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The EMF Directive and protection of MRI workers

Possible solutions

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This investigation has been performed by order and for the account of the Dutch Ministry of Social Affairs and Employment, within the framework of project "Protection of MRI Workers within the EU Directive - investigating possible solutions"

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Abstract

The EMF Directive and protection of MRI workers
Possible solutions

During a magnetic resonance imaging (MRI) scan, hospital personnel are sometimes exposed to electromagnetic fields stronger than is allowed according to the European Directive for workers. This is especially the case when a worker has to be close to a patient during scanning. By applying the latest scientific insights and by taking extra safety measures, there are possibilities to partially increase the exposure limits in the Directive. This increase could be applied in two different ways. The first is to partially increase the exposure limits in the Directive for all workers in the European Union than could potentially be exposed to electromagnetic fields. The second is to increase the exposure limits only for certain groups such as hospital workers or researchers, or for certain medical tasks. The European Directive has to be transposed into national law by 2012. Without these adjustments, certain MRI procedures could no longer be performed after that date. These are the results of an investigation by the National Institute for Public Health and the Environment in the Netherlands, at the request of the Dutch Ministry of Social Affairs and Employment.

MRI devices produce three types of field: a static magnetic field, a low frequency electromagnetic field and a radiofrequency electromagnetic field. A survey of scientific publications shows that the strength of the static and low frequency fields can be greater than the exposure limits in the workers Directive. The alternative strategies are possible because the exposure limits have a safety margin and additional safety measures are applied. The proposed general increase lies within this safety margin, would be accompanied by additional safety measures, and prevents tingling and nerve pain. Because of the extra safety measures, MRI workers could continue to perform their tasks but would still be adequately protected. The specific groups and exposure limits could either be defined in the Directive, or be agreed on in each employment sector by organisations representing workers and employers.

Key words:
electromagnetic fields, magnetic resonance imaging, regulation, workers, European Union

Rapport in het kort

De EMV-richtlijn en bescherming van MRI-personeel
Mogelijke oplossingen

Tijdens een MRI-scan wordt ziekenhuispersoneel soms aan sterkere elektromagnetische velden blootgesteld dan volgens de Europese richtlijn voor werknemers is toegestaan. Dit is vooral het geval als personeel tijdens een scan dicht bij een patiënt moet staan. Door het toepassen van de nieuwste wetenschappelijke inzichten en door extra veiligheidsmaatregelen zijn er mogelijkheden om de blootstellingslimieten in de richtlijn deels te verhogen. Deze versoepeling kan op twee manieren worden toegepast. De eerste is om de blootstellingslimieten deels te verhogen voor alle werknemers in de Europese Unie die aan elektromagnetische velden blootgesteld kunnen worden. De tweede is om deze limieten alleen te verhogen voor bepaalde groepen zoals ziekenhuispersoneel en onderzoekers, of voor bepaalde medische handelingen. De Europese richtlijn moet in 2012 in de nationale wetgeving zijn opgenomen. Zonder deze aanpassingen mogen bepaalde MRI-procedures niet meer worden uitgevoerd. Dit blijkt uit onderzoek dat het RIVM uitvoerde in opdracht van het ministerie van Sociale Zaken en Werkgelegenheid.

Apparatuur voor MRI (*magnetic resonance imaging*) produceert drie soorten elektromagnetische velden: een statisch magneetveld, een laagfrequent elektromagnetisch veld en een radiofrequent elektromagnetisch veld. Uit literatuuronderzoek blijkt dat de sterkte van het statische en laagfrequente veld groter kan zijn dan de blootstellingslimieten in de richtlijn voor werknemers. De alternatieve strategieën zijn mogelijk omdat de limieten een veiligheidsmarge hebben en extra veiligheidsmaatregelen aan de orde zijn. De voorgestelde versoepeling, in combinatie met extra veiligheidsmaatregelen, ligt binnen deze marge en voorkomt tintelingen en zenuwpijn. Door de extra veiligheidsmaatregelen kunnen werknemers hun taken blijven uitvoeren terwijl ze voldoende beschermd zijn. De specifieke groepen werknemers en limieten kunnen ofwel in de richtlijn worden beschreven, ofwel per bedrijfssector worden overeengekomen tussen de werkgevers- en werknemersorganisaties.

Trefwoorden:
elektromagnetische velden, MRI, regelgeving, werknemers, Europese Unie

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Preface

The contents of this report are the result of an investigation by the National Institute for Public Health and the Environment in the Netherlands, at the request of the Dutch Ministry for Social Affairs and Employment. Part 1 is meant as an overview for policy makers. Part 2 describes the fields generated by MRI, their possible health risks and the results of exposure measurements in more detail, with reference to the relevant research publications. Because of the importance of Magnetic Resonance Imaging (MRI) for healthcare, the discrepancies between the exposure limit values in Directive 2004/40/EC and actual worker exposure, and the limited possibilities for adjustment of MRI working practice to prevent overexposure, the focus in this report is on MRI workers. However, the analysis of possible solutions in the report provides a general framework that is also relevant for other professions and working environments. The options presented as alternatives for the current Directive are based on the published scientific literature until October 2008, interviews with relevant experts and stakeholders (appendix 2 and 3), and feedback received during a presentation of the results at a meeting of the Working Party "Electromagnetic Fields" of the EC Advisory Committee on Safety and Health at Work on 16 October 2008. Individual interviewees were given the opportunity to check a written summary of their statements for accuracy and completeness, and these corrected versions were used in writing the report. Because the information from the interviews was combined at a higher integration level, the scientific judgement presented in the final report does not necessarily represent the views of individual interviewees. I would like to thank all those who collaborated for their openness and many helpful suggestions, and hope that the findings will provide a constructive contribution to the decision process on a new EMF Directive.

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Abbreviations

CNS	central nervous system
Cenelec	Comité Européen de Normalisation Electrotechnique (European Committee for Electrotechnical Standardization)
EC	European Commission
EMF	electromagnetic field(s)
ESR	European Society of Radiology
EU	European Union
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IEEE	Institute of Electrical and Electronics Engineers
MRI	magnetic resonance imaging
NMR	nuclear magnetic resonance (magnetic resonance spectroscopy)
SAR	specific absorption rate

Part 1 Overview for policy makers

1 Introduction

On 29 April 2004 the European Parliament and Council of the European Union adopted Directive 2004/40/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) [1] (further to be called "Directive"), requiring member states to transpose it into national law within four years. The Directive states the obligations of employers to determine exposure and assess risks related to electromagnetic fields (EMF) in the workplace, to take measures to avoid such risks, to inform and train workers about the risks and to provide health surveillance of workers. The Directive also contains specific exposure limit values for EMF that shall not be exceeded for workers, as well as "action values", more easily measured properties of EMF that provide a first indication of whether exposure limit values might be exceeded.

Magnetic Resonance Imaging (MRI) is a medical diagnostic tool in which EMF are used to provide high-resolution images of soft tissues in the body. Manufacturers of MRI equipment raised concerns before its adoption that the Directive might limit the use of MRI in patient care and research. In March 2006 a delegation of radiologists and MRI scientists representing the European Society of Radiology (ESR) and other professional bodies met with the Employment and Social Affairs Commissioner and voiced their concern that the Directive would limit the use of MRI. A contact group of European Commission (EC) staff and ESR representatives was established to discuss the problem. Research instigated by the EC [2] and by the Health and Safety Executive in the United Kingdom [3] indicated that the exposure limit values in the Directive are exceeded in normal clinical use of MRI. The EC proposed to delay the transposition of the Directive in national law for four years until 30 April 2012 in anticipation of an amendment aimed at ensuring appropriate protection of workers without having an adverse impact on MRI [4]. The delay was approved by the European Parliament and Council on 23 April 2008 [5].

In the autumn of 2007 the Netherlands Ministry of Social Affairs and Employment asked the Laboratory for Radiation Research of the National Institute for Public Health and the Environment to investigate the degree to which the exposure limit values in the Directive are exceeded for MRI workers and to prepare a report listing possible solutions that adequately protect workers and still make the use of MRI possible. Firstly, an extensive analysis of the scientific literature on exposure measurements and possible health risks of the types of EMF used in MRI was performed. Secondly, scientific experts and stakeholders in the Netherlands and other member states were consulted about MRI working practice, worker exposure to EMF and possible alternatives to the Directive (Appendix 2 and 3). The possible solutions that emerged and their scientific rationale are presented in this report. Part 1 is meant as an overview for policy makers. Part 2 describes the fields generated by MRI, their possible health risks and the results of exposure measurements in more detail, with reference to the relevant research publications.

2 MRI worker exposure to EMF

2.1 Health risks of electromagnetic fields generated by MRI

Electric fields arise when there is a difference in electric potential between two locations. When the electric field changes in strength and direction, a magnetic field is induced that also changes in strength and direction. If the variations in the strength of the fields are regular, the speed of this variation is called the frequency. The unit of frequency is hertz. Because the variable electric and magnetic fields are closely linked, they are jointly called electromagnetic fields (EMF). The standard units in which the strength of the electric field are measured are volt per metre. The standard unit in which the flux density of the magnetic field is measured is tesla.

MRI devices produce three kinds of field. The first of these, the static field, is a magnetic field with a strength and direction that are constant in time. It is produced by a strong magnet and for the vast majority of systems it is always present unless the device is deliberately shut down for maintenance. The second kind, the gradient fields, are EMF with relatively low frequencies (several hundred to several thousand hertz) that are used to mark the location in the body where the magnetic resonance signal is produced. The third kind, the radiofrequency field, is an EMF with a relatively high frequency (between ten million and several hundred million hertz). It is used to transfer energy to the body, in response to which the body sends back a radiofrequency resonance signal that varies with the properties of the body's tissues and can be used to construct an anatomical image. The gradient and radiofrequency fields are only present when an MRI-scan is being made, or during certain development or maintenance procedures.

The main risks of the static field of MRI magnets are that it can attract metallic objects and turn them into projectiles, and that it can disturb electronic devices such as pacemakers. Apart from these indirect risks, since the body is mainly composed of fluids that are electrically charged, movements of the body in the static field can induce a time varying EMF in the body, which in turn can cause electrical currents to flow through the body. The gradient fields, which are time varying themselves, can induce EMF and currents in the body even when it is stationary. The EMF and currents generated in the body by gradient fields or movement in the static field could present a health risk if they are strong enough to affect the normal function of the nervous system and the heart. The energy deposited in the body by the radiofrequency field could present a health risk if it leads to a local or whole body temperature rise that can no longer be compensated by the body's normal regulatory mechanisms and leads to tissue damage.

2.2 Origin and nature of exposure limits

Various international bodies have developed guidelines for limiting the strength of EMF to prevent health risks. Higher limits are usually set for workers than for members of the general population, since workers are generally exposed under known conditions, are trained to be aware of the potential risks of EMF and take appropriate precautions, and are less variable in age and health status [6]. The two main international bodies that provide EMF guidelines are the International Commission on Non-Ionising Radiation Protection (ICNIRP) and the Institute of Electrical and Electronics Engineers (IEEE). The exposure limits for radiofrequency EMF of the two organisations are similar. The exposure limits for low frequency EMF differ both quantitatively and in the variables in which they are set. The ICNIRP

sets low frequency exposure limits in terms of the current density induced in the body [6]. The IEEE sets exposure limits in terms of the strength of the electric field induced in the body [7].

Neither the ICNIRP guidelines nor the IEEE guidelines are legally binding. However, the EU has chosen to base the exposure limit values in the Directive [1] and in its Recommendation for protection of the general public [8] on the guidelines provided by ICNIRP [6] and subsequent clarifications [9]. ICNIRP has also provided a guideline for protection of patients undergoing an MRI examination [10], which includes EMF exposure limits for patients that have been adopted in the European Standard for the safety of MRI equipment [11]. This standard is complied with by all manufacturers of MRI equipment. The more recent amendment 2 to the standard [12] introduces worker EMF exposure limits identical to patient exposure limits, but has not yet been harmonised as a European Standard. In the United States of America, The Food and Drug Administration has issued guidelines for patient exposure to MRI below the level where special approval must be sought for a research protocol [13]. Its advice on exposure limits is similar to that in the International Standard. Traditionally, Eastern European countries have used stricter guidelines with lower limits for both public and occupational exposure to EMF, mainly because they are based on the occurrence of biological effects in general, rather than only biological effects that pose health risks, and because they keep open the possibility of cumulative effects [14]. As a consequence, exposure limits in some Eastern European EU member states such as Poland are lower than those in the Directive [15].

The numerical limits for occupational exposure in the Directive are listed in two tables [1]. The first table contains "exposure limit values" derived from ICNIRP "basic restrictions". These are quantities that should not be exceeded in any circumstance. For low frequencies (up to 10 megahertz), exposure limit values are given as the maximal current density induced in the central nervous system in the head and trunk of the body. For higher frequencies (100 kilohertz to 10 gigahertz) exposure limit values are given as the maximal Specific Absorption Rate (SAR), the rate at which energy is deposited in the body per unit weight, resulting in heating. Separate SAR limits are given for whole body, for head and trunk, and for limbs, reflecting their differing capacities to store heat and different vulnerabilities for temperature change. For the highest frequencies (10 to 300 gigahertz), which do not penetrate deeply into the body, the exposure limit value is given as the maximal power density, the maximal rate at which energy reaches the skin per unit surface.

The second table contains "action values" derived from ICNIRP "reference levels". They are given in the physical properties of the EMF outside the body, which can be measured more easily than the variables used for the basic restrictions. Frequency-dependent action values are given for three interrelated properties of EMF: the electric field strength, the magnetic field strength and the magnetic flux density, and for frequencies higher than 10 megahertz also as the plane wave power density. When the measured properties of the EMF in the workplace are below the action values, no further action is necessary. When they exceed one or more of the action values, further calculations are necessary to determine whether the exposure limit values are exceeded. The exposure limit and action values in the two tables only apply to EMF whose strength shows a sinus-shaped variation in time. For EMF whose strength shows a more complex variation in time, such as the MRI gradient fields, the Directive states that "appropriate methods of assessment, measurement and/or calculation capable of analysing the characteristics of the waveforms and nature of biological interactions have to be applied, taking account of European harmonised standards developed by Cenelec" [1].

2.3 MRI worker exposure in relation to exposure limits

This paragraph summarises the main findings of exposure measurements near MRI devices in relation to the exposure limit and action values in the Directive. A more detailed discussion which includes references to the relevant scientific literature can be found in chapter 8.

2.3.1 Static field

Although ICNIRP has issued guidelines for limiting worker exposure to static magnetic fields [16], which are expected to be updated in 2009, there is no exposure limit value for static fields in the Directive. There still is an action value (0.2 tesla) in the Directive for the magnetic flux density of EMF with a frequency of 0 to 1 hertz, which strictly speaking includes static fields. Although this action value seems to derive from the 1994 ICNIRP static field guidelines, it omits ICNIRP's clause that it should be treated as an average over the whole working day. For instantaneous exposure, the action value for the static field in the Directive is exceeded closer than half a metre to the end of the bore of most MRI magnets. In current routine working practice, the action value is not exceeded by MRI workers if the exposure is averaged over the working day.

2.3.2 Movement in the static field

The Directive does not state whether it applies to EMF induced in the body as a result of movement in the static field. This would be logical, since the effect on the body is exactly the same as that caused by a very low frequency external EMF. When workers move in the static field at normal speed closer than half a metre from the end of the MRI magnet bore, the action values in the Directive can be exceeded. When the current induced in the central nervous system is calculated using computer simulations, it can exceed the exposure limit values in the Directive when moving close to or into the bore end of the MRI magnet.

2.3.3 Gradient fields (low frequency EMF)

Since the EMF produced by the MRI gradients do not show a sinus-shaped variation in time, the action values in the Directive are not directly applicable. One solution for an alternative action value is to calculate a maximal rate of change of the magnetic flux density (dB/dt) in the rapid rising phase of the gradient field strength, using the current density exposure limit values in the Directive as a basis and making certain assumptions about the shape and electrical conductivity of the body. When the assumptions of ICNIRP [17] are used, the calculated maximum dB/dt value for the gradient fields is exceeded when workers are closer than half a metre to the end of the MRI magnet bore during scanning. However, when the nerve stimulation threshold is used to calculate a maximum dB/dt value, it is unlikely that these action values are exceeded outside the magnet bore. When the maximum dB/dt value is exceeded, more detailed calculations are necessary to determine whether the exposure limit value is exceeded. Computer simulations indicate that the current density induced by the gradients fields in the central nervous system exceeds the exposure limit value in the Directive when the worker's head or trunk is next to or inside the end of the magnet bore.

2.3.4 Radiofrequency field (high frequency EMF)

For the MRI radiofrequency field, the action value in the Directive can be exceeded just outside the bore end of the magnet. When the Specific Absorption Rate is calculated, however, it does not exceed the exposure limit value in the Directive, except for the situation when a worker's whole body is located inside the magnet bore. The radiofrequency exposure can be close to the exposure limit value in the Directive when a worker has to bend the head into the bore end of the magnet during an intervention, but will only exceed the exposure limit value if the exposure lasts longer than a few minutes.

2.3.5 Laboratory animal MRI

Special MRI systems with a smaller diameter bore have been developed to produce images of small laboratory animals such as rats and mice. However, the combination of a smaller bore and strong shielding of the magnet means that the strength of the gradient and radiofrequency fields outside the magnet bore will generally remain under the action values in the Directive. If the 0.2 tesla action value in the Directive is applied to the static field without averaging exposure over the working day, it can be exceeded closer than half a metre from the bore end of the magnet. Note that animal experiments are sometimes performed in clinical MRI devices, in which case the previous four paragraphs apply.

2.3.6 Magnetic resonance spectroscopy

The principle of magnetic resonance can also be applied to study the molecular composition of chemical or biological samples. This technique is called magnetic resonance spectroscopy, but is often denoted by the more general historical term 'nuclear magnetic resonance' (NMR). Unlike MRI devices, devices dedicated to spectroscopy generally have no gradient fields, are strongly shielded, and are closed off during scanning. The action values for the static field and radiofrequency field in the Directive are not exceeded outside such spectroscopy devices, except for the moment when samples are placed in the device by a worker, when the static field action value of 0.2 tesla may be exceeded.

Apart from the dedicated spectroscopy devices described above, the technique of magnetic resonance spectroscopy is sometimes combined with MRI in the same scanner for patients, volunteers or laboratory animals. The basic scanning protocols that are used for the spectroscopy part of such a scan are unlikely to increase EMF exposure above the level used for MRI. In these situations, the previous five paragraphs apply.

3 MRI in the Netherlands

3.1 Overview of working practice

Interviews were held with medical specialists, MRI physicists and technicians, and safety officers of four university hospitals, one general hospital, two university research departments (one clinical, one preclinical), one veterinary MRI facility, a manufacturer of clinical MRI systems and a representative of a professional organisation for MRI technicians in the Netherlands (Appendix 3). From this sample, which is biased towards academic institutions and therefore not representative for all hospitals, a general picture of MRI working practice emerges. All worker categories (nurse/technician, radiologist, surgeon, anaesthetist, cleaner, scientist and system developer) are exposed to the static field, often on a daily basis. Movement-related symptoms such as vertigo are only reported near clinical systems with a static field of 3 tesla or higher. Only the nurse/technician, anaesthetist, scientist and system developer are occasionally exposed to gradient fields within half a metre of the bore end of the magnet. Only the nurse/technician and system developer are occasionally exposed to the radiofrequency field when they are inside the magnet bore during a test scan. Interventions during MRI are not currently performed in the Netherlands, but will start in the course of 2008 in one university hospital. In these procedures, the surgeon/radiologist stands at the bore end for a maximum of 5 minutes, during which he/she will briefly (seconds) bend into the magnet bore where head and arms will be exposed to all three MRI fields. MRI scanners for veterinary use generally have relatively weak static fields (0.3 tesla or less). Animals are usually scanned under anaesthesia and workers do not have to come closer than two metres to the magnet bore during scanning.

There is a wide variety of local MRI safety protocols and instructions and rules for cleaners, firefighters and pregnant workers. MRI safety instructions range from a combination of mandatory written and video instructions and a system of certified users to only a verbal check on metal objects or implants. Safety instructions for cleaners and emergency personnel such as firefighters vary from "cleaning performed by trained MRI technicians" or "local safety instruction of cleaners" to "training left to commercial cleaning company". Rules for pregnant MRI workers also vary, from "forbidden to enter MRI room" to "pregnant worker's choices are respected". In roughly half of the institutions interviewed, worker exposure to gradient and radiofrequency EMF inside the magnet bore for testing of scanning protocols is not demonstrably voluntary or covered by a protocol approved by the local medical ethics committee.

3.2 Need for standardisation: national working group consensus

A protocol for safe use of MRI was developed in 2008 by a national consensus working group with representatives of stakeholder organisations (universities, general hospitals, MRI equipment manufacturer, professional societies for radiologists, for radiological technicians and for medical physicists). Implementation of the protocol would remedy the variability in safety protocols and instructions reported under 3.1[18]. It contains detailed descriptions of all the risks associated with working with MRI, including EMF, noise, metal projectiles, and liquids used to cool the magnet. It recommends organisational and behavioural measures aimed at minimising those risks. Measures are subdivided according to three exposure situations: in the scanner room while scanning is not taking place; in the scanner room during scanning; inside the scanner (magnet bore) during scanning.

Recommendations are also made for strictly voluntary procedures for test scans on workers and for education, training and instructions of dedicated MRI workers. The authors state that if the rules in the protocol are followed, the safety of workers is sufficiently guaranteed in current practice and according to current scientific understanding. They conclude that minimum safety requirements for EMF in any future version of the Directive should make current working practice described in the protocol possible. The protocol has been endorsed by the following organisations: Radiological Society of the Netherlands; Dutch Society for Medical Imaging and Radiotherapy; Dutch Federation of University Medical Centers; Dutch Society for Medical Physics; Dutch Hospitals Association; Holland Health Care Technology Association.

4 Possible solutions: adequate protection of workers while enabling MRI

4.1 Optimisation of current MRI practice

4.1.1 Reduction of static field shielding

Shielding of the magnet limits the size of the static magnetic field outside many modern MRI scanners, so that the area where medical implants such as pacemakers may be influenced is as small as possible. Another advantage of this shielding is that it reduces the distance over which metal objects can be accelerated and become dangerous projectiles. A disadvantage of shielding is that it induces a zone close to the scanner where the strength of the static field shows a very big drop over a short distance. Movement in that zone is likely to induce electric currents in the body that exceed the exposure limit values in the Directive and may cause symptoms such as vertigo.

It is technically possible to reduce the strength of the shielding at the expense of reserving a larger space for the magnet room. This is expected to reduce symptoms, but cannot guarantee that movement-induced currents remain under the exposure limit values in the Directive. It also has two disadvantages:
a) Increased projectile risk: metal objects can be accelerated over a greater distance and thus reach greater speeds.
b) It would be mainly applicable to new, rather than existing, MRI systems, and to planned, rather than existing, MRI facilities.

4.1.2 Reduction of gradient field strength

In theory, gradient field strength could be reduced so that worker exposure remains below the existing exposure limit values in the Directive. This would have to happen in those situations where the worker performs a task in close proximity to the patient.

There are several objections to this option:
a) It is precisely in the situation when the MRI worker is close to the patient that fast scanning and steeply rising gradients are necessary. Examples are interventions when a moving biopsy needle must be tracked and imaging of blood vessels and of the beating heart during catheterisation.
b) MRI system developers already try to limit gradient field strength as far as practical for a certain imaging routine, since unnecessarily strong fields cost more energy.
c) It would be technically difficult to make such adjustments in existing systems in hospitals.

4.1.3 Improved scanner environment and working routines

The design of the MRI scanner and its environment and the working routines of MRI workers could be adjusted to reduce the need for their exposure to EMF at a level above the existing exposure limit values in the Directive. A number of these measures are already applied in many institutions, especially in university hospitals. Examples of such adjustments are:

- using automated injectors for injection of patients or volunteers during scanning
- making the control panel moveable so it can be placed at a greater distance from the end of the magnet bore

- mounting the radiofrequency coils on the moveable patient table so workers do not have to crawl into the magnet bore
- improving the design of magnet bore or of cleaning equipment so cleaning can be conducted by workers without having to crawl into the bore
- using disposable sheets under the patient to prevent fouling and having to clean the magnet bore
- using a mirror for inspection of patient or objects inside the magnet bore
- avoiding unintended use of MRI equipment such as having a second person (worker) in the magnet bore to accompany an anxious patient
- instructing workers on the fact that limiting the speed of movement near the bore end of the scanner may help prevent symptoms such as nausea and vertigo
- stimulating the use of robots for interventions during scanning
- standardising training and instruction of MRI workers about the risks associated with EMF
- clear indication and access regulation of areas where high levels of EMF exposure can be expected

Although these measures can reduce the number of workers that are exposed to EMF levels above the present exposure limit values in the Directive, there are several limitations to this option:
a) In hospitals, circumstances when the worker has to move fast or be close to the scanner can still occur, for example when the patient suddenly becomes unstable, when a family member who would accompany the patient does not show up, when an anaesthetist has to check the eyes or breathing of a patient during scanning, or during surgical or therapeutic interventions. Examples of interventions during scanning that lead to improved precision and reduced risk for the patient are localised drug delivery [19], localised destruction of tumours [20], taking a biopsy [21], vascular interventions [22] and brain surgery [23].
b) In research on patients or volunteers, it is not always possible to automate all measurement and testing routines which require a worker to sit next to the subject.
c) Developers and service engineers of MRI equipment sometimes have to be close to or inside the magnet bore to perform tests or make adjustments during scanning.
d) Recent developments in MRI scanner design tend to increase rather than decrease worker exposure to EMF: the length of the magnet bore is becoming shorter and its diameter wider, both to improve patient comfort and prevent claustrophobia.
e) Limiting the speed of workers in static field to prevent movement-induced currents above the exposure limit values is difficult to control because these currents do not necessarily cause notable symptoms, and may not be sufficient to reduce induced current to a level below the present exposure limit values in the Directive.

4.2 Alternative values for exposure limit and action values in the Directive

4.2.1 Static field exposure limit values

A minimal solution would be to specify that the 0.2 tesla action value should be averaged over a working day, in line with 1994 ICNIRP guideline for static fields from which it is derived. However, the scientific basis for such a working day average is weak, since there is currently no evidence for cumulative effects of exposure. It would therefore be more logical to introduce a static field exposure limit value in line with the new draft ICNIRP guideline for static fields [24]. For static fields, ICNIRP does not distinguish between exposure limit value and action value. There is a variety of biological mechanisms via which static fields could theoretically influence the body in ways that carry a potential health risk. The exposure limits are therefore set in terms of the flux density of the ambient magnetic field. Based on the new draft ICNIRP guidelines [24], these exposure limits would be: 2 tesla for head

and trunk, 8 tesla for head and trunk in a controlled environment, and 14 tesla for limbs. The controlled environment would be a working environment where appropriate working practices are implemented to control effects of movement in the static field such as vertigo and nausea. The controlled environment is therefore applicable to MRI workers. Its upper exposure limit is unlikely to be exceeded in currently available clinical MRI systems, but it may be that special provisions have to be made for research and development on systems with a static field greater than 8 tesla. It should be pointed out that a proposed amendment to the European Standard for MRI equipment has an upper limit of 4 tesla for workers in the controlled environment [12], which would have to be harmonised with a higher static field exposure limit in the Directive.

It should be stressed that these exposure limits are set to avoid certain effects on a precautionary basis, in the absence of firm data showing at which flux density of the static field the effects become large enough to carry a health risk (see section 6.1). There are therefore two options:

1. Omit static field exposure limit values from the Directive or provide guidance about limits on a voluntary basis, pending further research on health risks at high static field strength. This option leaves open the possibility of providing recommendations on an individual basis, since the threshold for movement-induced symptoms varies considerably.

2. Provide mandatory static field exposure limit values in the Directive, for example according to draft ICNIRP guidelines [24], but evaluate them regularly and allow for a rapid mechanism to adjust the limits when further scientific evidence about health risks becomes available.

For either option, the action value in the Directive which is now given for EMF in the frequency range of 0 to 1 hertz will have to be made applicable to frequencies greater than 0 hertz, that is it will have to exclude static fields.

4.2.2 Low frequency exposure limit values and movement-induced current

At present the Directive does not specify whether the exposure limit values should be applied to EMF that are induced in the body by movement of the worker in a static field. A blanket exemption of movement-induced EMF from the Directive is problematic for three reasons:

a) In terms of physical and biological effects, there is no fundamental difference between the EMF induced in the body by movement in a static field and that induced in a stationary body by a variable external EMF.
b) In normal MRI working practice, it is movement in the static field rather than the variable EMF of the gradients that sometimes causes perceptible effects on the body, causing problems in acceptance of any blanket exemption by workers.
c) Perception of movement-induced symptoms by some workers may lead to future legal challenges to any exclusion from the Directive.

In the light of the above, there are two options for dealing with movement-induced currents in the Directive:

1. Provide a clarification in the Directive stating that low frequency exposure limit values are not to be applied to EMF induced in the body by movement in a static field. Instead, exposure limit values for static field flux density are set to cover effects from movement in a static field (see section 4.2.1).

2. Provide a clarification in the Directive stating that low frequency exposure limit values are applicable to EMF induced by movement in the static field, and that movement-induced effects have been considered in setting these limits (see section 4.2.3).

Option 1 has the drawback that the strength of the induced currents is determined not just by the static field flux density, but by a combination of the speed of movement in the static field and the steepness of the decrease in flux density with increasing distance to the scanner. For option 2 it can not be excluded that movement-induced currents in the body will exceed the exposure limit values for low frequency EMF.

4.2.3 Low frequency exposure limit values and gradient fields

The exposure limit values in the Directive in terms of induced current density for frequencies up to 10 megahertz are based on the 1998 ICNIRP guidelines [6]. The scientific literature on which these guidelines are based dates from the early 1990s and earlier. Based on more recent scientific insights there is reason to update low frequency current density limits. There are two main options for amending the Directive:

1. Increase the exposure limit value for current density in nervous system of head and trunk above 20 hertz. This limit was mainly based on the risk for induction of magnetophosphenes (light flashes in the eyes). These can be disturbing or cause a startle reaction, but the effect rapidly falls off above a frequency of 20 hertz. Using stimulation of nerves as a basis for frequencies above 20 hertz, and applying safety factors because of gaps in the data, the Health Council of the Netherlands proposes exposure limit values of 10 milliampère per square metre up to 20 hertz, then rising to 100 milliampère per square metre at 200 hertz, and rising again to 250 ampère per square metre between 4 kilohertz and 10 megahertz [25].

2. Introduce a higher exposure limit value for current density in nervous system of head and trunk, based on the threshold for nerve fibre stimulation without an extra safety margin for other effects whose relevance for health is unclear (magnetophosphenes, electrical stimulation of cell bodies in the central nervous system). Translated to current density, the threshold for nerve stimulation would lie in the order of approximately 1000 milliampère per square metre for all frequencies up to 10 kilohertz.

It is expected that option 1 will substantially decrease the number of situations in MRI working practice where exposure limit values will be exceeded. However, it can not be excluded that the new exposure limit values will be exceeded in situations where the worker's body is (partially) located inside the MRI magnet bore during scanning. It is unlikely that the current density limit under option 2 will be exceeded for MRI workers.

Two other issues will have to be addressed in an amended Directive:
a) At present the Directive states that higher current densities may be permitted outside the central nervous system (brain and spinal cord), but it does not specify how high and in what tissues. Most relevant for health risks would be a specification of a limit for peripheral nerves, and a limit for heart muscle which would be higher than that for nerves.
b) At present the Directive requires that, for purposes of comparison with exposure limit values, the induced current has to be calculated for one square centimetre of homogeneous tissue. Provisions need to be made for areas such as the spinal cord where cross-sections of homogeneous nervous tissue are often smaller than one square centimetre, leading to overestimation of current density in nervous tissue [26].

4.2.4 Low frequency action values and gradient fields

In general, action values (electric and magnetic field strength, magnetic flux density) should be increased to correspond with higher exposure limit values, for example following the line of reasoning employed in the 1998 ICNIRP guidelines [6]. For MRI gradient fields and for pulsed fields in general, however, separate action values should be set in terms of the speed of change in magnetic flux density (dB/dt; see section 4.3.2).

4.2.5 High frequency exposure limit values and radiofrequency field

The high frequency exposure limit values in the Directive, set in terms of power absorption by the body (specific absorption rate, SAR), are generally accepted to have a firm scientific basis. They are not exceeded in any MRI working routine including bending into the magnet bore for interventions, provided such exposure does not last longer than a few minutes. There is therefore no present need for any change in the Directive, provided that longer lasting, whole body exposure of workers in the magnet bore occurs on a strictly voluntary basis, preferably using an informed consent procedure.

In the future, the use of MRI scanners with a ultra-high static field (7 tesla and higher) will probably increase and could then be used for routine clinical scanning, that is scanning outside research protocols overseen by a medical ethics committee. Such ultra-high fields also require higher frequencies of the radiofrequency field which are associated with more efficient coupling of EMF to the body. This can potentially lead to greater and less homogeneous power deposition in the body of workers ('hot spots'). Research into conditions for, and effects of, local heating is still ongoing. It may therefore be prudent to re-assess high frequency exposure limit values in the Directive at a later date when more data are available.

4.2.6 Procedures for future revision of exposure limit values

Sections 4.2.1 to 4.2.5 suggest alternatives for the exposure limit values in the Directive, based on current scientific knowledge. It is possible that new scientific knowledge will necessitate changes in the exact exposure limit values or action values at a future date. This would require following official procedures for amending the Directive which may take up to four years. A faster alternative would be to keep the structure of the main text of the Directive, but periodically revise the annex with exposure limit values and action values, following procedures similar to those laid our in article 3, paragraph 2 and article 12, paragraph 1 of Council directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work [27]. However, this would require that exposure limit values be defined as indicative, rather than binding.

4.3 Alternative variables for exposure limit and action values in the Directive

4.3.1 Induced electric field strength limit for low frequencies

The mechanism by which nerve cells are stimulated is a change in the voltage across the cell's membrane. The degree of nerve cell stimulation by an external EMF is therefore determined by the strength of the electric field that the EMF induces in the body. Although differences in the strength of the induced electric field between different parts of the body may result in electrical currents, the calculation of the current density requires assumptions on tissue conductivity which increase the uncertainty in setting exposure limit values. Using the induced electric field would also solve the tissue

averaging problem described under 4.2.3. b). The IEEE has opted to set low frequency exposure limits in its guidelines in terms of the induced electric field [7]. There are indications that ICNIRP is also considering switching to this variable in its next update of low frequency EMF guidelines. The IEEE exposure limit values ("basic restrictions") are frequency-dependent, but are generally lower for the brain than for nerves and muscles in the rest of the body, based on effects with a low threshold such as magnetophosphenes. There are two main options for amending the Directive:

1. Set low frequency exposure limit values in terms of electric field strength induced in the body, using either the IEEE or the updated ICNIRP guidelines (which may prove to be similar). This would include a lower threshold for the brain than for the rest of the body, based on limitations in scientific understanding of low threshold effects.

2. Set low frequency exposure limit values in terms of electric field strength induced in the body, using only the well-characterised risk for stimulation of nerve fibres. Stimulation of nerve fibres may result in unpleasant sensations or pain, which can be considered to be negative health effects.

In the case of option 1, it is expected that worker exposure to the MRI gradient fields near or in the bore end of the magnet will result in an induced electric field in the brain ranging from somewhat below to more than ten times above IEEE exposure limits, depending on modelling assumptions. The electric field induced in the body by movement in the static field is likely to exceed IEEE limit for the brain. The exposure limit values for other parts of the body are unlikely to be exceeded.

In the case of option 2, MRI worker exposure to gradient fields or movement-induced fields is unlikely to exceed the exposure limit values. The limits for nerve fibre stimulation are higher than the precautionary limits set for stimulation of nerve cell bodies in the eyes and brain. Some caution is necessary in setting the exact limits, since most of the data on nerve fibre stimulation are based on a person lying in the magnet bore, for whom the distribution of the induced electric field in the body may be different from that in a worker standing next to, or bending into, the bore end (see 4.3.2, option 4).

4.3.2 Action values for pulsed fields

The action values in the directive are only specified for EMF whose variation in time is sinus-shaped. The variation in strength of the EMF of the MRI gradients is not sinus-shaped, but increases rapidly during pulses, which are interrupted by periods when EMF strength goes back to zero. The relevant property of the pulsed EMF that determines the effect on the body (the induced electric field and current density) is the rate of change in magnetic flux density over time during a pulse (abbreviated as dB/dt). There is a direct relationship between dB/dt and the strength of the electric field induced in the body, and thus with the main biological effect (stimulation of nerve cells). The duration of the pulses is also important, because longer pulses are more likely to stimulate nerve fibres. The dB/dt can be directly measured with appropriate detectors.

In its present form, the Directive states: "With regard to pulsed or transient electromagnetic fields [...] appropriate methods of assessment, measurement and/or calculation capable of analysing the characteristics of the waveforms and nature of biological interactions have to be applied, taking account of harmonised European standards developed by Cenelec." There are four main options for specific methods to set action values for pulsed fields in terms of dB/dt:

1. Calculate action values for pulsed fields according to 2003 ICNIRP guidance [17]. This method uses the present (ICNIRP) current density limits in the Directive and assumptions about tissue conductivity to calculate a dB/dt action value that increases with frequency.

2. Calculate action values for pulsed fields according to IEEE guidance [7]. This method uses the IEEE action value ("maximum permissible exposure level") for flux density of the ambient magnetic field and the pulse duration to calculate a dB/dt limit. IEEE action values are related to the IEEE exposure limits for the strength of the electric field induced in the body (see 4.3.1).

3. Calculate action values for pulsed fields according to methods applied in German sector safety rules for EMF [28-30]. These are mainly based on the risk of stimulation of nerve fibres. The exact action value depends on the pulse duration.

4. Calculate action values for pulsed fields according to the risk for uncomfortable or painful peripheral nerve stimulation. The exact action value depends on the pulse duration. The International Standard for MRI equipment advises the same action value for workers and patients [12]. The Health Council of the Netherlands advises an additional safety factor for workers, resulting in a dB/dt action value that is 50% lower than that for patients [31].

In the case of option 1, the dB/dt action values calculated from the exposure limit values in the Directive are exceeded for MRI gradient fields close to and inside the magnet bore. Option 1 has two other disadvantages: it does not take the duration of the pulse into account (which determines the efficiency of its effect on nerves) and it uses an extremely conservative model to relate current density to dB/dt, resulting in overestimation of the current density associated with a given dB/dt.

In the case of option 2, the dB/dt action values calculated from the IEEE flux density action values and pulse duration are exceeded close to and inside the magnet bore, though less frequently and in a smaller area than the ICNIRP action values under option 1.

In the case of option 3, the dB/dt action values also vary with the duration of the pulses. For frequencies between 1 and 1000 hertz, the dB/dt action value would be exceeded for long duration pulses, but not for short duration pulses. However, the reference document for option 3 [29] also has the provision that the action value may be further increased to an unspecified extent in MRI locations, provided that a safety analysis is performed and expert or medical supervision is provided. Thus, the upper limit of the action value would only be restricted by whether exposure limit values in the Directive are exceeded, requiring complex calculations.

In the case of option 4, the dB/dt action value would only be exceeded inside the MRI magnet bore. Option 4 has two disadvantages. Firstly, it uses conscious perception of peripheral nerve stimulation as the basis for setting an action value, ignoring the possibility of health risks from nerve stimulation that is not consciously perceptible. Secondly, the measurement data on which the International Standard bases its dB/dt limit concern persons lying in the magnet bore, for whom the greatest strength of the induced electric field occurs in the periphery rather than the core of the body. The distribution of the induced electric field in the body may be different for workers standing next to the bore end. These two uncertainties lend support to the additional safety factor of 50% advised by the Health Council of the Netherlands [31].

It should be stressed that if the dB/dt action values are exceeded, this does not necessarily mean that exposure limit values for induced current or electric field are exceeded. More detailed calculations are needed to determine this.

4.4 Two-level exposure limits

A fourth type of solution, which could be applied in combination with one of the options in the previous paragraphs, would be to set higher exposure limit values for certain categories of workers or for certain tasks than for workers in general, based on a case-by-case risk/benefit analysis. The main motivation is that, due to the nature of EMF risks and the wide safety margins employed in setting exposure limit values, there is no sharp boundary between high, potentially harmful and low, intrinsically harmless EMF strengths [25,32]. Although the basic principle is still that all workers have equivalent protection from the risks of EMF exposure, higher exposure limit values are set in specific situations in which worker protection is guaranteed by additional control measures.

The two main options are:

1. Application of higher exposure limit values to certain *categories of workers* from the general exposure limit values in the Directive, based on the acute and reversible nature of the effects on the body, in combination with measures such as a highly controlled working environment, training and instruction, documented personal risk assessment and medical supervision.

2. Application of higher exposure limit values for certain *tasks* from the general exposure limit values in the Directive, based on the acute and reversible nature of the effects on the body, in combination with measures such as a highly controlled working environment, training and instruction, documented personal risk assessment and medical supervision.

An example of a worker category for option 1 would be "MRI worker". Examples of tasks for option 2 would be "bend into MRI magnet bore to check patient vital signs", "assist anxious or unstable patient in MRI magnet bore" or "bend into MRI magnet bore to perform a brief surgical intervention". A higher exposure limit value for surgical interventions alone is unlikely to be sufficient to cover all possibilities. In both options, a higher exposure limit value could be set based on the known risk of stimulation of nerve fibres. Such a limit is unlikely to be exceeded in any working routine with MRI scanners that are presently in use. The lower exposure limit value could be set based on a precautionary basis to guard against low-threshold effects on the brain for which the relevance for health is still unclear. In this case, EC guidelines on the use of the precautionary principle could be applied [33]. Any EMF exposure at levels between this higher limit and the lower precautionary limit in the Directive could be allowed in specified cases on the basis of a risk/benefit analysis.

4.5 Minimised Directive and social sector agreements

Even if the proposed solutions enable safe working practice with MRI under the present conditions, it can not be guaranteed that they will do so indefinitely. Technological development is rapid and likely to lead to further increases in static field strength and radiofrequency energy and to more widespread use of interventional MRI. Little is known about possible long-term effects of exposure and detailed statistics about degree and duration of worker exposure in the sector as a whole are lacking. Research has been initiated that addresses these gaps in scientific understanding of EMF risks. Such information is necessary if clear risk analyses and regulatory procedures are to be implemented, as they have been for the risks of worker exposure to chemicals. Any legislation with fixed exposure limit values may therefore be premature or will soon be outdated, and the willingness of the sector to invest in adaptations of working environment may be limited. It would therefore be prudent to consider ways of

dealing with future scientific developments that lead to a reassessment of health risks of EMF, or with technological developments that increase EMF exposure of workers.

One possibility for a more flexible system that addresses these concerns is to describe general considerations for protection of workers in a minimised ("skeleton") directive or guideline, but leave specifications including exposure limit values to international sector-specific bodies with specialist knowledge about the particular working conditions in that sector. The original idea for a more self-regulating system derives from an advisory report to the British government on safety and health at work [34]. One possible regulatory sector would be hospitals and research facilities, covering medical and scientific applications of EMF. Such bodies could contain representatives from workers, employers and government and relevant exposure experts. They would weigh the risks of the specific source, frequency and shape of the EMF involved against worker training and health monitoring, relevance for public health, economic impact, regulation pressure etc. Such a weighing of risks against benefits would be in line with ICNIRP's general approach for protection against EMF, which recognises that when beneficial health effects or other benefits of EMF are involved, a balanced judgement has to be made as to how the exposure limits are used in societal policies [35].

This approach would take into account the fact that there is a wide variety between sectors in the degree of worker training and specialisation, worker health monitoring and controlled access to areas of increased exposure. The upcoming EU regulatory impact assessment for the Directive could help define the conditions for such an approach. It would also be possible to include other risks from EMF-generating equipment in a social sector agreement. In the case of MRI this would concern risks of metal projectiles, noise and cooling liquids. This approach would also be in line with the EC's strategy on health and safety at work for 2007-2012, which invites initiatives from the social partners in the context of social sector dialogue and in ensuring a greater role of workers in the systematic management of occupational risks [36].

The technical developments in applications that generate EMF are rapid and scientific understanding of the risks of EMF is still evolving. It would therefore be useful to include a mechanism for re-assessment of risks and adjustment of specific limits or behavioural rules based on new scientific insights. The mechanism for such adjustments on the level of European directives or guidelines is relatively slow and complicated (but see section 4.2.6). Adjustments on the level of an existing social sector agreement are likely to be faster and more flexible. Regulation of EMF exposure on a social sector level may also provide a possibility to allow a role for individual assessment of sensitivity to symptoms, for example for those symptoms related to movement in a static field, and for rules that cover workers volunteering for test scans that are needed to optimise MRI protocols.

Part 2 Scientific background

5 Types of electromagnetic field generated by MRI

5.1 Static field

Devices for magnetic resonance imaging (MRI) used in patient care and research generate three types of electromagnetic field (EMF). For most devices, the static field is always present unless the device is deliberately shut down for maintenance, and has a fixed strength and direction. The magnetic flux density of the static field usually ranges between 0.5 and 4 tesla for devices routinely used in clinical care, but can reach 11 tesla for devices used only for research and development. The purpose of the static field is to align the directions of magnetic spin of the nuclei of hydrogen atoms in the body to the direction of the static field. Since electrical currents are induced in conductors that move in a static magnetic field, and the blood and tissues can conduct electricity, movement of the body in a static field can generate electrical fields and currents in the body that may influence the function of muscles, nerves and sensory organs [37].

5.2 Gradient fields

The gradient fields are time-varying magnetic fields that are superimposed on the static field to produce small linear variations in magnetic flux density along the three dimensions of the body: left-right (x-gradient), anterior-posterior or front-back (y-gradient) and rostral-caudal or head-feet (z-gradient). These spatial variations in flux density enable the magnetic resonance signal to be localised to specific parts of the body. The strength of the gradient fields fluctuates over time, because the technique used to mark the three-dimensional position of hydrogen nuclei in the body requires the gradient field to be switched on and off in rapid succession. A time-varying magnetic field with a relatively low frequency can generate an electrical field and current in a conductor. Since blood and tissues can conduct electricity, the time-varying (switching) gradient fields can generate electrical fields and currents that may influence the function of muscles and nerves. The rapidly switching gradient field also induces vibrations in the gradient coils that generate acoustic noise [38] .

5.3 Radiofrequency field

The time-varying radiofrequency field is emitted by a radiofrequency coil inside the magnet bore. Pulses of radiofrequency energy emitted by the coil cause nuclear spins of hydrogen nuclei in the body to change direction, away from the longitudinal axis of the static field. With a certain time delay, these nuclear spins then spontaneously re-align themselves with the direction of the static field, emitting energy in the form of radiofrequency EMF (magnetic resonance). Since the time delay depends on tissue properties, the amount of radiofrequency energy emitted in a small time period varies between different kinds of tissue, generating contrast. The energy needed to change the direction of nuclear spins increases with the flux density of the static field. Hence, the frequency needed for radiofrequency pulses also increases with the static field flux density, as does the amount of energy deposited in the body as heat [39]. For magnetic resonance spectroscopy, where the aim is to determine the concentration of specific molecules in the body, hydrogen nuclei are usually targeted but heavier nuclei with a lower resonance frequency can also be investigated [40]. In that case, the amount of energy deposited in the body will also be lower.

6 Possible health effects of electromagnetic fields generated by MRI

This section is not meant as an exhaustive review of the literature, but serves to highlight the most important biological effects with a possible health risk. Recent overviews can be found in the World Health Organisation's Environmental Health Criteria for static fields [41] and low frequency EMF [42].The focus is on human subjects. Indirect health risks resulting from interactions with metal implants or medical devices are not considered here.

6.1 Static field

Plausible mechanisms for possible acute health effects of the static magnetic field associated with MRI mainly involve differences in magnetic susceptibility between tissues and the induction of electric fields and currents in the body. Such fields and currents can arise either when the entire body moves in the static field, or because electrically conducting tissues move within the body (blood, heart muscle). If they are strong enough, these fields could either interfere with the function of electrically excitable tissues such as heart and nerves or induce a force that opposes the flow of blood from the heart to the body tissues [43]. So far, no effects on heart rate, cardiac arrhythmias or blood flow that may pose a health risk have been reported near magnets of up to 8 tesla [44-46].

In or near magnets of above 4 tesla, both animal studies and research on human volunteers and patients indicate that movement of head or body in the static field can generate nausea, vertigo or a metallic taste [47-52]. The actual dB/dt at which these effects occur varies widely between individuals, between 1 and 6 tesla per second [50]. Possible mechanisms for induction of vertigo and nausea include magnetic susceptibility differences between the maculae of the inner ear and their surroundings, magnetohydrodynamic effects in the semicircular canals and electric stimulation of the firing rate of vestibular cells [50].

There is some evidence for a reduction of less than 5 percent in concentration, memory, visuomotor speed and performance after movement near 1.5-7 tesla magnets [53-56]. These do not seem to pose a direct health risk to the worker, but could affect the quality of a surgical intervention or other tasks performed by the worker in or near the magnet bore. It is still unclear whether these are direct effects of the static field or indirect effects of vertigo or nausea. One important caveat is that quality epidemiological studies of possible long-term effects of static field exposure are lacking [57]. Further research is needed. An upcoming epidemiological study in the Dutch "Electromagnetic Fields and Health" research program will address this question [58].

Magnetophosphenes are perceived light flashes that originate in the stimulation by low frequency EMF of cells in the retina of the eye. Although magnetophosphenes can be induced by an external low frequency EMF with an optimum frequency of 20 hertz [50,59], they can also be induced in a minority of individuals when moving in the static field of an MRI magnet [60,61]. Although their relevance for health is unclear, they could conceivably cause indirect risks when they interfere with certain working routines.

6.2 Gradient fields

The main mechanism for acute effects with a health risk of the MRI gradient fields is how the induced electrical fields and currents stimulate nerve fibres and muscle cells. Other effects with lower thresholds on neuronal cell bodies in the brain have not been well-characterised and are based on research that mainly uses sinusoidal EMF at frequencies (around 50 hertz) lower than those of gradient fields. They involve a depolarisation of the neural cell membrane to a degree that does not generate an action potential, but may influence their function as transmitters and integrators of information in the brain. Possible low-threshold effects include changes in the threshold for excitation by second, artificial electrical stimulus and changes in the size or direction of the electrical activity of the brain following a visual stimulus (evoked potentials) [62,63]. The implication of these effects for health and their relevance for the higher frequencies and pulsed fields of MRI gradients is unclear. No effect on visual evoked potentials is found when the brain is exposed to a gradient field with a frequency of 500 hertz [64].

Gradient fields are not sinusoidal, but pulsed. Their strength rapidly increases during a pulse, and decreases to zero between pulses. The rapidly changing magnetic field outside the body during a pulse induces an electric field in the body. If it is strong enough, this induced electric field can depolarise and stimulate nerve fibres. The strength of nerve stimulation depends both on the strength of the induced field (and therefore on the rate of change of the external magnetic field, dB/dt) and on the duration of the pulses. Long pulses are more effective in stimulating nerves than short pulses [65]. When stimulation of sensory nerves is strong enough to be perceived, it varies from a mild tingling feeling to intolerable pain, depending on the field strength. The lowest threshold (corresponding to a pulse duration greater than 1 ms) for feeling lies in the order of 15 tesla per second, for painful stimulation in the order of 25 tesla per second, and for intolerable stimulation in the order of 35 tesla per second [38,65-67]. The corresponding lowest threshold for perception of nerve stimulation in terms of the induced electric field is approximately 5 volt per metre [68]. Peripheral nerves are more sensitive to gradient field stimulation than nerves in the central nervous system, because their diameter is greater and because the electric field induced in a person lying in the magnet bore is stronger in the periphery (limbs) than in the body core (brain, spinal cord) [63]. The dB/dt threshold for electrical stimulation of the heart is approximately ten times higher than that for peripheral nerve stimulation [65].

6.3 Radiofrequency field

The main heath risk of radiofrequency EMF is heating of the body or of parts of the body to a level where normal compensatory mechanisms are inadequate and damage to cells or tissues may occur. Based on studies in laboratory animals and human volunteers, the threshold for tissue damage is estimated to lie above a core body temperature rise of 1°C, corresponding with a specific absorption rate of 4 watt per kilogram [6] (see section 7.2}. The most sensitive organs in the body are the eyes and testes, because they have a reduced capacity for heat dissipation compared to the rest of the body [39]. MRI devices with higher static field flux density require higher radiofrequencies to induce magnetic resonance. At these higher frequencies, the radiofrequency energy is coupled more efficiently to the body ("resonance") and can cause more uneven heating ("hot spots") [69]. A conducting loop with risk of burns can occur when areas of skin between two limbs or limbs and trunk make contact [70]. The human body has a considerable capacity to dissipate heat and redistribute heat from warmer to colder regions. However, this capacity for heat regulation can be reduced by a higher ambient temperature, medication or disease [71].

7 Origin of exposure limits in Directive 2004/40/EC

7.1 International context, ICNIRP guidelines

To protect workers and the general public against the risks of EMF, guidelines have been issued by various national and international scientific bodies. There are three main approaches for setting exposure limits based on such risks. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) sets low frequency limits in terms of the induced current density [6]. The Institute of Electrical and Electronics Engineers (IEEE) sets low frequency limits in terms of the induced electric field strength [7]. Despite the difference in exposure metric, the health risks on which the low frequency limits of the two organisations are based are similar: low-threshold effects on the electrical activity of nerve cell bodies in the brain for frequencies in the tens to hundreds of hertz, and nerve fibre stimulation for frequencies in the hundreds of hertz to hundreds of kilohertz. Exposure limits for high frequencies in the megahertz range in ICNIRP and IEEE guidelines are virtually identical and set in terms of absorbed power to prevent tissue heating. ICNIRP exposure limits for workers are based on the threshold for aforementioned biological effects with health risks, divided by a factor 10 to account for variability in environmental conditions and individual differences in sensitivity for EMF effects. A third approach has traditionally been taken in Russia and a number of other Eastern European nations. It is based on avoiding biological changes induced by EMF without necessarily weighing the likelihood of a health risk. The exposure metrics are similar to those used by the ICNIRP and IEEE, but the actual values of the exposure limits are often lower and also dependent on the duration of exposure [15,72]. The EU has elected to base both its guidance for protection of the public [8] and Directive for protection of workers [1] on ICNIRP guidelines.

7.2 Exposure limit values

Exposure limit values in the Directive are set in terms of the effects induced by EMF in the body and may not be exceeded under any circumstances. They are identical to ICNIRP basic restrictions for occupational exposure [6]. For frequencies up to 10 megahertz, exposure limit values are set in terms of the current density induced in the central nervous system (CNS) of head and trunk (symbol: J; unit: ampère per square metre). The proviso that the exposure limit values apply to the CNS derives from ICNIRP explanatory notes about their guidelines [9]. Neither the Directive nor ICNIRP specify what, if any, exposure limit values should apply to other tissues in the body. Current densities should be averaged over a tissue cross-section of 1 square centimetre perpendicular to the current direction. This rule may cause problems for parts of the CNS such as the spinal cord, where a cross-section of 1 square centimetre may include cerebrospinal fluid, which has a much higher conductivity than neural tissue, leading to overestimation of induced current in the CNS. Since the effects against which the low frequency limits are to protect are instantaneous, it is the maximum induced current that should be compared to exposure limit values, not some sort of average exposure over time. For pulsed EMF, the Directive states that the current densities associated with the pulse should be calculated from the maximum rate of change of magnetic flux density (dB/dt) and the duration of the pulses, applying an equivalent frequency of (1/[2 × pulse duration]). The method of calculation is not specified, but the Directive states that "appropriate methods of analysing the characteristics of the waveforms and nature of biological interactions have to be applied, taking account of European harmonised standards developed by Cenelec" (see section 7.4).

For frequencies between 100 kilohertz and 10 gigahertz, exposure limit values are set in terms of the Specific Absorption Rate (SAR), the rate at which energy from EMF is absorbed per unit mass of body tissue (unit: watt per kilogram). Different SAR limits are set for the whole body average, reflecting the capacity of the body as a whole to transfer heat to the outside world, and localised SAR in head, trunk and limbs, reflecting the capacity of specific areas of the body to transfer heat to the outside world and to other parts of the body via the circulation. All SAR values are to be based on an average over any 6-minute exposure period. Although the Directive and ICNIRP guidelines do not specify why, the IEEE high frequency guidelines (which have identical SAR exposure limit values) indicate that the 6-minute averaging period derives from the heating time constant of smaller body parts like the eye [73]. EMF with frequencies above 10 gigahertz do not penetrate deeply into the body but mainly cause surface heating. The exposure limit value for these frequencies is therefore set in terms of the power density (unit: watt per square metre).

7.3 Action values

Action values in the Directive are set in terms of properties of the ambient EMF, which are more easily measured than their effects on the body for which the exposure limit values are set. The action values are identical to ICNIRP reference levels for occupational exposure, which are obtained from basic restrictions by mathematical modelling and extrapolation from laboratory measurements at specific frequencies. They assume maximal coupling of the external EMF to the body, providing maximal protection against worst-case conditions [6]. For time-varying EMF, action values are given for the strength of the electric field (units: volt per metre), for the strength of the magnetic field (units: ampère per metre) and for the magnetic flux density (unit: tesla). Action values are frequency-dependent, reflecting the different efficiency with which various biological effects are induced at different frequencies. Since the lowest frequency band is specified as 0 to 1 hertz, strictly speaking the corresponding action value for magnetic flux density (0.2 tesla) should be applied to static magnetic fields. For frequencies above 100 kilohertz, where heating is the predominant risk, the measured electric and magnetic field strength are to be averaged over any 6-minute period. When the measured field strength or flux density exceeds the action value, further assessments and calculations must determine whether the exposure limit value is exceeded.

7.4 Methodology for measurement and calculation

The specific exposure limit values and action values in the Directive refer to continuous, sinusoidal EMF of one frequency. For simultaneous exposure to multiple frequencies of EMF, or for pulsed or transient EMF, the Directive states that measurement and calculation methods appropriate to the characteristics of the waveform and its biological effect have to be used, taking account of harmonised European standards developed by Cenelec. Draft European standards that are presently under consideration describe assessment and calculation procedures for human exposure in general (50413) [74] and procedures for assessment of worker exposure to EMF (50499} [75]. Draft standard 50499 includes guidance for calculation of simultaneous exposure to multiple frequencies. Neither draft standard 50413 nor draft standard 50499 specifies methods to calculate induced current from pulsed EMF. Standard 50499 recommends that if a specific standard is applicable to the working environment, this should be used for assessment. The International Standard for safety of magnetic resonance equipment is mentioned as a candidate specific workplace standard, but standard 50499 requires that "if

this standard contains other exposure limits than those stated in the Directive then the exposure limits from the Directive shall be applied".

8 MRI worker exposure in relation to exposure limits

8.1 Extent of the problem

Postal surveys indicate that in 3% of MRI investigations workers are present in the MRI room during scanning, for anaesthesia, sedation, injection of contrast fluid, surgery or comforting of patients [76]. Exposure may be more widespread for those workers involved in research. A British survey indicates that 70% of clinical and preclininal MRI researchers are present in the MRI room during scanning (active gradient and radiofrequency fields), but the majority of these less than 3 times per week and less than 30 minutes per scan. Of these, 77% are within 1 m of the machine. Static field flux density is likely to be higher in the research setting (up to 9 tesla) than in routine patient care [77].

8.2 Worker exposure modelling

Computer simulations indicate that movements of workers at normal speed during routine clinical activities in the static field within 0.5 to 1 m of 1.5 to 7 tesla MRI scanners can induce currents in the CNS in excess of the exposure limit value for time-varying EMF in the Directive [3,78]. Movement into the magnet bore and head rotation inside the bore can also induce currents in excess of the exposure limit values in parts of the body that contain CNS tissue [79,80]. Numerical modelling of the gradient fields indicates that the induced current in the CNS exceeds the exposure limit value in the Directive when a worker is closer that 0.5 to 1 m to the outer end of the gradient coils, in a worst-case scenario when all 3 gradients are simultaneously active. This distance will decrease with fewer simultaneously active gradients and a smaller dB/dt [3,81,82]. Based on numerical modelling, it is possible that the exposure limit value in the Directive for localised SAR in the head is exceeded if the worker is in the same position in the bore as a patient [83]. Calculations on existing open MRI systems used for surgical intervention (0.7-1 tesla) indicate that the draft ICNIRP static field limit of 2 tesla for workers is unlikely to be exceeded, but the static field action value of 0.2 tesla in the Directive may be exceeded. Gradient field exposure limit values in the Directive are likely to be exceeded and radiofrequency action values could be exceeded during longer exposure (minutes or more) to the imaging area of an open MRI system [84].

8.3 Worker exposure measurements

Based on actual exposure measurements, the 0.2 tesla action value for static fields in the Directive is likely to be exceeded at a distance of closer than 0.4 to 0.6 m to the end of the magnet bore [3,85-87]. However, when the action value is interpreted as a time-weighed average for the whole working day, as it was originally defined in the ICNIRP static field limits [16], this average exposure is lower than the action value in the Directive [3]. The draft ICNIRP static field exposure limit of 2 tesla [24] will not be exceeded in normal activities of workers near the bore end of the MRI apparatus with a static field flux density of up to 4 tesla [3,85,87,88], except when the worker bends into the core of a magnet with static field flux density of 4 tesla [3].

When workers move in the static field (1.5 to 4 tesla) at normal speed (around 1 m/s), the action value for rate of change in magnetic flux density (dB/dt) derived from the exposure limit value in the

Directive is often exceeded, where specified closer than 0.6 m to the end of the magnet bore [3,88,89]. The measured magnetic flux density and dB/dt of the gradient fields exceed the action values derived from the exposure limit value in the Directive when workers are closer than 0.3 to 0.6 m from the end of the magnet bore end during scanning [3,87-89]. The measured magnetic flux densities and dB/dt correlate well with those used in model calculations to compute induced CNS current [90]. When the current density induced by the gradients is calculated from these field measurements using ICNIRP guidance [17], it exceeds the exposure limit value in the Directive [88], but this study neglects the proviso that the exposure limit value applies only to induced current in the central nervous system. Radiofrequency exposure remains under the action value in the Directive outside the magnet bore of a 1.5 tesla MRI scanner, but can exceed the action value inside the bore [88,91]. Whole body SAR for radiofrequency energy for a person lying inside the bore is also likely to exceed exposure limit value in the Directive [92].

Recently, the results of an extensive investigation, ordered by the EC, into occupational EMF exposure near four types of MRI devices in Europe (static fields 1, 1.5, 3 and 7 tesla) were published [2]. Electric and magnetic field strength and magnetic flux density were measured for various spatial positions and working routines and were translated to induced current density and SAR using numerical calculations based on phantoms. The results indicate that the 0.2 tesla action value for the static field in the Directive is exceeded close to the bore end. Currents induced by movement in the static field were estimated by simulation of a moving phantom next to a generic solenoid magnet of 1, 1.5, 3 or 7 tesla. Based on these simulations, the exposure limit value in the Directive for induced current in the CNS may be exceeded 1.2 to 1.7 times when moving next to or bending into the bore end of the magnet. However, rotation of the head was not assessed. For the gradient fields, taking account of their non-sinusoidal nature, field strength and dB/dt are up to 9 times higher than the action values in the Directive just outside the end of the magnet bore, and up to 180 times higher inside the bore. The induced current calculated from these measured values exceeds the exposure limit value in the Directive just outside the bore end and when head or trunk are inside the bore. The transgression is substantial when induced currents are calculated for all body tissues, but relatively small when only nerve tissue is considered. The magnetic flux density of the radiofrequency field can be 2 times higher than the action value in the Directive just outside the bore end. However, the SAR calculated from these field measurements does not exceed the exposure limit value in the Directive, except for the situation when a worker accompanies a patient in the magnet bore during scanning. This type of exposure does not fall under the intended use of MRI scanners. Radiofrequency exposure for interventional MRI can be close to the exposure limit values in the Directive, but excessive exposure could be prevented via hardware or behavioural restrictions if real-time information on radiofrequency exposure level were available during the intervention [2].

Two general reservations can be made of the EC measurement report and other published exposure measurements and calculations. Firstly, modelling of exposure to gradient fields and EMF induced by movement in the static field has so far been limited to a relatively small number of movements and locations near a relatively small number of MRI scanners. It can not be guaranteed that the data reported so far effectively cover all typical exposure situations in present day MRI practice, nor is it likely that they take into account the full range of variability between individuals in the effects on the body. Secondly, the anatomical models used so far to calculate induced current and electric field are still limited in the degree to which details in the exact distribution of the external field translate to details in the distribution of the field and current induced in the body, especially when the body is moving in the external field. Nevertheless, the results published so far are the best that were available at the time this report was written, and as such formed the only basis to determine whether exposure limit values or action values in the Directive and possible amendments (part 1 of the report) are exceeded.

8.4 Animal MRI devices and magnetic resonance spectroscopy

As far as could be ascertained, no information is presently available in the international peer-reviewed literature on worker exposure near small bore systems used for research on laboratory animals such as rats and mice. The diameter of the magnet bore of such systems is relatively small (0.2 to 0.4 m), and their stray fields are therefore weaker than those of MRI systems for scanning human volunteers or patients. Measurement data obtained from two manufacturers of small bore systems indicate that the present action value of 0.2 tesla for the static field in the Directive is exceeded closer than 0.1 to 0.4 m to the end of the magnet bore, depending on the flux density of the static field (between 4 and 12 tesla). The draft ICNIRP exposure limit of 2 tesla for head and trunk [24] is not exceeded anywhere outside the edge of the magnet bore [H. Liebel, Bruker BioSpin MRI Gmbh, personal communication; R. Warner, Varian Inc., personal communication]. No data were available for the dB/dt associated with movement in the static field of small bore systems. Data of the stray fields of three commonly used types of gradient coils were available from one manufacturer. The relevant 30.7 microtesla action value for magnetic flux density in the Directive was only exceeded for one type of gradient at the very edge of the magnet bore. It remained below the action value at all measured points outside the scanner [R. Warner, Varian Inc., personal communication]. No measurement data were available for the radiofrequency field, but computer simulations indicate that the electric and magnetic field strength between 0.25 and 0.5 m outside the edge of the magnet bore are at least 3 orders of magnitude lower than the action values in the Directive [H. Liebel, Bruker BioSpin MRI Gmbh, personal communication]. It should be noted that in most situations where small animals are scanned, it is also possible to physically close off the end of the magnet bore with additional shielding, reducing the stray fields of gradient and radiofrequency coils to a minimum.

Magnetic resonance spectroscopy is a technique in which the magnetic resonance signal is used to provide information about the chemical composition of samples or body tissues. The exact frequency of the radiofrequency pulses used is determined by the particular atomic nuclei targeted, but generally speaking the frequency is highest for hydrogen nuclei (which are also the targets in MRI) and lower for other nuclei. Spectroscopy is usually performed on samples placed in a closed and heavily shielded device, in which case the traditional name of NMR (Nuclear Magnetic Resonance) is still used. Published measurements indicate that the magnetic flux density of the static field around such NMR devices usually remains below the 0.2 tesla action value in the Directive [93,94]. It cannot be excluded that the 0.2 tesla action value is exceeded near some NMR devices for which no measurement data are available, particularly during the short periods when samples are changed by hand. It is unlikely, however, that the 2 tesla exposure limit for head and trunk in the draft static field guidelines of ICNIRP [24] will be exceeded. Since NMR devices are closed when the radiofrequency field is active, the present radiofrequency action values in the Directive will not be exceeded. Although magnetic resonance spectroscopy can also be applied in combination with MRI in human subjects or laboratory animals [40], relatively basic scanning protocols are normally used that do not increase EMF exposure above that already applied for MRI.

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Appendix 1 Glossary of EMF measurement variables

variable:	symbol or abbreviation:	units (abbreviation):
magnetic flux density	B	tesla (T)
rate of change in flux density	dB/dt	tesla per second (T/s)
electric field strength	E	volt per metre (V/m)
magnetic field strength	H	ampère per metre (A/m)
current density	J	ampère per square metre (A/m^2)
specific absorption rate	SAR	watt per kilogram (W/kg)
power density	S	watt per square metre (W/m^2)

Appendix 2 List of international scientific experts interviewed

Dr. Myles Capstick, Associate Director, Foundation for Research on Information Technologies in Society (ITIS), Zurich, Switzerland

Dr. Phil Chadwick, Senior Scientist (EMF exposure), MCL Technology Ltd., Dingestow, United Kingdom

Mr. Malcolm Darvill, Head of Non-Ionising Radiation Policy, Health and Safety Executive, London, United Kingdom

Mr. Georg Frese, Dipl.-Phys., Standards and Regulation Manager, Siemens AG Medical Solutions, Erlangen, Germany

Dr. Paul Glover, Magnetic Resonance Physicist, Sir Peter Mansfield Magnetic Resonance Center, and Lecturer, School of Physics and Astronomy, University of Nottingham, Nottingham, United Kingdom

Dr. Hannah Heinrich, Coordinator, 'Safety in Electromagnetic Fields' International Research Association, and Independent Physicist, 2H-Engineering & Research, Hausen, Germany

Dr. Stephen Keevil, Head of Magnetic Resonance Physics, Guy's and St.Thomas' NHS Trust, and Honorary Senior Lecturer Imaging Sciences, King's College, London, United Kingdom

Dr. Frank de Vocht, Lecturer in Occupational and Environmental Health, Faculty of Medical and Human Sciences, University of Manchester, Manchester, United Kingdom

Dr. Gabriel Krestin, Professor of Radiology and Head, Department of Radiology, Erasmus University Medical Center, Rotterdam, the Netherlands, and Research Committee Chairman, European Society of Radiology

Dr. Hans Kromhout, Professor of Occupational Hygiene and Exposure Assessment, Institute for Risk Assessment Sciences, Utrecht University, Utrecht, the Netherlands

Dr. Zenon Sienkiewicz, Principal Scientist Non-Ionising Radiation, Radiation Protection Division, Health Protection Agency, Chilton, United Kingdom

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Appendix 3 List of Dutch MRI staff interviewed

Dr. Wilbert Bartels, Magnetic Resonance Physicist, Division of Radiology, University Medical Center Utrecht, Utrecht the Netherlands

Mr. Jos van Diessen, Safety Expert, Sector Occupational Safety and Environment, Erasmus University Medical Center, Rotterdam, the Netherlands

Dr. Rick Dijkhuizen, Senior Scientist and Head, Biomedical Magnetic Resonance Imaging and Spectroscopy Laboratory, University Medical Center Utrecht, Utrecht, the Netherlands

Dr. Hans Engels, Chair, Magnetic Resonance Safety Team, Philips Healthcare B.V., Best, the Netherlands

Dr. Jurgen Fütterer, Interventional Radiologist, Department of Radiology, Radboud University Medical Centre, Nijmegen, the Netherlands

Ms. Sija Geers-van Gemeren, Society Manager, Dutch Society for Medical Imaging and Radiotherapy, Utrecht, the Netherlands

Dr. Marcel Greuter, Medical Physicist, Department of Radiology, University Medical Center Groningen, Groningen, the Netherlands

Mr. Ronald van Haren, Medical Technician and Coordinating Radiation Expert, Department of Radiology, Erasmus University Medical Center, Rotterdam, the Netherlands

Dr. Mark Hofman, Medical Physicist and Instructor Radiology (Imaging Techniques), Department of Radiology, Free University Medical Center, Amsterdam, the Netherlands

Mr. Peter Kappert, System Specialist MRI, Department of Radiology, University Medical Center Groningen, Groningen, the Netherlands

Ms. Carolien Leijen, Senior Radiation Safety Officer, University Medical Center Utrecht, Utrecht, the Netherlands

Dr. Peter Luijten, Professor of Functional Medical Imaging, Division of Radiology, University Medical Center Utrecht, Utrecht, the Netherlands

Dr. Willem Mali, Professor of Radiodiagnostics, Division of Radiology, University Medical Center Utrecht, Utrecht, the Netherlands

Dr. David Norris, Professor of MR Physics in Relation to Applications in Cognitive Neuroscience, Radboud University, and Principle Investigator, F.C. Donders Centre for Cognitive Neuroimaging, Nijmegen, the Netherlands

Mr. Lex van der Star, ME, MSc, MSHE, Senior Manager Quality, Safety and Licences, University Medical Center Groningen, Groningen, the Netherlands

Mr. Percy Stubbs, Occupational Health Officer, Haaglanden Medical Centre, and Project Leader, Dutch Association of Hospitals, Leidschendam, the Netherlands

Dr. Annette van der Toorn, Magnetic Resonance Physicist, Biomedical Magnetic Resonance Imaging and Spectroscopy Laboratory, University Medical Center Utrecht, Utrecht, the Netherlands

Mr. David de Vries, Head MRI Unit, Department of Radiology, Erasmus University Medical Center, Rotterdam, the Netherlands

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