. Complete and correct submission of application details for the issuance of a Pre-operational permit as prescribed in the current rules and regulations on the licensing and registration of radiation facilities

B. Uploading of regulatory requirements as shown below:

1. CT-MRISP certificate/s and valid PRC ID/s of radiological medical practitioner/s.

2. PRC Board Certificates and valid PRC IDs of radiologic technologists and certificate of training as specified in Annex F of this AO.

3. Notarized contract of employment between the facility and

a. Radiological Medical Practitioner;
b. Radiologic Technologist/s;
c. MR Safety Officer;

d. MR Safety Expert

4. Acceptance Test Certificate signed by the technical representative of the equipment manufacturer/supplier and board certified DRMP.
5. Performance testing report of MRI units in the MRI facility
6. Pre-licensing report or Safety Assessment Report of the CDRRHR Health Physics team on the MRI facility

C. Payment of corresponding fee

ANNEX C

ROLES, DUTIES, AND RESPONSIBILITIES

(Ref: *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use.* (2014). London: Medicines and Healthcare Products Regulatory Agency (MHRA))

I. Referring Physicians

Referring clinicians should be made aware of the safety aspects and contraindications associated with MRI equipment that are specifically relevant to their patients, prior to submitting them for scanning.

II. Radiological Medical Practitioner (RMP)

The RMP shall be responsible for all aspects of the study, including but not limited to reviewing all indications for the examinations, contraindications, specifying the pulse sequence to be performed, specifying the use and dosage of contrast agents, interpreting images, generating written report, and assessing the quality of both the images and interpretation.

III. MRI Radiologic Technologist

A. Prepares the patient for procedures. The MRI technologist shall:
    1. Explain the process of the procedure to the patient
    2. Ensure that the patient is scanned and free of any metals prior to entering Zone IV
    3. Ensure that the patient is equipped with hearing protection during the procedure
B. Reports any incident that seems unusual/deficient to supervisor
C. Follow all proper policies, procedures, and protocols to ensure patient safety at all times
D. Maintain visual and verbal contact with the patient during the exam

IV. MR Safety Committee

MRI Facilities may establish an MRI Safety Committee to assist with policy reviews and the management of incident reports. The Head of the Facility (Responsible Person), the Safety Officer and Safety Expert should be members of such committee.

V. Head of the Facility (MR Responsible Person[1])

Responsibility for the safe operation of the MRI site shall be explicitly assigned to the head of the MRI facility.

A. The MR Responsible Person ensures that adequate written safety procedures, work instructions, emergency procedures and operating instructions, are issued to all concerned after full consultation with the MR Safety Expert and all MR workers who have access to the equipment.

[1] *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use.* (2014). London: Medicines and Healthcare Products Regulatory Agency (MHRA).

B. He/She shall be responsible for the formulation and application of policies and procedures that ensure the safety of patients, MR workers, and others in the MRI environment.
C. He/She may be called upon to assess the balance of risk and benefit for unusual scanning situations, and should therefore be a medical practitioner with substantial experience in MRI.

VI. MR Safety Officer (RSO)

The head of the MR facility, delegate some MRI safety-related tasks to an MRI Safety Officer. An MRI Safety Officer shall be:

A. Responsible for the day-to-day implementation of the site's safety policies.
B. To be readily accessible and available (e.g. to the operators of the MR system) at all times.
C. Developing, documenting, and introducing, in conjunction with and under the authority of the Head of the Facility safe working procedures for the MR environment.
D. Ensuring that adequate written safety procedures, work instructions, emergency procedures, and operating instructions are issued to all concerned.
E. Ensuring that appropriate measures for minimizing risks to health and managing hazards that arise from the use of or exposure to the MR equipment are implemented and monitored.
F. Ensuring that all Heads of Departments and senior medical staff members who are responsible for personnel who will be involved with the MR system are informed of the formal procedures for training and authorization.
G. Ensuring that medical, technical, nursing, and all other relevant staff groups (including ancillary workers) who may be exposed to the MR environment are educated appropriately on a regular basis as to the safety requirements and updated as necessary.
H. Assess, review and keep records of the personnel who have been educated appropriately as to the safety requirements.
I. Consulting the MRSE when further advice is required regarding MR safety.
J. Provide feedback to the head of the facility in a timely fashion any and all MR safety-related issues.
K. Ensuring that there is a policy for the procurement, installation, testing, and marking of all equipment that will be taken into the MR-related critical areas. Providing and/or ensuring the provision of MR safety education and training in cooperation with, and as per the policies.
L. Maintaining regular contact with other relevant groups or committees responsible for the safety and welfare of personnel on site, such as, but not limited to, the local ethics committee and the local safety committee.

VII. MR Safety Expert

A. It is recommended that MRI facilities have access to MRI expert/s. Third party MRI safety advice, an experienced MR Medical Director from another practice may fill this role. The MR Safety Expert shall be invited to review existing policy documents, conduct external audits of procedures, advice on proposed building plans, and other safety MRI safety matters.

B. They should be in a position to adequately advise on the necessary engineering, scientific and administrative aspects of the safe clinical use of MR devices including site planning, development of safety framework, advising on monitoring the effectiveness of local safety procedures, procurement, adverse incident investigation and advising on specific patient examinations.

ANNEX D

SAFETY PROGRAM IN A MAGNETIC RESONANCE FACILITY

The MR safety program shall include the following information:

I. General Information of the Facility

A. Description of the whole facility including the services it offers.
B. Description of the MR department, equipment, MRI services, and patient workload.
C. Organizational structure including the management commitment on compliance to regulatory requirements and the practice of MR safety.
D. Number of staffs involved in the operation of the MR facility. Provisions to ensure that only qualified personnel assume the responsibility for using the MR device.
E. Appointment of the MR safety officer (MRSO) and its qualification.
F. Roles and responsibilities of the MRSO, CMP-Diagnostic Radiology Medical Physicist, and radiologic technologists. Provisions that these roles and responsibilities are understood by personnel concerned.

II. MR Safety Program

A. Security of MR Equipment and MR-safe equipment

1. Describe the procedure for inventory of all MR equipment and policy to prevent unauthorized access and use of MR equipment.
2. Describe the rules and procedures for purchasing, use, and repairs of the MRI machine.

B. Protection for Occupational Exposure

1. Provisions to inform the workers about their obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources.
2. Description of the policy on pregnant workers.
3. Local Rules and Supervision - Procedures for ensuring adequate levels of protection and safety of workers; Provisions to make sure that these procedures, the protective measures, and safety provisions are known to those workers to whom they apply and to other persons who may be affected by them; Supervision to ensure observance of the procedures.
4. Describe the procedure for inventory of personal protective equipment including the policy on their proper use.
5. Health Surveillance – Describe the program for health surveillance of workers based on general principles of occupational health designed to assess the initial and continuing fitness of workers for their intended tasks.

C. Protection for Medical Exposure

1. Responsibilities

Assignment of the overall responsibility for patient protection and safety to a medical practitioner; Assignment of the responsibility for conducting or supervising calibration of equipment, and QA to a qualified

expert on diagnostic radiology physics; Provision and documentation of continuous education and training of all staff; Training shall include lessons from accidents and their prevention included in the training.

2. Justification of medical exposure

Describe the policies and procedure in place for the prescription and administration of medical exposure to ensure that these are justified; If applicable, indicate the department's policy to justify research involving application of radiation on humans.

3. Optimization

Policy for optimization to ensure that the exposure of patients is the minimum required to achieve the intended diagnostic objective, considering relevant information from previous examinations in order to avoid unnecessary additional examinations, and taking into account the relevant guidance levels for medical exposure.

4. Investigation of accidental medical exposure

a. Policies and procedures in place to investigate and report any equipment failure, accident, error, mishap or other unusual occurrence with the potential to cause a patient exposure which is significantly different from that intended.
b. Provisions to estimate the SAR received, and indicate and implement corrective measures and to follow-up of patients who received high exposure procedures, such as prolonged interventional procedure.

D. SAFETY PROTOCOLS/POLICIES

The safety program shall include safety protocols/principles the following:

1. Access to Zones
2. Screening
3. Emergency/Accidents
4. Level 1 and Level 2 MR-Personnel

1202 **ANNEX E**

1203

1204 **MINIMUM PERFORMANCE CRITERIA OF AN MRI UNIT**

1205

1206

Test Parameters	Performance Criteria[1, 2]	Frequency of Test
A. Visual/ Mechanical Checks	• All moving parts shall be properly working and free from obstruction. • Surfaces in contact with the patient shall be smooth. Cables shall be properly kept.	Daily
B. Emergency System Checks (three levels emergency stop systems)	• The **first level** typically disconnects power from the RF and gradient hardware in the magnet bore. • The **second level** may disconnect power to all system components, including the computer systems and, on some systems, the cold head on the superconducting magnet. • The **third level**, on superconducting magnet systems, "quenches" the superconducting magnet. This quench circuit should only be tested by the MR system installation/service personnel, but the medical physicist should ensure that the test was performed and the results documented.	• **1st and 2nd level**: it is recommended to perform Emergency Checks semi-annually. • **3rd level**: only during installation, prior to commissioning of the MR machine.
C. PHYSICS TESTS		
Geometric accuracy	• All measured lengths should be within ± 2 mm of their true values. • Images submitted for accreditation will fail if any measured length differs more than +/- 3 mm from its true value.	Annually
High-contrast spatial resolution	• The field of view and matrix size for the axial ACR series are chosen to yield a resolution of 1.0 mm in both directions. • The measured resolution of both axial ACR series shall be 1.0 mm or better in both directions. If the resolution score for either of the ACR series is more than 1.0 mm, then evaluate the site series. If both site series can resolve 1.0 mm then the scanner passes this test. • A scanner shall pass on both the ACR T1 and T2 series, or on both the site T1 and T2 series. A scanner cannot pass on just one of ACR series and one site series.	Annually

[1] *ACR Guidance Document on MR Safe Practices.* (2013**).** USA: American College of Radiology.

[2] For other phantoms: To check the specifications in approved test protocol used

Slice thickness accuracy	• For both ACR series the measured slice thickness should be 5.0 mm ± 0.7 mm. Errors greater than +/-1.0 mm fail. • If the thickness error for either ACR series is greater than +/-1.0 mm, then evaluate the site series. If slice thickness for both site series is 5.0 mm +/-1.0 mm, then the scanner passes this test.	Annually
Slice position accuracy	• The absolute bar length difference should be 5 mm or less, but up to 7 mm is acceptable. • A bar length difference of more than 4 mm for slice 11 will adversely affect the low-contrast object detectability score. So, although 5 mm is acceptable for this test, it is advisable to keep the bar length difference to 4 mm or less.	Annually
Image intensity uniformity	• For MRI systems with field strengths less than 3 Tesla, PIU should be greater than or equal to 87.5% and will fail if less than 85%. PIU for 3T systems should be greater than or equal to 82.0% and will fail if PIU is less than 80%.	Annually
Percent-signal ghosting	• The ghosting ratio shall be less than or equal to 0.025 (2.5%). • Images submitted for accreditation will fail if the ratio exceeds 0.030 (3.0%).	Annually
Low-contrast object detectability	• For scanners with field strength of less than 3T, both ACR series should have a total score of 9 spokes, but shall have at least 7 to pass. • If either ACR series fails this test, then evaluate the site series. • If the LCD score for both site series is at least 7, then the scanner passes this test.	Annually
D. DISPLAY MONITORS		
Visual Analysis	• The visual impression should be an even progression of gray levels around the ring of gray level patches. All gray level steps in the ring of gray levels shall be visibly distinct from adjacent steps. • The 5% patch shall be visible in the 0/5% patch; the 95% patch shall be visible in the 95/100% patch. • If these conditions are not met, do not adjust the display window width/level in an effort to correct the problem. Corrective action for the monitor is needed. • Ensure that the finest line pair pattern can be visualized in the center and at each of the 4 corners.	Monthly or Quarterly

	• There shall not be visible bleed-through in either direction of all black-white transitions. All high-contrast borders shall be straight, not jagged. • There shall not be scalloping of the gray scale. There shall not be geometric distortion in the image.	
Photometric Analysis	• The minimum brightness shall be less than or equal to 1.2 cd/m^2. The maximum brightness shall be greater than or equal to 90 cd/ m^2. • The measured response curve should be compared visually to the prior year's result, verifying no significant change to the curve. • Calculate the nonuniformity of the display brightness using the equation $\% \, difference = 200 \times \frac{(L_{max} - L_{min})}{(L_{max} + L_{min})}$ where Lmax and Lmin are the maximum and minimum measured luminance values, respectively. The nonuniformity should not exceed 30% for CRTs and should be within ±15% for flat-panel displays.	Monthly or Quarterly

1207

ANNEX F

MR SAFETY EDUCATION

I. The MR Safety Officer or MR Head should conduct annual refresher presentations to MR radiologic technologists who work routinely in Zones III or IV on advanced MRI safety topics as specified in the training modules.

II. There should also be annual education sessions for staff / visitors who occasionally interact with the MRI department from other departments, explaining the MRI environmental zones, basic MRI safety principles, and procedures for gaining access to appropriate parts of the MRI environment.

A. Documentation

1. There shall be a safe practice manual to include procedures for all aspects of scanning, with particular attention to emergency situations: cardiac arrest, contrast reaction, fire and quench (as a minimum). This should form part of a larger MRI or department-wide procedure manual. This should be reviewed periodically (at least annually, and with every hardware and major software modification).

2. There shall also be an incident reporting system involving at least one of the Responsible Person or the Safety Officer (incidents report within 24 hours), reports to which shall be monitored and reviewed periodically (with documented responses). Where it exists, the MR Safety Committee shall review incidents, analyze their root causes, and implement recommendations for improvement.

3. Records of Training provided and attended shall be maintained.

4. Records of Examinations

a. Key technical parameters (name, date, sequence identifier, slice no., F.O.V., thickness, contrast use) shall be recorded on images (film, or electronic archive). For images provided in digital format, additional detail will be available from the DICOM header.

b. Examinations transmitted on film shall include appropriate reference ('scout', 'pilot') images showing the location and orientation of 2D cross-sectional images relative to known anatomical landmarks (see *RANZCR-SSA Joint Guidelines for Confirming Vertebral Levels in Spine Imaging).* Images transmitted electronically shall allow cross referencing between sequences, to allow demonstration of the position and alignment of one cross-sectional image relative to another.

c. A record of all scans performed on each MRI system should be maintained. This may be a written logbook, an electronic record within the system console (appropriately backed up), or stored in the practice RIS (appropriately backed up).

d. For examinations in which a contrast agent is administered, a written or electronic record shall be kept of the name and dose of the agent administered, the route by which it was administered, and the authorizing MR physician.

5. Internal Review

a. There shall be periodic quality assurance activities and reviews of reported incidents.

b. Audits of the performance and accuracy of screening procedures may be appropriate. Such activities may be conducted by the MR Safety Committee, if from ICNIRP constituted, or by the MR Responsible Person and / or MR Safety Officer.

6. Maintenance and Service

a. Formal delineation of the responsibilities of the site and its service organization/s for safety before, during, and after service periods is strongly recommended.

b. Records of maintenance and service records shall be kept. These should comply with DIAS Standards.

III. MR Safety Training Levels

Training topic/coverage
LEVEL 1 MR SAFETY TRAINING
Fully aware of the relevant content of the MRI instructions for use.
Aware of the location of the MR Environment and its hazards. *
Understands the local regulations and procedures in connection with the MR diagnostic equipment and its locations
Understands the significance of the MR Controlled Access Area, MR Environment, and MR Projectile Zone and be able to differentiate clearly between them. In particular, they shall be fully conversant with:
A.1.d.i.1.L.1. The projectile effect*
A.1.d.i.1.L.2. The effect of magnetic field upon implants and prostheses. *
A.1.d.i.1.L.3. The effect of magnetic fields upon personal effects such as credit *cards and watches
LEVEL 2 MR SAFETY TRAINING (with Level 1 MR Safety Training)
Full training and instructions from the supplier and manufacturer in the use of the equipment, its hazards and what action to take in the case of an emergency. Those with the necessary training and experience should form the basis of the team training subsequent members of this category
They shall understand the safety aspects relating to:
• The electrical safety of the equipment
• The main static magnetic field and associated equipment*
• Radio-frequency (RF) fields and associated equipment
• Gradient magnetic fields and associated equipment
Understands the emergency procedure arising from causes other than equipment failure
Understands the consequences and effects of quenching of superconducting magnets
Fully aware of the recommendations on exposure to MR
Shall have had full instruction in, and shall understand the consequences of, the correct selection, fitting, and use of ear protection.

*Coverage for MR Safety Awareness training for Non-MR Personnel.

ANNEX G

SAFETY ASSESSMENT PLAN FOR MRI FACILITIES AND PRACTICES

I. Safety Assessment Plan for Initial Facilities

A. Name and location of the facility: (Provide a detailed location of the facility)

B. Organizational Structure

1. Describe your organizational and management control systems including assignment of responsibilities and clear lines of authority related to radiation safety.

2. Identify the radiological medical physicians, by name and include their training, qualifications, and experience in diagnostic radiology.

3. Identify ancillary personnel who will be involved in authorized activities and describe the training that will be provided to these individuals for working with the MRI equipment.

C. Layout of the facility

1. Describe factors such as the layout of the facility and its immediate surroundings, building materials, shielding.
2. Provide sketch or drawing of the above conditions reflecting the actual room size, MRI machine placement/location, control console, electrical room, waiting area, image interpretation room/area, and other adjacent areas to the MRI Examination Room (Zone IV).
3. Delineation of MRI Safety Zones.
4. Provide magnetic fringe field mapping.

D. MRI Machines

1. Detailed condition and specification of the MRI machine (brand new, reconditioned, refurbished, modified, brand name/manufacturer, date of manufacture, etc.)

2. Certificates/documents of equipment compliance to the International standards (ISO / IEC)

3. Acceptance testing and commissioning reports for the MRI machine

4. Operation and service manuals, and

E. Inventory of Protective Equipment (PE)

1. MR safe plugs, ear defenders, or other means of hearing protection for patient use (condition, maintenance, etc.)

2. Ferromagnetic detectors (condition, maintenance, location, etc.)

F. Maintenance and Services

1. Identify who will be authorized to perform service and maintenance on each MRI machines

Equipment:	Technical Service Provider (Company/Address/Contact No.)	Name/s of Maintenance/Service Personnel
1.		
2.		

2. Certificate/s of training of the maintenance/service personnel.

G. Safety assessment of the facility

1. Installation of grounding for the MRI machine, electrical and mechanical safety checks.
2. Environment working condition (i.e. ventilation) of MRI examination rooms
3. Warning signs and notices.
4. Labelling of all equipment for use in an MRI facility shall be posted on identified equipment and visible enough to be read from a distance (approx. 1.5m) as stated in Annex J.

H. Local rules and supervision

1. Local rules and procedures regarding: protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction.
2. Operating and safety procedures per radiological examinations including: area access control.
3. Training program to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety as stated in Annex E.
4. Policies regarding female workers who become pregnant (notification, adoption of working conditions to protect fetus/embryo) and the instructions you will provide to them.
5. Health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks.

I. Notarized Certificate that the above requirements are completely complied and verified by the licensee.

J. Proposed date of operation

K. Name, signature and contact details of the authorized officer of the licensee. (Radiological medical practitioner, Radiation Protection Officer)

II. Safety Assessment Plan for <u>Renewal</u> Facilities

A. Name and location of the facility (Provide an updated detailed location of the facility)

B. Layout of the facility (updated, if applicable)

1. Describe factors such as the layout of the facility and its immediate surroundings, building materials, shielding.
2. Provide sketch or drawing of the above conditions reflecting the actual room size, MRI machine placement/location, control console, electrical room, waiting area, image interpretation room/area, and other adjacent areas to the MRI Examination Room (Zone IV).
3. Delineation of MRI Safety Zones.
4. Provide magnetic fringe field mapping

C. MRI Machine

1. Detailed condition and specification of the MRI machine/s (brand new, reconditioned, refurbished, modified, brand name/manufacturer, date of manufacture, etc.)
2. Certificates/documents of equipment compliance to the International standards (for additional, newly installed equipment)
3. Acceptance testing and commissioning reports for the MRI machine/s (for additional, newly installed equipment).
4. Operation and service manuals (for additional, newly installed equipment).
5. Preventive maintenance reports and records pertaining to Quality Control of machine

D. Service and maintenance

1. Identify who will be authorized to perform service and maintenance on each Machines.

Equipment:	Technical Service Provider (Company/Address/Contact No.)	Name/s of Maintenance/ Service Personnel
1.		
2.		

2. Certificate/s of training of the maintenance/service personnel.

E. Safety assessment of the facility

1. Protocols on QA MRI Safety.
2. Condition/s of the labels of all equipment for use in an MRI facility.
3. Incident report/s and action/s done due to abnormal operations of equipment (electrical and mechanical mishaps and other human errors resulting to patient overexposure to radiation)
4. Environment working condition (i.e. ventilation) of MRI examination rooms

F. Inventory of Protective Equipment (PE)

1. MR safe plugs, ear defenders, or other means of hearing protection for patient use (condition, maintenance, etc.)
2. Ferromagnetic detectors (condition, maintenance, location, etc.)

G. Local rules and supervision

1. Local rules and procedures regarding: protective measures and safety provisions, providing adequate supervision, providing workers information regarding health risks due to occupational exposure, and emergency planning instruction.
2. Operating and safety procedures per radiological examinations including: area access control.
3. Training program to ensure that all appropriate personnel are adequately trained in the correct operating procedures and how their actions may affect safety as stated in Annex E.
4. Policies regarding female workers who become pregnant (notification, adoption of working conditions to protect fetus/embryo) and the instructions you will provide to them.
5. Health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks. Health surveillance based on general principles of occupational health and designed to assess the initial and continuing fitness of workers for their intended tasks.

H. Notarized Certificate that all the above requirements are continuously complied by the licensee. Affix the following:

5. Name, signature and contact details of the licensee.
6. Name/s, signature/s and contact details of the authorized representative of the licensee. (Radiological medical practitioner or Radiation Protection Officer)

I. Name, signature and contact details of the authorized officer of the licensee. (Radiological medical practitioner, Radiation Protection Officer)

Note: Complete information is expected from the facility as to the details of operation. The FDA may require additional information to fully consider this application prior to issuance of authorization.

ANNEX G-1

MRI SAFETY PROGRAM ASSESSMENT CHECKLIST

(Adopted with revisions from *Magnetic Resonance Imaging Quality Control Manual. (2015).* USA: American College of Radiology)

MRI Facility Name: _____

MRI Facility Address: _____

The MRI Facility's written MRI safety policy addresses the following:	**Yes/No/NA**
1) Designated MR Medical Director	
2) Facility access restrictions (MR Safety Zones)	
3) Documented MR Safety education/training for all personnel	
4) Patient and non-MR personnel screening	
5) Pediatric Patients	
6) Magnet Quench	
7) Cryogen safety	
8) Acoustic Noise	
9) Pregnant patient and staff	
10) Contrast agent safety	
11) Sedations	
12) Thermal burns	
13) Emergency code procedures	
14) Device and object screening	
15) Designation of MR safe/MR conditional status	
16) Reporting of MR safety incidents or adverse incidents	
17) Patient communication	
18) Infection control and medical waste	
Criteria for compliance:	**Yes/No/NA**
1) Written policies are present and readily available to facility staff	
2) Written policies are reviewed and updated on a regular basis	
3) Facility has appropriate MR safety warning signage and methods of controlled access	
Overall Pass/Fail	

Comments

Reviwed by: _____ _____

CMP-Diagnostic Medical Physicist / MRSE Date

ANNEX H

ROLES AND RESPONSIBILITIES OF A MEDICAL PHYSICIST

(Adopted with revisions from the International Organization for Medical Physics (IOMP) Policy Statement No. 1)

I. MR Safety

A. Establishing and implementing programs to ensure the quality, safety, correct maintenance, and effective use of MRI machines.
B. Formulating radiation protection guides and procedures specific to hospital environment and other professional groups and organizations; conducting specialized measurements and producing protocols to optimize radiation exposure of patients, and minimize radiation dose to staff and the general public.
C. Performing risk assessment, radiation protection design, shielding calculation on radiological installations.
D. Supervising and managing radiation workers and other health professional workers in terms of radiation protection and safety.

II. Clinical Medical Physics

A. Calibrating MRI machine and measuring radiation in diagnostic and interventional procedures to ensure the correct and accurate delivery of radiation dose to a patient at standard image quality criteria established by QA team.
B. Optimizing the physical aspects of diagnostic and interventional imaging procedures.
C. Participating in the implementation of new clinical procedures through supervising and advising on the details of radiation protection and safety.
D. Developing, implementing, and supervising a quality assurance program for equipment and procedures involving the delivery of ionizing and non-ionizing radiation in diagnostic and interventional procedures.
E. Participating at patient discussion conferences and advising healthcare personnel with regard to issues involving the use of radiation in diagnostic and interventional procedures.
F. Advising and consulting with physicians on the development of safe and effective techniques and procedures in the application of ionizing and non-ionizing radiation in diagnostic and interventional procedures.
G. Providing consultation and support on medical informatics and computer network management.

III. Management and Planning:

A. Providing support and consultation on the conduct of specialized examinations of patients, improving patient care and clinical services, developing innovative imaging and other diagnostic procedures for specific medical applications.
B. Planning, directing, conducting, and participating in supporting programs and remedial procedures to ensure effective and safe use of ionizing and non-ionizing radiation in patients.
C. Performing or providing consultation on planning, development and implementation of new clinical services and facilities.
D. Providing consultation on strategic planning of medical equipment technology; preparing specification for equipment acquisition; performing or supervising testing, commissioning, and management of medical equipment.
E. Liaising with the regulatory body and other accreditation agencies with regards to regulatory and accreditation compliances.

IV. Research and Development

A. Conducting research and development of new technology, methodology and procedure in diagnostic radiology and other clinical services.
B. Supporting the physical aspects of clinical trials and research involving the delivery of ionizing and non-ionizing radiation to patients for diagnostic purposes.
C. Developing novel instrumentation and physiological measurement techniques, mathematical analysis and applications of computers in medicine in response to clinical need for patients.
D. Preparing, publishing and presenting scientific papers and reports.

V. Teaching

Teaching the principles of medical physics and radiation safety to physicians, residents, graduate students, medical students, radiologic technologists, and other health care professionals.

Mentoring trainees and junior staff in medical physics.

ANNEX I

MR EXPOSURE LIMITS

(Ref: *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use.* (2014). London: Medicines and Healthcare Products Regulatory Agency (MHRA))

I. Occupational Limits

Occupational noise action values and limits

	Daily or weekly personal exposure dB(A) (average value)	Peak sound pressure dB
Lower exposure action values	80	135
Upper exposure action values	85	137
Exposure limit values	87	140

II. Limits for the General Public

A. Static Magnetic Fields

Exposure characteristics	Magnetic flux density
Exposure of any part of the body	400 mT

[a] ICNIRP recommends that this limit should be viewed operationally as spatial peak exposure limit.
b Because of potential indirect adverse effects, ICNIRP recognizes that practical policies need to be implemented to prevent inadvertent harmful exposure of persons with implanted electronic medical devices and implants containing ferromagnetic material, and dangers from flying objects, which can lead to much lower restriction levels such as 0.5 mT.

B. Time varying magnetic fields

Frequency range	Magnetic flux density (T)
1 − 8 Hz	$4\times10^{-2} / f^2$
8 Hz − 25 Hz	$5\times10^{-3} / f$
25 Hz − 50 Hz	2×10^{-4}
50 Hz – 400 Hz	2×10^{-4}
400 Hz − 3 kHz	$8\times10^{-2} / f$
3 kHz − 10 MHz	2.7×10^{-5}

Note: In the frequency range above 100 kHz, RF-specific basic restrictions need to be considered additionally.

C. RF Fields

Body part Units	SAR limit Wkg^{-1}	Tissue mass Grams	Time period Minute
Whole body average	0.08	-	6
Localized SAR (head and trunk)	2	10	6
Localized SAR (limbs)	4	10	6

Note 1) These apply for RF fields from 100 kHz to 10 GHz
Note 2) SAR is averaged over the tissue mass and over the time period.

ANNEX J

QUALITY ASSURANCE PROGRAM

The responsibility for long-range planning of quality assurance goals and activities shall be assigned to the QA/QC committee especially for large facilities.

I. Requirements of a Quality Assurance Program (QAP):

Implementation, monitoring and overall quality assurance program of the institution/facility is one of the primary responsibilities given to the licensee. The licensee shall ensure the following:

A. Creation of a QA/QC Committee

Creation of this committee ensures the commitment for the establishment and maintenance of a quality assurance program. This committee shall be responsible for all the QA activities in the radiology department. The QA/QC committee shall be composed of the following personnel/staff in a radiology department:

1. Head of the Facility
2. Chief Radiological Medical Practitioner
3. Medical Physicist
4. Chief Radiologic Technologist
5. Radiologic Technologists
6. Resident physician/s
7. other radiology staff (e.g. nurses, administrative staff, etc.)

Each member shall have clearly identified roles and responsibilities and should be documented. Meetings regarding QA/QC shall be conducted periodically. Records of the minutes of the meetings shall be kept.

B. Establishment of Standards or Criteria in the Evaluation of Magnetic Resonance Images per MRI procedures performed in the MRI facility.

Each MRI procedures performed in the facility shall have a basis for classifying radiographs as *either* good, poor or reject. It is the responsibility of all the MRI radiologists to come up with standards/criteria in the classification of images.

C. Conduct of an Image Analysis Program

This shall be done prior to and after the establishment of a QAP. Image analysis is conducted to ensure the reduction of repeated MR images. Monthly reports of image analysis shall be kept and reviewed by the QA/QC Committee to verify frequent causes of poor and reject images, which shall consequently initiate corrective actions and improvement of the image quality.

D. Formulation / Development of Quality Assurance Manual

The quality assurance manual should be written in a format permitting convenient revision as needed. It should be made readily available to all personnel. The content of the manual should be determined by the facility staff. The quality assurance manual should also be reviewed, at least annually, to determine effectiveness and improvement of the QAP. The manual shall contain the following:

1. List of the individuals responsible for the monitoring and maintenance of QAP;
2. Description of the MRI examinations performed and standard operating procedures, including a description of the standards, criteria of quality, or limits of acceptability for images;
3. Description of the quality control procedures and criteria of acceptability for each MRI equipment;
4. Description of procedures to be followed when errors are detected;
5. Description of appropriate training to be attended by all personnel involved with quality assurance responsibilities;
6. Description of the standards for image quality to ensure that they are consistent with the needs and resources of the facility;
7. Description of the preventive maintenance program for each MRI equipment; and
8. Description of service arrangement with other organizations and qualified experts.

E. Maintenance of room logs containing the records of quality control (QC) test results per MRI equipment, MR-compatible equipment, ferromagnet detectors, and other protective equipment (e.g. safe plugs, ear defenders, other means of hearing protection)

F. Records of maintenance and repair work for each MRI equipment and ferromagnet detection system.

G. Provisions of appropriate training for all personnel with responsibilities to quality assurance program.

II. Scope of a Quality Assurance Program

The QAP shall include:

A. Image quality assessments

Image quality assessments are assessed by quantitative measurements and clinical images based on anatomical criteria.

B. Image reject analysis / Reject analysis Program

This has to be performed prior to the establishment of QAP and thereafter. Image quality criteria shall be discussed among the radiologists and radiologic technologists so as to come up with a standard image quality and techniques.

C. Provision for Comfort and Privacy of Patients

Analysis of patient waiting time, clean and well-ventilated room as well as provision of clean and comfortable patient gown, linen, pillows and couch is of importance in this aspect.

D. Periodic Quality Control Program for MRI Unit

Quality Control includes the visual/mechanical inspection and performance testing of all available MRI units and accessories in the hospital/institution.

E. Monitoring and maintenance

1. Routine quality control monitoring and maintenance procedures for MRI equipment and accessories shall be established and conducted on a regular schedule. The purpose of monitoring is to permit evaluation of the performance

of the facility's MRI machines in terms of the standards for image quality established by the facility and compliance with the relevant regulatory requirement/s. The maintenance program should include preventive maintenance, which could prevent unexpected breakdowns of equipment and disruption of departmental routine. This should also include corrective maintenance to eliminate equipment problems before they have a serious deleterious impact on patient care.

2. The QA/QC Committee shall ensure that the preventive and corrective maintenance of the equipment shall be conducted by competent maintenance/service personnel certified and trained by equipment manufacturers and or by manufacturer-certified maintenance/service personnel. The certified maintenance/service personnel shall have completed an appropriate training in radiation protection conducted by an organization recognized by the FDA.

III. Quality Control (QC) Program

Identification of the various parameters to be monitored in an MRI equipment that greatly affects both the image quality and its performance shall be carried out prior to the establishment of QC Program.

Routine Performance testing and QC comprises those tests that are undertaken either regularly or after maintenance or repairs, to detect whether any change in the performance of the equipment has occurred that would require corrective action.

Routine performance tests are really a subset of the commissioning tests and will generally involve staff with different levels of expertise, some of whom may be external to the radiology facility. The more frequent tests that are to perform are usually undertaken locally with advice from a medical physicist, while the more complex and time-consuming tests may require special expertise and instrumentation. A collaborative, multidisciplinary approach to routine performance testing is essential.

IV. Outline of QC Tests:

These tests are intended to verify the stability in the operation of the equipment or elements used to acquire the image. The tests can be described in three ways with some of their key characteristics described below:

A. Frequency - The recommended frequency of a routine performance test varies from daily to yearly. It is often given as a range (e.g. three to six monthly) because the frequency selected should depend on the equipment characteristics (e.g. age reliability) and the clinical workload to which the equipment is subjected. A lower frequency of tests may be appropriate for simple imaging equipment that is used less frequently or for equipment where experience shows that parameters are unlikely to change. The frequency of tests may also be designated as essential and desirable, for example, a test may be essential every year but desirable every six months.

B. Priority - The priorities for indicating whether a routine performance test is recommended may be denoted as:

1. **Essential**: Represents the minimum recommended standard; conformance to this standard of testing would be regarded good practice.
2. **Desirable**: The inclusion of this level of testing would be regarded as best practice. However, it is recognized that the implementation of these tests

may be constrained by test equipment costs, personnel availability, equipment characteristics, clinical workload or other factors.

C. Performance standards - QC tests help maintain equipment performance through the use of tolerance criteria that are applied to QC test results. These performance standards can be characterized as acceptable and achievable;

1. **Acceptable**: Indicates that performance shall be within these tolerances and if it is not, the equipment should not be used.
2. **Achievable**: Indicates the level of performance that should be attained under favorable circumstances; if feasible, this is the level at which a facility should work.

ANNEX K

MR SAFETY LABELS FOR DEVICES AND MR ZONES WARNING SIGNAGES

Medical devices shall be labelled before entering Zone IV. It shall have an information on MRI safety status. These labels shall be posted on identified equipment and visible enough to be read from a distance (approx. 1.5m). It shall be assessed into three (3) categories namely:

I. MR-SAFE

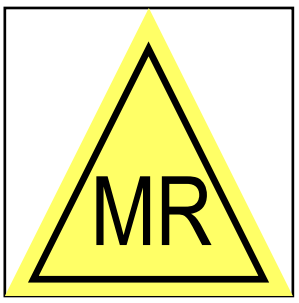
These devices are composed of materials that are electrically non-conductive, non-metallic, and nonmagnetic. A medical device is non-conductive if the conductivity is less than 1 S/m of a medical device in the MR environment. These devices pose no known hazards in all MR environment. The label for MR-SAFE is a square with white background, with green (RGB 0,176,80) borders and with letters "MR" at the center printed in green font color and Arial bold.

II. MR-UNSAFE

Devices labelled as unsafe in all MR environment should remain outside the MRI Scanner room or Zone IV at all times. For non-implanted medical devices, the MR Unsafe label should appear directly on the medical device if possible. The label for MR-UNSAFE devices shall consist a white square with letters "MR" in black and Arial bold in the middle with a superimposed "Not Allowed" symbol in red (RGB 192,0,0).

III. MR-CONDITIONAL

These devices have been demonstrated to pose no know hazards in a specified MR environment with specified conditions of use. The label for MR-CONDITIONAL consists of a yellow (RGB 255,255,102) equilateral triangle with a smaller triangle within it bordered in black and letters "MR" in black and Arial font at the center.



Annex K-1

MRI ZONE I

ACCESS AREA

Annex K-2

MRI ZONE II

SCREENING AND PREPARATION

Annex K-3

MRI ZONE III

CAUTION

RESTRICTED ACCESS

SCREENED MRI PATIENTS AND MR PERSONNEL ONLY

Annex K-4

MRI ZONE IV

DANGER

RESTRICTED ACCESS

SCREENED MRI PATIENTS AND MR PERSONNEL ONLY