Using MRI safely

PRACTICAL RULES FOR EMPLOYEES

rivm

NFU
NEDERLANDSE FEDERATIE VAN UNIVERSITAIR MEDISCHE CENTRA

NVZ vereniging van ziekenhuizen

NVMBR

Nederlandse Vereniging voor Radiologie
Radiological Society of the Netherlands

SZW
Ministerie van Sociale Zaken en Werkgelegenheid

Holland HealthTech

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Using MRI safely – practical rules for employees

Foreword

The European Directive on electromagnetic fields, known as EMF Directive 2004/40/EC, was issued on 29 April 2004. Originally, this guideline was to be implemented in national legislation by no later than 30 April 2008. This meant that companies whose work involves the exposure of staff to electromagnetic fields would have to comply with the requirements of this directive.

In the original formulation of the Directive, experts from the field were only involved at the margins. It only became clear in 2006 that the exposure limits stated in the Directive might inhibit the practical use of MRI in healthcare and research. This could have wide-ranging ramifications for the application of this technology, which has been used in patient care for more than 25 years. This undesirable development was also confirmed in various publications by the RIVM [National Institute for Public Health and the Environment] and in an alert from the *Gezondheidsraad* [Health Council of the Netherlands]. Based on extensive interventions by members of the European Parliament, a large number of scientific organisations and above all numerous patient groups, it was finally decided in April 2008 to postpone implementation of the Directive until 2012. In the context of this postponement, both the content and the consequences of the Directive will be examined, looking in particular at avoiding restricting the use of MRI in practice.

The Netherlands has played an important positive role in the postponement process. Those responsible within SZW [Ministry of Social Affairs and Employment] acknowledged the negative effect of the Directive on the use of MRI in patient care at an early stage. Based on their recommendation, a working group was set up comprising representatives from employers' and employees' organisations plus a number of additional experts, with the aim of developing practical rules defining safe ways for employees to work with MRI. These practical rules could be the basis for drawing up an *arbocatalogus* [working conditions catalogue]. Because I was closely involved in the discussions about the Directive both in the Netherlands and at the European level, I was asked to take on the chairmanship of this working group. Mathieu Pruppers of the RIVM has supported me expertly as the secretary. The Working Group has defined the rules of conduct described in this document in an exceptionally constructive and progressive way; the Working Group believes that these will ensure that MRI can be used safely in practice.

Rotterdam, juli 2008.

Gabriel P. Krestin
Hoofd Radiologie Erasmus MC
Past-president ESMRMB.

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1 Introduction

MRI, magnetic resonance imaging or nuclear magnetic resonance tomography, is a powerful diagnostic tool that has been in use for 25 years now in healthcare and for scientific studies. The use of MRI has major benefits for the patients. It has now become an essential part of the diagnosis and treatment of illnesses and in medical research. Using magnetic and electromagnetic fields, MRI makes it possible to produce detailed images of the interior of the human body. MRI therefore plays a key role in the routine treatment of numerous diseases, such as cancer, cardiovascular disease and neurological conditions. Further scientific investigations into the application of MRI to other illnesses and into functional and interventional applications are still forging ahead. MRI provides a much higher contrast between soft tissues than CT (computer tomography) and, unlike CT, does not use ionising radiation.

1.1 Background and Objectives

To be able to work safely with MRI, it is important that staff are aware of the safety aspects and handle them appropriately. Organisational and technical measures are needed in order to reduce the potential hazards. This document describes the various safety aspects and the corresponding practical rules. It has been drawn up by the MRI Working Group, an *ad hoc* working group of institutions with interests affected by the application of MRI in the Netherlands (please refer to Appendix 1 for an overview of the members of the Working Group). The purpose of this document is to protect all employees[1] who are involved with MRI and to do so at the most practical level possible. This document will be brought to the attention of those who are involved in the discussion about changes to the EU Directive for the protection of employees from the dangers of exposure to electromagnetic fields. This document is also the framework for drawing up a working conditions catalogue for handling MRI.

In order to produce a document in which practical rules for staff involved in MRI are described, a summary is given of the various situations

1 This document primarily considers occupational working conditions for employees. Safe use of MRI has consequences for the way patients are handled; these are not covered in this document (e.g. instructions for the patient, the use of upper and lower SAR limits, positioning of the patients, checking for contra-indications, etc.). The description of good practice is limited to the 'imaging of people and animals'.

in which employees can be exposed to magnetic fields due to the application of MRI. The possible effects that could arise when working with MRI scanners are then listed. Finally, precautions are recommended for each of these effects, grouped according to the working situations.

The Working Group is convinced that if the rules in this document are observed, the safety of staff during current working practices and according to the current state of knowledge is sufficiently guaranteed. Exposure limits have not been discussed in this document, partly because of the ongoing international discussions about how high these limits should be.

1.2 Concepts and definitions

Scanner room
The room in which the MRI scanner is located and in which usually only the patient is present during scanning.

Controlled access area (around the scanner)
According to NEN-EN-IEC standard 60601-2-33, the controlled access area is the *"area to which access is controlled for safety reasons"*. Outside the controlled access area, this standard states that the stray field from the static magnetic field may not exceed 0.5 mT (the field strength above which hazards can occur for medical implants such as pacemakers). In clinical practice, the controlled access area is often the same as the scanner room. It is possible that the magnetic field may be greater than 0.5 mT in auxiliary areas below or above the scanner area, and additional measures are required in such cases.

Static magnetic field
The static magnetic field is one of the elements required to obtain an MRI signal. In an MRI scanner, this field is generated with a solenoid coil that is often made of a superconducting material. When the magnitude and direction of the magnetic field do not vary over time, then this is referred to as a static magnetic field. In almost all MRI systems, this static magnetic field is continuously present, i.e. 24 hours a day. The magnetic field strength of MRI systems varies from 0.2 to 1.0 T for open systems with a vertical static magnetic field, and from 0.5 to 3.0 T for the classical cylindrical systems with a horizontal field. Systems using 7 T are also in operation in the Netherlands for scientific research. For comparison: the strength of the earth's (static) magnetic field is about 50 microtesla in the Netherlands, whereas the order of magnitude for

the strength of a refrigerator magnet is a few millitesla.

Switched gradient fields
As well as a static magnetic field, switched magnetic fields are needed in order to localise the MRI signal and thereby generate an image. These switched magnetic fields generate a linear field gradient and are therefore also referred to as "gradient fields". The gradient fields are switched on and off in timeframes in the millisecond range, thereby producing a magnetic field in the kilohertz range.

Radio-frequency fields
In order to obtain the MRI signal, a radio-frequency magnetic field is required in addition to the static magnetic field and the switched gradient fields. The frequency of this magnetic field depends on the strength of the static magnetic field and the atoms used. For hydrogen under a field of 1.5 T, this frequency is 63 MHz. Magnetic fields with these frequencies are also known as radio-frequency fields, or RF fields for short.

Cryogenic liquids
The majority of MRI scanners have a superconducting solenoid coil. To generate a strong magnetic field, a high current must be passed through the solenoid coil. This is achieved technically by using a superconducting coil. This can only be done at very low temperatures, cooling the coil with liquid helium (sometimes with a secondary layer of cooling using liquid nitrogen).

1.3 Legislation and regulations in the Netherlands

Under the *Arbowet* [Working Conditions Act], the employer will ensure (with the cooperation of the employee) that the work does not have any negative effects on the health and safety of the employee. The *Arbobesluit* [Working Conditions Decree] discusses the risks in greater depth.

The Working Conditions Decree states among other things that devices that produce electromagnetic fields must be properly manufactured, must be in good working order and must be located and assembled in such a way or screened in such a way that damage to health as a result of electromagnetic fields is avoided as far as possible. In order to prevent or restrict exposure to noise, it also states that appropriate technical or organisational measures must be taken so that the risks of exposure are eliminated at the source or

restricted to a minimum. If cryogenic liquids are present that could present a hazard to the health or safety of staff, due to the very low temperature or the oxygen displacement effect, then facilities must be provided so that the dangers associated with those materials in the event of an undesirable incident are avoided as far as possible.

The approach to occupational health and the occupational hygiene strategy for taking precautions consists of four steps, in order of decreasing preference[2]: measures taken at the source, measures aimed at collective protection, measures aimed at individual protection, and personal protection equipment. Combining the four different steps is also permissible. Practical rules can also make a contribution here. The Working Conditions Decree also contains specific stipulations for particularly vulnerable groups who need greater attention paid to them, such as employees who are pregnant.

Electromagnetic fields

The field strength above which electromagnetic fields are deemed to be hazardous in terms of the Working Conditions Decree is defined in European Union regulations. These include a large safety margin. For staff in a working situation, European Directive 2004/40/EC[3] of 29 April 2004 defines limits. Those who published comments about the possible restrictions on MRI if this directive were to be introduced included the *Gezondheidsraad*[4] [Health Council of the Netherlands] and the Belgian *Hoge Gezondheidsraad* [High Health Council]. The latest date for implementation of this directive in the member states' national legislation has now been postponed[5] until 2012. European standards are being prepared for situations requiring detailed evaluation, measurement or calculation to determine if the exposure remains below the limit. The exposure limits in the EU directive are based on recommendations by the ICNIRP (International Commission on Non-Ionizing Radiation Protection)[6,7]. The ICNIRP is working on new recom-

2 NTA 8050:2007 nl. (Nederlandse Technische Afspraak = Netherlands technical agreement) Guideline for producing working conditions catalogues. Publication date: 01-Jun-2007.

3 Corrigendum to Directive 2004/40/EC of the European Parliament and the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). OJ 2004, L184.

4 Health Council of the Netherlands. Comments concerning possible MRI restrictions due to implementation of an EU directive. The Hague: Gezondheidsraad, 2007; publication number 2007/17.

5 Directive 2008/46/EC of the European Parliament and of the Council of 23 April 2008 amending Directive 2004/40/EC on minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ 2008, L114/88-89.

mendations for static magnetic fields and (extremely) low-frequency electric and magnetic fields.

MRI equipment must comply with the essential requirements that are defined in European Directive 93/42/EEC of 14 June 1993 (Medical Devices)[8]. MRI equipment must be designed and manufactured in such a way that its use does not create any hazards for the clinical condition or the safety of the patients, nor for the safety and health of the users or, should such cases arise, any other persons. The equipment must also be used in the prescribed manner and for the purposes for which it is intended. It should also be understood that any risks that may be associated with its use must be acceptable, taking account of the usefulness of the equipment for the patient, and compatible with a high degree of protection for health and safety. When choosing the most suitable solutions for the design and construction of the equipment, the manufacturer must adopt the following principles in the sequence given below:

- risks must be excluded or restricted as far as possible (also meaning a safe design and safe construction)
- in relevant cases, appropriate measures will be taken, including alarm features if necessary, to protect against those risks that cannot be excluded, and
- the users must be informed about any risks that may still be present as a result of any shortcomings in the protective measures

The IEC (International Electrotechnical Committee) has issued a standard that defines safety procedures and threshold values for patients and staff for exposure to electromagnetic fields during MRI procedures. This standard, which is primarily intended for the equipment manufacturers, has been published by the European and Dutch governments as a harmonised standard under the Medical Devices Directive[9]. According to this standard, the static magnetic field is limited in principle to 4 T. Above

6 ICNIRP. Guidelines on limits of exposure to static magnetic fields. Health Phys, 1994, 66(1) 100-106.

7 ICNIRP. Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). Health Phys, 1998, 74(4) 494-522.

8 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. OJ 1993, L169 of 12-Jul-1993 pp. 0001-0043.

9 NEN-EN-IEC 60601-2-33:2002 en;fr. Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosisMedical electrical equipment, Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. Publication date 01-Nov-2002. This standard has now been modified by two amendments in 2005 and 2008 (NEN-EN-IEC 60601-2-33:2002/A1:2005 and NEN-EN-IEC 60601-2-33:2002/A2:2008); please refer also to Commission communication (2001/C 319/05) and "New NEN norms" in the Staatscourant [Dutch Government Gazette] (13 December 2002, no. 241 / page 47); the second amendment had not yet been published as a harmonised standard under the Medical Devices Directive on the date upon which this document from the MRI Working Group was finalised (see page 1).

that, according to the IEC, use on patients or test subjects is permissible as long as the consent of the local Medical Ethics Committee has been obtained.

Noise

In 2006, the Working Conditions Decree was modified regarding the exposure of employees to the risks of noise[10]. This amendment was implemented as a result of European Directive 2003/10/EC dated 6 February 2003[11]. Noise in the workplace is harmful if the daily average exposure of an employee on a nominal working day of 8 hours or more is greater than 80 dB(A)[12] [or a peak acoustic pressure of 112 Pa[13]]. If this is the case, the employer must provide ear protection and arrange for information and training. If the noise level is higher on a daily basis than 85 dB(A) [or a peak acoustic pressure greater than 140 Pa], the employee must wear ear protection and the employer must take protective measures. Whether or not sound causes harm depends on how long the employee is exposed to a particular sound level through the day and on the given peak acoustic pressure. The average level to which the employee is subjected during the day is hence an important parameter. For example, if the employee works for four hours a day at 90 dB(A) and four hours at 75 dB(A), then the daily exposure is above 80 dB(A).

Cryogenic liquids

Policy rule 4.4-5 is applicable to the use of cryogenic liquids, in order to prevent undesirable incidents when working with dangerous materials. This is based on article 4.4 of the Working Conditions Decree, in which the specific circumstances contributing to elevated risk levels from these materials are named, such as the extremely low temperature that can cause severe frostbite and the expansion during evaporation, which can displace oxygen and cause suffocation.

10 Decree dated 25 January 2006 amending the Working Conditions Decree, containing rules relating to the exposure of employees to the risks of noise. Staatsblad [Dutch Bulletin of Acts, Orders and Decrees] 2006, number 56, 1 25.

11 Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ 2003, L42, 38.

12 The daily exposure is expressed in dB (decibels). For filtering, the A filter is generally used, which corresponds to the sensitivity of the human ear; this is therefore referred to as dB(A).

13 The peak acoustic pressure is taken to mean the unweighted acoustic pressure that is measured with a noise level meter in the peak hold position, expressed in Pa. This uses a frequency weighting according to the C filtering. This measurement allows the maximum value (peak acoustic level) of brief or momentary noise signals to be measured.

2 Practical risks

In the application, development, or maintenance of MRI systems, employees may be exposed to various types of risks, namely those resulting from exposure to magnetic fields and to noise, and as the result of ferromagnetic projectiles, and risks deriving from cryogenic liquids.

2.1 Exposure to electromagnetic fields

During scanning, three types of magnetic fields are present: the static magnetic field, the field generated by the switched gradient fields (in the kHz range) and the radio-frequency (RF) field (in the MHz range). These fields have to have a particular value in the centre of the MRI scanner in order to ensure the desired picture quality for the diagnostic images. The most significant risks are the currents induced in the body by movement through the static field and by the gradient fields, and the heat that the radio-frequency field can impart to the body.

For all three types of field, there are stray fields around the magnet to which an employee can be exposed. This stray field is considerably lower immediately outside the ends of the MRI scanner's magnet core than the fields in the centre of the scanner, and it decreases rapidly with distance from the system. The stray field from the static magnetic field is always present, whereas the stray fields from the switched gradient fields and the RF fields are only present during scanning.

The stray field from the static magnetic field is present all around the magnet, and exposure is directly related to the distance from the magnet. If a person moves within this magnetic field, electrical currents are induced in the body. The employee's speed of movement is important in determining the strength of these currents.

In practice, the stray field from the RF fields directly outside the scanner is so small that it cannot cause any effects. It would only be possible for effects to be conceivable if an employee's body (or part thereof) were to be in the centre of the scanner during scanning. This situation can occur in hospital practice if a staff member accompanies a patient (a child) in the scanner during scanning, or if a member of staff from an MRI manufacturer has to be inside the system during scanning for trouble-shooting operations, for example to trace a fault.

The situation as regards the switched gradient fields needs examining with greater care. These stray fields are also considerably lower immediately outside the system than are the fields in the centre of the system, but it is nevertheless possible that these stray fields might cause effects. This depends on the scanning technique being used, because the strength and the switching speed of the gradient fields can vary.

Finally, a new technique is being developed: MRI-guided interventions. This is a technique in which e.g. a physician or other professional practitioner carries out interventions with the help of MRI imaging, such as taking biopsies, introducing catheters, and so forth. This may mean that it is necessary for the employee to be close to the magnet core during scanning, with hands or head in the switched gradient field and the RF field.

2.2 Exposure to noise

The switched gradient fields create noise in the scanner room due to vibrations in the gradient coils. This depends on the mechanical construction of the system and the length of the exposure. The noise level depends on the location and can reach levels of greater than 80 dB(A) in the majority of systems. NEN3418 is generally adopted as the measurement protocol.

2.3 Risks due to ferromagnetic projectiles

In the static magnetic field of an MRI scanner, there is the risk of ferromagnetic items flying around. Employees could be injured as a result of an item turning into a projectile, or get trapped between the magnet and the ferromagnetic material. This can only happen in the scanner room itself.

2.4 Risks from cryogenic liquids

There is a risk of freezing effects because parts of the magnet are highly cooled. Under normal operational situations this does not engender hazardous situations for employees (other than the MRI maintenance staff), because these parts are located out of reach on top of the magnet. If the magnet quenches[14] in excep-

14 The term 'quench' refers to the process in which the superconductive coils of the magnet become resistive. This converts the energy of the static field into heat, which causes part of the liquid helium (and the liquid nitrogen, if present) to be vaporised. This large amount of gas is vented outside through a special pipe, known as the quench pipe. There is a quench button to activate this process in emergency situations.

tional circumstances, then parts of the sides of the magnet can become cold. This can clearly be seen from the ice deposition and the formation of a "cloud". The evaporating cryogenic liquids are vented outside via the quench pipe. Gaseous helium is only released into the scanner room (with the concomitant danger of suffocation) in those quenches where this pipe leaks or is blocked.

3 Defined working situations

The scanner room does not restrict the stray field from the switched gradient fields, but the strength of this field is so low outside the scanner room that it can no longer have any effect. The stray field from the RF fields is shielded by the 'Faraday cage' that is constructed around the scanner room and sometimes around the scanner itself. The noise levels outside the scanner room will in general be lower than the legal limits. If not, additional measures will be necessary for the adjacent rooms. The risks due to cryogenic liquids are also present outside the scanner room. For this, the only checks required are that the quench pipe does not vent into areas where staff could come into contact with it and that the quench pipe is constructed in such a way that no condensed air can drip onto the patient or employees in the event of a quench.

All the working situations mentioned here are the cases in which employees are present within the controlled access area and, in the majority of cases, in the scanner room. No special measures are applicable outside the controlled access area. The working situation in which the controlled access area extends outside the scanner room is only discussed tangentially here. This then refers to adjacent work areas that are directly related to the MRI application and to which access is restricted for safety reasons, such as rooms for access, administration, operating the equipment, and waiting. These rooms are only accessible after controls (including screening and instruction) and have the necessary warnings on view.

The relevant distinction between the various situations is the question of whether or not scanning is being performed, and where the employee is at that time. This means that three working situations can be distinguished for staff whose activities have to be carried out in the vicinity of MRI equipment.

I The situation in which a staff member has to carry out work in the scanner room while scanning is not taking place.
In this situation, the employee can be exposed to risks as a result of:
- stray fields from the static magnetic field (including moving within this field)
- ferromagnetic projectiles, and
- cryogenic liquids

II The situation in which a staff member has to carry out work in the scanner room during scanning.
In this situation, the employee can be exposed to risks as a result of:
- stray fields from the static magnetic field (including moving within this field)
- stray fields from the switched gradient fields
- stray fields from the RF fields
- noise
- ferromagnetic projectiles, and
- cryogenic liquids

III The situation in which a staff member is partly or entirely inside the scanner during scanning.
In this situation, the employee can be exposed to risks as a result of:
- the static magnetic field (including moving within this field)
- the switched gradient fields
- the RF fields
- noise
- ferromagnetic projectiles, and
- cryogenic liquids

Areas for working situation I are in principle accessible to any employee, as long as they have been both screened (for metal objects, metals implants, active medical implants, etc.) and have been given instruction about the potential risks. Staff who can only occasionally be in this situation and therefore require special attention to be paid to them are e.g. internal and external emergency service staff (fire brigade, first aiders), people who are being trained (work experience staff etc.), cleaning staff, guards and security staff, and visitors. Working situation I is also applicable to staff who have to carry out activities in the scanner room of a small bore system[15] such as an MRI system for experimental animal research.

Areas for working situation II are only accessible to staff who have been screened (for metal objects, metals implants, active medical implants, etc.), who have been given instruction about the potential risks, and who are strictly required in the scan-

15 A small bore system is an MRI scanner with a magnetic core of less than approximately 30 cm in diameter. Such systems are mostly used for scanning small experimental animals and for scanning the limbs of human beings.

ner room during scanning, due to the activities to be carried out. Working situation II is also applicable to staff members who have to be close to the magnet of a small bore system during scanning, for example in order to start an infusion.

For each type of employer (hospital, scientific research institute or MRI manufacturer), consideration must be given to staff with the following occupations and/or duties:

A Hospital
- radiological technologist (radiographer)[16]
- physician
- anaesthesiology staff member
- nurse
- technical or medical researcher
- maintenance staff
- patient supervisor

B Scientific institute
- operator / biotechnician
- researcher
- maintenance staff

C MRI manufacturer
- applications specialist
- researcher
- developer
- system tester
- production staff member
- maintenance staff

Working situation III is applicable when an employee:
- is entirely or partially within the scanner for intervention work[17]
- is in the scanner together with a patient as part of their work, for example when accompanying a child, or
- has to be inside the scanner e.g. to track down a fault

A member of staff will be treated as a pregnant employee as soon as she has reported to the employer that she is pregnant. Consideration may be given to excluding a pregnant employee from working situations II and III as a precautionary measure.

4 Types of effects

The term 'effects' is interpreted in a wide sense in this document, i.e. covering everything that could be associated with exposure to all the identified risks. It is moreover important that not all physical and biological effects lead to transitory or permanent effects on health.

The ICNIRP distinguishes three types of effects that electromagnetic fields can have on health (their terminol-

16 As of 17 April 2008, the new professional term for medical nuclear science workers, radio-diagnostic and radio-therapeutic technicians in Dutch is MBB'er (Medisch Beeldvormings- en Bestralingsdeskundige = medical imaging and radiation expert).

17 It is possible that people will in future carry out MRI interventions on experimental animals. In terms of the exposure of the employees, these situations are comparable with working situations II and III respectively.

ogy is given in parentheses)[18]. Firstly, effects that can be objectively determined with measurement devices (*results*), such as heating or injury as a result of ferromagnetic projectiles. Secondly, indications that can be determined by experts such as doctors (*signs*). Thirdly, effects that are experienced subjectively by the persons exposed (*symptoms*). Examples of these would be flashes of light or dizziness.

A subdivision widely used in the literature is into thermal and non-thermal effects. However, this nomenclature is confusing. The effect itself is not thermal, but the chain of bodily processes capable of leading to the final effect starts with heating.

Another subdivision commonly adopted in the literature is between direct and indirect effects. Direct effects derive from direct links between electromagnetic fields and bodily processes, such as muscle stimulation. Indirect effects arise through the way an object is affected and its effect in turn on the body. Examples of the latter are burns due to clothing containing metal (that is heated by the radio-frequency field) and disruption of a pacemaker's functioning.

This document categorises the effects according to two characteristics. The first is the degree of certainty with which an effect can be determined, i.e. whether it is an objective observation (a *result* or *sign*) or a subjective one (a *symptom*). The second characteristic is associated with the question of whether the effect is transitory, i.e. disappears immediately when exposure ends, or may inflict permanent harm.

The effects on the employee differ according to the various working situations. The following effects can be distinguished for each identified risk.

Electromagnetic fields

1. Static magnetic field

a objective, possibly permanent harm: disruption of the functioning of active implanted medical devices (AIMDs) such as pacemakers or infusion pumps

b objective, possibly permanent harm: injury as a result of attractive or torsional forces on ferromagnetic objects within the body

c subjective, transitory: dizziness / vertigo, nausea, metallic taste and/or light flashes (phosphenes)
These effects only occur

18 ICNIRP. General approach to protection against non-ionizing radiation. Health Phys, 2002, 82(4):540-548.

when the staff member moves within the static magnetic field, with the speed and direction also being important. The fact that the static magnetic field outside the magnet is not homogenous is also important. There is also variability in individual sensitivities to these effects. The stronger the magnetic field is, the more often such effects are reported.

d subjective, transitory: cognitive effects
Examples are a possible worsening of hand-eye coordination and memory effects. Unlike other well-documented effects, these are only based on a few references in the literature. It is thought that these effects are caused by the above-mentioned effects, such as dizziness and nausea. There is also variability in individual sensitivities to these effects.

2. Switched gradient fields

a subjective, transitory: nerve stimulation
Stimulation of the peripheral nervous system in the limbs, head and torso. The first sensation observed is a slight tickling. The threshold at which this occurs varies from one person to another.

b objective, transitory: muscular contractions
As a result of nerve stimulation, muscular contractions can arise which may be painful (subjective).

c objective, possibly permanent harm: disruption of the functioning of active implanted medical devices (AIMDs) such as pacemakers or infusion pumps

3. RF fields

a objective, possibly permanent harm: direct heating of tissues (although the effect itself is transitory)
Tissue heating can cause burns and therefore give rise to permanent injury.

b objective, possibly permanent harm: injuries as a result of heating (although the effect itself is transitory) of metals or implants containing metals, wires, piercings, tattoos, permanent makeup, etc.
This heating can cause burns and therefore give rise to permanent injury.

c objective, possibly permanent harm: disruption of active implanted medical devices

(AIMDs) such as pacemakers or infusion pumps

4. ***Noise***
   a objective, transitory: ringing in the ears
   b objective, permanent: hearing damage

5. ***Ferromagnetic projectiles***
   a objective, possibly permanent harm: injuries as a result of loose ferromagnetic objects becoming projectiles, or of getting trapped between the magnet and loose ferromagnetic objects

6. ***Cryogenic liquids***
   a objective, permanent harm: frostbite
   b objective, permanent harm: suffocation due to lack of oxygen

5 Precautions and rules of conduct

5.1 General precautions

In line with the essential requirements imposed on MRI equipment by the Medical Devices Directive, the MRI scanner itself has a number of intrinsic safety features. Clinical MRI systems have internal monitors to ensure that the RF level is so low that direct heating of tissues (3a) remains below 1 °C, that muscular contractions (2b) are avoided, and that peripheral nerve stimulation (2a) should not generally be experienced.

The difference between working situation I and the other working situations guarantees that staff who do not have to carry out activities that must necessarily be done in the scanner room during scanning are protected against exposure to (stray fields) from the static magnetic field, the switched gradient fields and the RF fields, as well as against noise. The scanner room (or the controlled access area) must therefore be made recognisable as such by the application of warning signs.

The key measure that can be taken in all the working situations is to keep

as far away from the scanner as possible. The greater the distance, the lower the exposure to the electromagnetic fields. As a precautionary measure, it can also be recommended that people do not remain in the scanner room longer than strictly necessary, that additional measures are taken to minimise exposure, and that awareness of the possible effects is encouraged.

For exposure to the static magnetic field in particular, in all the working situations, an extra control measure is that the changes in magnetic flux density can be minimised by moving slowly through those areas where the static magnetic field gradient (dB0/dx) is greatest, so that the product of the speed (dx/dt) and the field gradient (dB0/dx) produces the smallest possible value for the flux change (dB0/dt). Within 1m of the aperture of the magnet core, the gradient of the static field is at a maximum and the employee must therefore move slowly. The gradient of the field is much less at the sides of the magnet.

For both the RF field and the switched gradient field, the exposure can only be minimised by keeping at a distance from the MRI scanner and by avoiding tasks near to the magnet core as much as possible. It is therefore advisable to automate infusions of anaesthetics, medications or contrast liquids during scanning as fully as possible and to place operating consoles, anaesthesia equipment and so forth as far away from the magnet core as possible. It should also be noted here that the minimum distance that should be kept depends strongly on the strength of the RF field and the switched gradient field that the system can generate. In practice, a distance of more than approximately 1m is sufficient to prevent the switched gradient fields from having any effect. There is in practice no effective personal protection equipment available yet for shielding against the switched gradient fields. Marking out the 1m limit on the floor of the scanner room can help make people aware of the risk.

The following sections contain additional rules of conduct for the three different working situations. Appendix 2 lists the measures to be taken, grouped by the type of area, working situation and type of activity.

5.2 Rules of conduct for working situation I

In this working situation, the important effects are those resulting from

the static magnetic field, ferromagnetic projectiles, and cryogenic materials.

Static magnetic field

To prevent disruption in the functioning of AIMDs (1a) and the attraction of ferromagnetic materials in the body (1b), staff who enter the scanner room must be screened for AIMDs and ferromagnetic implants; these are contraindications. These criteria are in principle the same as the contraindications for patients with regard to the static magnetic field.

Dizziness, nausea, metallic tastes and light flashes (1c) can occur when moving close to the scanner. Moving slowly around the scanner – particularly when the head is moving – can keep these effects as small as possible. The cognitive effects (1d) can also be kept to a minimum by moving slowly. Staff must be instructed about these effects and the associated rules of conduct.

Ferromagnetic projectiles

Employees may not bring any objects into the scanner room that contain ferromagnetic components[19]. These can become uncontrollable projectiles that can injure staff and patients severely and could damage the MRI scanner severely. MRI-compatible alternatives must be available for e.g. wheelchairs, stretchers, cleaning trolleys and anaesthesia trolleys. Less obvious objects that must be avoided are metal jewellery, clothing (wired bras, belts), footwear, keys and cigarette lighters. For the staff themselves, it is important to know that watches can be damaged and that cards containing chips or magnetic strips can be wiped. The operator has the job of instructing everyone who enters the scanner room. Outside working hours, this instruction must also be arranged for staff such as cleaners. The fire brigade and security staff must be given separate instruction and non-magnetic gas cylinders and fire extinguishers must be present. Staff must be taught the circumstances under which the quench button should be activated.

Cryogenic liquids

In the event of a quench, the staff and patients or test subjects must leave the scanner room as quickly as possible. When doing so, they must take care that they do not touch any parts on which ice has formed and do not use naked flames, because of the danger of fire due to condensed oxygen. Maintenance staff, the fire brigade, and the security services must be informed as quickly as possible. For these staff members, additional instruction on working with

19 De ontwikkeling van nieuwe ferromagnetische detectorpoortjes is veelbelovend. In het ACR document (zie voetnoot 20) wordt het gebruik van deze nieuwe technologie aanbevolen.

cryogenic liquids and the specific maintenance procedures for the MRI scanner is essential. For example, the large clouds of "smoke" may initially look like a fire, but fire extinguishing measures could cause a great deal of damage. Staff must be taught what to do in the event of a quench.

5.3 Rules of conduct for working situation II

All the points mentioned above for working situation I are applicable here, plus the following extra rules of conduct. When screening employees, there must also be a check of contraindications for the switched gradient fields and the RF fields. In this working situation, the effects resulting from stray fields from the switched gradient field and from noise are important. The effects of stray fields from RF fields are probably not significant in this working situation for the current generation of MRI scanners.

Switched gradient fields
Instruction must comprise elucidating the 'peripheral nerve stimulation' effect (2a and 2b) and keeping away from the scanner. A clinical MRI system has a safety circuit to limit peripheral nerve stimulation so that the threshold value is attained for less than 50% of the population[8,9]. This nerve stimulation can be felt clearly by the most sensitive individuals. Nerve stimulation that produces intolerable muscular contractions or that can affect the heart muscles only occurs with fields that are at least ten times stronger, and these are prevented by the safety circuit.

It is recommended that exposure should be limited as much as possible to prevent any effects.

Noise
If the daily exposure during scanning is above 80 db(A), the employer must provide ear protection. If e.g. a level of 86 db(A) is only "experienced" for a total of one hour a day, then it is not mandatory because the daily dose is in this case 77 dB(A). When work is carried out at these kinds of daily exposures, the employer must provide the employees with the opportunity of a periodic hearing test (e.g. once every four years) so that incipient hearing damage can be detected early. Staff may refer to the occupational health service or expert for this.

5.4 Rules of conduct for working situation III

All the points mentioned above for working situation II are applicable here, plus the following rules of conduct. An employee in this working situation will only receive an RF dose that could lead to effects during MRI intervention, or an occasional one during maintenance.

RF fields
To avoid direct heating of tissues (3a), the clinical MRI system has a safety system that limits the RF output in such a way that the local heating of the tissues is less than 1°C, the power input into the entire body is less than 4 W/kg, and to the head is less than 3.2 W/kg[8, 9].

To avoid injury as a result of local heating of metals or implants and so forth containing metals (3b), employees who enter the scanner room must be screened for contraindications to RF effects and the effects of the switched gradient fields. These criteria are in principle the same as the contraindications for patients.

For the exposure to RF fields, an average may be taken over an exposure duration of 6 minutes. In line with the recommendations of the *Gezondheidsraad* [Health Council of the Netherlands] Electromagnetic Fields committee[3], staff members must ensure that they limit their time near the scanner as much as possible and that they maintain as much distance as possible from the scanner.

As a precautionary measure, it is recommended that exposure should be limited as much as possible so that effects are prevented.

Going into the scanner with a patient, for example when accompanying a child, is strongly discouraged. This does not apply if the manufacturer has listed this method as an "intended use" and has therefore prevented the specific aspects of undesired interactions of RF fields with the patient or the accompanying person by means of a special scanner design.

5.5 Test subjects – the voluntary basis

The question of the voluntary nature is very important for an employee who is acting as a test subject. An employee entering an MRI system as part of the optimisation of MRI protocols or testing new MRI protocols is not part of the employment contract or public law appointment. This

is because the employment contract or public law appointment does not provide a basis for the infringement of personal integrity that is involved in acting as a test subject. Moreover, the Working Conditions Act states that the employer must avoid psychosocial work stresses. The employee is clearly in a dependent position with respect to the employer, and feeling obliged to act as a test subject in order to maintain a good working relationship could cause stress. Stress is deemed to be a psychosocial work burden. Test subjects must be recruited passively (no compulsion) and must be properly informed about the possible risks. Handling of any incidental findings (reported or not) must also be explained clearly to the test subject beforehand. It is desirable that the 'agreement' between the employer and the employee should be recorded in writing by means of an informed consent form.

5.6 Education, training and instruction

Given the central role of the technologist/operator on the work floor in implementing the working methods indicated here, such employees must be trained regarding the MRI safety issues discussed in this document and the practical rules needed. This training must match the local situation and can be arranged e.g. by the clinical physicist or MR physicist.

Clinical MRI scans will generally be carried out in hospitals or MRI centres. This means that the clinical investigations will be performed by qualified radiological technologists[16]. They will have been trained in how to deal with patients and in the interpretation of anatomical images. This background also means that they will be familiar with the operation of equipment such as X-ray and irradiation equipment. Since the arrival of MRI, the basic principles of MRI have also been included in the initial training of the radiological technologists, also covering the safety aspects.

One possible way for technnologists working with MRI to obtain the required extra training regarding safety issues is by following a post-HBO [*higher vocational education*] MRI course. This course emphasizes the theory and techniques required to be able to perform the optimum examinations. This addresses the risks and effects of electromagnetic fields once again, plus the major importance of screening everyone who enters the scanner room properly.

Staff who do not belong to the group mentioned above and who carry out their duties in working situation I must be screened by the qualified technologist/operator and informed about the potential risks. If there are practical reasons why this is not possible, these employees must follow a separate safety training course. This training must be tuned to match the local situation, the equipment at the site, and the activities performed.

Staff members who do not belong to the groups mentioned above and who may have to carry out their duties in working situations II or III must also have followed a training course about safety. Given the importance of safety, MRI operators must regularly receive refresher training regarding safety aspects (for further information, please refer to the ACR Guidance Document 2007[20]).

20 ACR Blue Ribbon Panel on MR Safety (Kanal et al.). ACR Guidance Document for Safe MR Practices: 2007. American Journal of Roentgenology, 188:1–27, June 2007.

Appendix 1
Members of the MRI Working Group

G. P. Krestin, MD, PhD
Radiological Society of the Netherlands (NVvR)
c/o Erasmus MC – University Medical Center Rotterdam, Radiology (Working Group chairman)

P. C. J. Leijh, PhD
Netherlands Federation of University Medical Centres (NFU)
c/o Leiden University Medical Center

P. Stubbs
Dutch Hospitals Association (NVZ)
c/o Medical Center 'Haaglanden'

A. van der Star, MSHE
Netherlands Federation of University Medical Centres (NFU)]
c/o UMC Grongingen, AVM/ Quality Development Department

S. Geers-van Gemeren
Netherlands Medical Imaging and Radiotherapy Association (NVMBR)

M. B. M. Hofman, PhD
Dutch Society for Medical Physics (NVKF)
c/o VUMC Amsterdam, Physics and Medical Technology

D. G. Norris, PhD
FC Donders Centre for Cognitive Neuroimaging

H. Engels, PhD
Philips Healthcare, MR Safety Director

A. Vermeulen
Ministry of Social Affairs and Employment
Working Conditions Directorate

M. J. M. Pruppers, PhD
National Institute of Public Health and the Environment (RIVM/LSO, Working Group secretary)

Appendix 2
Task and risk analysis for MRI staff

TYPE OF ROOM	WORKING SITUATION	ACTIVITY	RISK	MEASURES
adjacent working areas and corridors, outside the controlled access area	Various, no MRI application	access, longer presence, walking routes	sMF * < 0.5 mT	none
technical areas, outside the controlled access area	Various, no MRI application	maintenance	release of cryogenic gases	protect the quench pipe; warning signals; detection if required
			sMF< 0,5 mT	none
controlled access area: area outside the scanner room	Area where access is restricted for safety reasons	access	sMF> 0,5 mT	screening; instruction; access control; warning signals;
		administration; operation	sMF> 0,5 mT	none
		waiting	sMF> 0,5 mT	none
		cleaning	sMF> 0,5 mT	none
controlled access area: scanner room	Working situation I: situation in which a staff member has to carry out work in the scanner room while scanning is not taking place	accessing the room to position or fetch the patient, or to get people out of the scanner room in the event of a quench, or for maintenance	moving in a sMF	instruction; move slowly
			ferromagnetic projectiles	special tools; screening; instruction
			burning by liquid helium/ nitrogen	visual inspection; instruction
			release of helium	quench pipe; ventilation
	Working situation II: situation in which a staff member has to carry out work in the scanner room while scanning is taking place	monitoring / accompanying the patient	moving in a sMF	instruction; move slowly
			gF*	scanner switching restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			RF *	SAR scanner monitor restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			burns	screening (incl. clothing, loose metal objects)
			noise	ear protection equipment
			ferromagnetic projectiles	special tools; screening; instruction

* *sMF = static magnetic field, gF = switched gradient fields, RF = radio-frequency fields*

TYPE OF ROOM	WORKING SITUATION	ACTIVITY	RISK	MEASURES
controlled access area: scanner room (cont.)	Working situation III: situation in which a staff member is partly or entirely inside the scanner while scanning is being performed	interventions on the patient	moving in a sMF	instruction; move slowly
			gF	scanner switching restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			RF	SAR scanner monitor restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			burns	screening (incl. clothing, loose metal objects)
			noise	ear protection equipment
			ferromagnetic projectiles	special tools; screening; instruction
		repair	moving in a sMF	instruction; move slowly
			gF	scanner switching restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			RF	SAR scanner monitor restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			burns	screening (incl. clothing, loose metal objects)
			noise	ear protection equipment
			ferromagnetic projectiles	special tools; screening; instruction
			burning by liquid helium/nitrogen	visual inspection; instruction
			release of helium	quench pipe; ventilation
		preventive maintenance	gVF	scanner switching restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			RF	SAR scanner monitor restrictions; screening; instruction; keeping at a distance; limit duration of exposure
			burns	screening (incl. clothing, loose metal objects)
			noise	ear protection equipment
			ferromagnetic projectiles	special tools; screening; instruction

This document has been approved by
the following organisations:

Dutch Federation for University Medical Centers (NFU)
Dutch Society for Medical Imaging and Radiotherapy (NVMBR)
Dutch Society for Medical Physics (NVKF)
Dutch Hospitals Association (NVZ)
Radiological Society of the Netherlands (NVvR)
Holland Health Care Technology Association (HHT)

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for their collaboration:

Ministry of Social Affairs and Employment (SZW)
National Institute for Public Health and the Environment (RIVM)