

# **Magnetic resonance imaging safety guidelines**

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Prepared by Marie Allan (NRL), Raewyn Feast (MSc MRI), Martin Gledhill (NRL),  
Dr Mike Hurrell (RANZCR), Jill Oliver (NZIMRT), Dr Richard Tremewan (ACPSEM,  
NZ Branch)

## **Introduction**

These guidelines are based on the findings and recommendations of the International Commission on Non-Ionizing Radiation Protection, the British National Radiological Protection Board, the National Health and Medical Research Council, the Food and Drug Administration, the International Electrotechnical Commission and the Society for Magnetic Resonance Imaging. They indicate circumstances under which examinations may proceed with no special precautions, and those where a more careful evaluation may be necessary. They do not displace the need to maintain a current knowledge of the relevant medical literature.

The guidelines have been endorsed by the Australian College of Physical Scientists and Engineers in Medicine (NZ Branch), the NZ Institute of Medical Radiation Technologists and the Royal Australasian College of Radiologists (NZ Branch) as being supportive of good practice in MRI. They are based on information available at the time of publication. MRI imaging is an evolving technique, and it is recognised that future research and experience may require modifications to these recommendations. In recognition of this fact, they will cease to be valid on 31 March 2007. It is intended that they should be reviewed and modified where necessary before that date.

## **Scope**

These guidelines are intended to ensure the safe operation of MRI equipment, and indicate means to eliminate or minimise possible harmful effects. It is assumed that the installation already satisfies building, electrical and fire safety requirements. The guidelines apply to all people involved directly or indirectly with the MRI operation: patients, operating staff, ancillary staff (such as nursing and cleaning staff) and visitors.

## **General considerations**

Experience to date indicates that compliance with these guidelines will minimise any possible risks to patients, staff and the public. Nevertheless, the following general considerations also apply:

MRI examinations should only be performed when the clinical advantage to the patient outweighs any possible risk.

The clinical advantages and disadvantages should be compared with other diagnostic techniques available.

If MRI examinations form part of a research project, the project should be approved by an appropriate ethics committee and the subject's informed consent obtained.

MRI users should be properly trained in the principles and operation of the equipment, indications and contraindications for its use, record-keeping requirements, and safety precautions. There should be a system in place for the continuing education of all staff (including non-clinical staff) who work in or around the equipment.

All Medical Radiation Technologists who practise MRI need an exemption to practise unless they have a specific MRI qualification. If they have a qualification they can be registered in MRI after the qualification has been reviewed and accepted by the MRT Board.

There should be local procedures in place for handling emergencies, especially where there is sole operation of equipment. Wherever possible such procedures should be rehearsed.

## **A Physical Hazards**

This section of the guidelines covers potential physical hazards which may be posed by the MRI equipment itself or by the static, gradient and radio-frequency (RF) fields it produces. Although many of these factors may be fixed at the time of installation, they might be altered by subsequent modifications to the hardware or scanning protocols.

### **A1 Access to the MRI scanner**

Access to the MRI equipment should be controlled using defined areas:

**Controlled area** Access to any area where the static magnetic field may exceed 0.5 mT, or where gradient or RF fields may interfere with electronic devices, should be controlled, by warning signs or some other means, in order to exclude people who may have pacemakers, or implanted defibrillators or neurostimulators. Any areas adjacent to the MRI equipment to which there is unrestricted access (corridors, adjacent rooms or outside areas) should have fields less than 0.5 mT and be shielded from RF fields.

**Restricted area** Access to any area where static magnetic fields may exceed 3 mT should be restricted to qualified MRI staff, or people under the supervision of such staff. Qualified MRI staff are expected to be aware of precautions which must be taken inside such areas and the possible hazards that may arise. This would normally include MRI operating staff and maintenance engineers, and possibly trained cleaning staff. Ferromagnetic materials, and anything which has not been shown to be compatible with MRI equipment, should not be brought into the restricted area.

### **A2 Static magnetic fields**

Research carried out to date suggests that there are no adverse effects caused by short term exposure of the trunk and head to static magnetic fields of up to 2 Tesla (T), and there are reasonable grounds to believe that limbs are unaffected in fields up to 5 T. Volunteers exposed in 4 T scanners have reported nausea and vertigo, and there may also be slight effects on blood pressure. Objects made of iron or some other magnetic material can be moved by fields stronger than 3 mT, and may be hazardous to people or equipment. Credit cards, watches and magnetic tapes may also be affected. The operation of some pacemakers can be affected by fields stronger than 0.5 mT.

Recommended maximum exposure limits are:

**Patients** Exposure of the whole body should not exceed 4 T, with cardiovascular monitoring required in fields greater than 2 T. Exposures of limbs should not exceed 5 T.

**MRI Staff** Exposure averaged over a working day should not exceed 200 mT, with absolute maximum of 2 T over the trunk and head, or 5 T for limbs.

**Visitors, ancillary staff** Visitors and ancillary staff should not enter the restricted area except under the supervision of MRI staff.

**Implementation of A1 and A2** As users of MRI equipment are unlikely to have equipment to determine static field levels, 0.5, 3 and 200 mT contours should be supplied by the manufacturer or supplier. For new installations, inclusion of these should form part of the purchase specification. Records of MRI staff duty rosters should be kept so an estimate of staff exposures can be made.

### **A3 Gradient Fields**

Gradient fields are rapidly changing magnetic fields, which induce currents in electrical conductors by electromagnetic induction. Sufficiently high current densities can stimulate nerves, produce magnetophosphenes (apparent flashes of light on the retina) or even fibrillation. The shorter the stimulus time, the greater the rate of change required to produce an effect. Gradient fields are limited to the area immediately around and within the imager.

Maximum rates of change for axial gradients at different pulse widths should either satisfy requirements for Food and Drug Administration approval, or the scanner should operate in accordance with International Electrotechnical Commission (IEC) Standard 601-2-33 *Particular requirements for the safety of magnetic resonance equipment for medical diagnosis*<sup>1</sup>.

Gradient field specifications and compliance details for particular scanners should be obtained from the manufacturer or supplier.

### **A4 Radio-frequency fields**

Pulses of radio-frequency (RF) energy heat the body. This heat can be dissipated by the body, provided that the rate of heating is not excessive. Some conditions (cardiovascular disease, hypertension, diabetes, fever, old age and obesity) and some medications (diuretics, beta-blockers, calcium blockers, amphetamines, muscle relaxants and sedatives) may impair the normal cooling mechanisms. No adverse effects are expected if the core temperature rises by less than 1 °C. However, for infants, pregnant women and patients with impaired cooling mechanisms, core temperature rises should be restricted to 0.5 °C. RF fields are restricted to the imaging room. Temperature increases are best predicted by the specific absorption rate, measured in Watts of RF power absorbed per kilogram of tissue.

The IEC and FDA have both set guidelines on acceptable temperature rises and specific absorption rate levels. Scanners should either comply with the IEC Standard 601-2-33, or have FDA approval.

Notwithstanding this requirement, the patient's temperature and cardiovascular function should be monitored if the whole-body average specific absorption rate exceeds 1.5 W/kg averaged over any period of 15 minutes. Monitoring should also be considered if there is a clinical assessment that the patient's thermoregulatory mechanisms may be impaired.

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<sup>1</sup> A summary of the relevant sections is given in Appendix A

## **A5 Quench**

In MR facilities using superconducting magnets there is a rare possibility that the liquid helium coolant may suddenly evaporate. If the gases are not vented to the outside, they may pose an asphyxiation hazard.

MR equipment (including the examination room and any other areas where the coolant may be stored) should be installed with an appropriate exhaust system to vent gases to the outside in the event of a quench. As a precaution in the event of this failing, an emergency evacuation procedure should be established and rehearsed. Oxygen monitors with an alarm audible in the control room should be in the examination room and other areas where coolants are stored.

It is recommended that emergency quench buttons be installed both inside and outside the examination room.

## **A6 Noise**

Operation of an MR system can be noisy, which may cause the patient annoyance, anxiety, distress and even temporary hearing loss. Staff or visitors in the imaging room may also be affected.

Earplugs should be made available to anyone present in the imaging room during a scan, especially if noise levels exceed 94 dBA. MR-compatible headphones which also muffle external noise can be used to communicate with the patient during a scan.

## **B Conditions requiring clinical judgement**

This section of the guidelines considers situations where an individual assessment is required for each patient. The possible risks need careful evaluation or balancing against the benefits to the patient.

### **B1 Implanted and externally worn devices**

The static and time varying fields produced by MR equipment may affect implanted or externally worn materials or devices. Objects made of, or incorporating, ferromagnetic materials (foreign bodies, clips, filters, valves, halo vests, transdermal patches etc) may be moved, dislodged or create thermal hazards, and may also distort the image. The functioning of electrically or magnetically activated implants such as pacemakers and neurostimulators may be severely affected.

A patient with any implant or externally worn device should not undergo an MR scan unless the exact nature and location of the implant or device, and the materials of which it is made, have been determined, and a careful evaluation made of the potential for harm and any precautions which might be necessary. Information which could assist in such evaluations is published in the medical literature. This should be readily accessible to the MR unit and kept up to date.

Unless specific information is available to the contrary, patients with pacemakers should not be scanned.

The same considerations must be applied to MR staff, ancillary staff and visitors who enter the imaging room.

## **B2 Patient Monitoring**

All patients undergoing MR examinations should be visually and verbally monitored. Patients who are sedated, anaesthetised or unable to communicate readily with the MRI staff or accompanying ancillary staff should be physiologically monitored by appropriate means. Monitoring may also be appropriate in strong magnetic fields and certain RF fields (see sections A2 and A4). The type of monitoring should be determined by the MRI staff in consultation with the patient's referring doctor.

If monitoring is by electrical or mechanical devices, they should have been previously demonstrated to be compatible with the MR system, both from the point of view of patient safety and mutual interference between the monitoring device and the MR imager.

## **B3 Contrast Agents**

Several Gadolinium-based contrast agents have been introduced, and more are in development. Adverse reactions have been relatively few and mostly minor, and cautionary notes are included with the packaging. Contrast agents should be administered with the same care and attention as any other pharmaceutical product.

Some agents have been shown to cross the placenta readily. When the rate of clearance from the amniotic fluid is not known, a careful assessment of the possible risks and benefits of contrast agents in pregnant women should be made.

Caution should be exercised before administering contrast agents to lactating mothers, as some agents are excreted in breast milk.

## **B4 Pregnancy**

There has been no indication that MR imaging during pregnancy has harmful effects, and no clear evidence from laboratory research that adverse effects would be expected. Nevertheless, in view of the limited evidence available and the relatively high exposures to static and time-varying fields, a cautious approach should be taken, particularly in the first trimester of pregnancy.

**Patients** MR imaging may be used if it has the potential to affect the therapy or intervention offered to the mother or fetus, and the information cannot be obtained by ultrasound or would otherwise involve exposure to ionizing radiation. Guidelines in section A4 give maximum exposures to RF fields.

**Staff** Limited studies on pregnant MRI staff indicate no adverse effects from exposures to the static magnetic field incurred during normal work. Pregnant staff should still be permitted to carry out MRI procedures, but should keep out of the imaging room while a scan is in progress.

## **B5 Claustrophobia**

Some patients may experience claustrophobia, even those who have no personal or family history of the condition. This may be precipitated by the restricted space inside the MR bore, anxiety about the scan and the possible outcome, noise, and the duration of the examination. Staff should be aware that claustrophobic reactions may occur, and of the techniques which may avert them.

## **C Pre-scan assessment**

The presence or absence of the above risk factors, and therefore the suitability of a patient for an MR scan, should be ascertained prior to the scan. The exact form of the assessment should be decided locally, so as to tie in with local working practices. An example is included in Appendix B for reference.

This assessment should preferably be done first by the physician at the time of referral, and should be included on the referral form signed by the physician. This will allow both the referring clinician and the supervising radiologist to make an informed judgment on the suitability of the patient for a scan, and if any special precautions or monitoring are necessary.

A second assessment should be performed by the MRT when the patient arrives for the scan through a systematic pre-scan assessment signed by the patient. Particular care should be taken to exclude the presence of cardiac pacemakers and metallic foreign bodies, and a plain PA radiograph should be obtained when there is the possibility of metallic orbital foreign bodies.

## **D Quality Assurance and Preventive Maintenance**

Accurate diagnoses can only be made from good quality images. Incorrect diagnoses due to poor quality images or malfunctioning equipment can be as harmful as any of the other factors considered here. Equipment operators should establish appropriate quality assurance and maintenance programmes to detect and prevent gradual degradation in image quality.

## References

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National Health and Medical Research Council, 1991. Safety guidelines for magnetic resonance diagnostic facilities (1991). Radiation Health Series no. 34. Australian government printing service, Canberra.

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Shellock F G. Pocket guide to MR procedures and metallic objects: update 2001. Lippincott Williams and Wilkins. 2001.

Shellock F G, Kanal E, Society for Magnetic Resonance Imaging (SMRI) safety committee, 1992. Patient monitoring during MR examinations. *Journal of magnetic resonance imaging* 2: 247-248.

### Internet sites:

[www.MRIsafety.com](http://www.MRIsafety.com)

[www.kanal.arad.upmc.edu](http://www.kanal.arad.upmc.edu)

## Appendix A

### IEC 601-2-33 requirements for gradients and RF fields

(This summary highlights the main points of IEC 601-2-33, but is not exhaustive. A revision is anticipated by 2004.)

The IEC Standard takes a three tier approach to controlling patient exposures to gradient and RF fields. The Standard defines three *operating modes*, and stipulates requirements for each mode as below:

*Normal operating mode:* only routine patient monitoring (audio and visual) required.

*First level controlled operating mode:* Equipment operator to be warned that the equipment will be operating in this mode, deliberate action needed to start scan. Specific absorption rate or gradient values to be recorded on scan. Medical supervision by qualified medical practitioner required, possibly including physiological monitoring.

*Second level controlled operating mode:* Equipment operator to be warned that operating conditions are potentially hazardous and should not be applied for normal clinical use. Access to this mode restricted by key lock, software password or similar and only possible under the authorisation of the medically responsible person. Operation in this mode only permitted with approval of local Ethics committee or Investigational Review Board or similar body.

Maximum levels of the gradient fields and specific absorption rate in the different operating modes are tabulated below.

*Gradient fields - maximum levels for normal and first level controlled operating modes:*

Operating mode	Pulse width $\tau$ (microseconds)	Maximum rate of change (T/sec)
<b>Normal</b>	$\tau > 120$	20
	$2.5 < \tau \leq 120$	$2400/\tau$
	$\tau \leq 2.5$	960
<b>First level</b>	$\tau > 3000$	20
	$45 < \tau \leq 3000$	$60000/\tau$
	$\tau \leq 45$	1330

The second level controlled operating mode comprises rates of change exceeding the upper limit of the first level controlled operating mode.

*Specific absorption rate (SAR) - maximum levels in different operating modes*

<b>Operating mode</b>	<b>Whole body SAR</b> (W/kg, averaged over 15 min)	<b>Head SAR</b> (W/kg, averaged over 10 min)	<b>Local tissue SAR</b> (W/kg, in any gram of tissue, averaged over 5 min)
<b><i>Normal</i></b>	SAR<1.5	SAR<3	SAR<8 (head, torso) SAR<12 (extremities)
<b><i>First level</i></b>	1.5<SAR<4	N/A	N/A
<b><i>Second level</i></b>	SAR>4	SAR>3	SAR>8 (head, torso) SAR>12 (extremities)

## MAGNETIC RESONANCE IMAGING (MRI)

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
 Weight: \_\_\_\_\_

**Please answer the following questions carefully. These items can interfere with MRI scanning and may be hazardous to your health during the MRI examination.**

	YES	NO
Do you have a cardiac pacemaker or an artificial heart valve?		
Have you ever had any other type of heart surgery?		
Do you have any aneurysm clips in your head? (these clips can be inserted during some types of brain surgery).		
Are you fitted with a neurostimulator or electrical wiring in your back?		
Do you have any metal implants or joint replacements?		
Have you ever had a surgical procedure or operation of any kind? Please specify -		
Have you ever had any type of injury from a metallic foreign body? e.g. bullets, shrapnel, etc		
Have you ever had an injury to your eyes from a metallic foreign body? e.g. metal shavings or slivers from working with a lathe.		
Do you have a cochlea implant or hearing aid?		
Do you wear dentures?		
Do you suffer from Epilepsy or Diabetes?		
Do you wear a calliper or have an artificial limb?		

**To be answered by women of child bearing age.**

Are you currently breastfeeding?		
Could you be or are you pregnant?		

**Important:**

**Please remove all metal objects from your person, e.g. watches, credit cards, keys, etc. Items may be left in the lockers provided.**

**Patient declaration:**

I declare that I have answered the above questions to the best of my knowledge.

Patient signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_