EUROPEAN SCIENCE FOUNDATION
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ESF-EMRC Position on the Implications of the EMF Directive 2004/40/EC for European Biomedical Magnetic Resonance Research

Foreword

The aim of this paper of the European Medical Research Councils (EMRC), the Standing Committee for Medical Sciences at the European Science Foundation (ESF), is to provide an input into the discussions on the revision of the EU 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). Directive 2004/40/EC was adopted by the European Parliament and Council in April 2004, and was originally due to be implemented no later than April 2008. In March 2008 the European Commission proposed that the transposition deadline be postponed by four years, until 30 April 2012.

This paper summarises the current scientific and technical positions on Directive 2004/40/EC and its consequences for magnetic resonance imaging (MRI), which, while apparently unintended, are potentially disastrous. It has become clear that this Directive will have a major negative impact on the use of MRI both for research and in the clinic, severely hindering further developments of the technology for patients with life-threatening diseases.

An acceptable and responsible solution for the use of MRI in clinical and research settings would be an exemption from any limit values.

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Introduction

The EU Physical Agents (Electromagnetic Fields) Directive 2004/40/EC[1] puts limits on the exposure of workers to electromagnetic fields (EMF) with frequencies in the range from zero to 300 GHz. The limits proposed, particularly in the lower frequency range of up to 100 kHz, are based on cautious extrapolation from very limited experimental data. The Directive has consequences for magnetic resonance imaging (MRI), which, while apparently unintended, are potentially disastrous. It has become clear that this Directive will have a major negative impact on the use of MRI both in the clinic and for research, severely hindering further developments of the technology for patients with life-threatening diseases such as cancer, myocardial infarction and stroke. These impacts are outlined in the paper.

The hypothesis underlying Directive 2004/40/EC is that there are instantaneous, detectable health effects resulting from exposure to low-frequency time-varying magnetic fields. Guidelines published in 1998 by the International Commission on Non-Ionising Radiation Protection (ICNIRP) on time-varying field exposure[2] were based on cautious interpretation of sparse scientific evidence in order to exclude any possibility of adverse effects, rather than on established thresholds for actual effects. Revision of these guidelines is imminent, but although it is proposed to raise the exposure limits, the new guidelines are still based on sparse data and speculation relating to the neuroelectrophysiological effects of electromagnetic fields. The limits at higher radiofrequencies (RF) are based on tissue heating due to energy absorption, a well understood physiological effect which is restricted to safe levels by design features of MRI scanners.

MRI is a leading example of where the EU is in the forefront of cutting edge research, and as such contributes to an innovative and competitive Europe. Implementation of Directive 2004/40/EC into national legislation will threaten Europe's position as a world leader in MRI research and consequently will have a severe impact on patient diagnosis and treatment. In the last 30 years, two Nobel Prizes related to the field of MRI have been awarded to European scientists, one Nobel Prize in Physiology and

1. Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on theminimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). Official Journal of the European Union L 159 of 30 April 2004. [Available online at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:184:0001:0009:EN:PDF]
2. ICNIRP. Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz). Health Physics 1998;74:494-522. [Online at http://www.icnirp.org/documents/emfgdl.pdf]

Abbreviations

dB/dt	rate of change of magnetic flux density
CT	computed tomography
EC	European Commission
EMRC	European Medical Research Councils
EMF	electromagnetic field(s)
EFOMP	European Federation of Organisations for Medical Physics
EPSRC	Engineering and Physical Sciences Research Council
ESMRMB	European Society for Magnetic Resonance in Medicine and Biology
ESR	European Society of Radiology
HSE	Health and Safety Executive
ICNIRP	International Commission on Non-Ionising Radiation Protection
IEC	International Electrotechnical Commission
ISMRM	International Society for Magnetic Resonance in Medicine
kHz	kilohertz
MR	magnetic resonance
MRI	magnetic resonance imaging
MRC	Medical Research Council
NMR	nuclear magnetic resonance
RF	radiofrequency
PNS	peripheral nerve stimulation
T	tesla
UEMS	European Union of Medical Specialists
WHO	World Health Organisation

Medicine (2003) and one Nobel Prize in Chemistry (1991). Moreover, the Joint Programming Initiative (JPI) on combating Neurodegenerative Diseases may be affected by this Directive, due to the impact on MRI research. Not only would this Directive have an impact on scientific research and healthcare but also on education, with students choosing other fields, potentially leading to a 'brain drain' of MRI scientists from Europe. Finally, the European economy will also be affected by the possible relocation of major MRI manufacturing companies outside the EU.

Any decision to severely curtail the development and use of MRI must be based on firm scientific evidence as MRI has been safely used for over 25 years, and around 500 million patients have been exposed at up to 100 times the occupational exposure limit set by Directive 2004/40/EC without evidence of harm to workers or patients. It is essential that this major diagnostic technology is not threatened by burdensome legislation when concerns can be addressed through responsible guidance to medical and service personnel on good working practices. The EMRC therefore supports the exemption of MRI from any limit values as an acceptable and responsible solution for the research and clinical use of MRI.

Background: Directive 2004/40/EC

Directive 2004/40/EC was adopted by the European Parliament and Council in April 2004, and was originally due to be implemented no later than April 2008. Its content was based on recommendations issued in 1998 by ICNIRP.

MRI is a medical diagnostic tool in which EMFs are used to provide high-resolution images of soft tissues in the body. Manufacturers of MRI equipment raised concerns before adoption of Directive 2004/40/EC that it might limit the use of MRI in patient care and research. A parliamentary enquiry in the United Kingdom in 2006 was extremely critical of the Directive, the Commission and ICNIRP. In March 2006 a delegation of radiologists and MRI scientists representing the European Society of Radiology (ESR) and other professional bodies (ISMRM, ESMRMB, UEMS, EFOMP)[3] met with the Employment and Social Affairs Commissioner, Vladimír Špidla, and voiced their concern that the Directive would limit the use of MRI. Commissioner Špidla reassured them that the Commission would not hesitate to change legislation already adopted if it was proved that it would have adverse effects on the use of MRI.

A working group of European Commission (EC) staff and ESR representatives was established to discuss the problem. The Commission then launched a study to look into exactly what implications Directive 2004/40/EC exposure limits would have for MRI and identify potential problems that could arise. Results of projects funded by the Health and Safety Executive (HSE)[4] in the United Kingdom and by the EC Directorate General of Employment, Social Affairs and Equal Opportunities[5] indicated that the exposure limit values in the Directive are exceeded in normal clinical and research use of MRI.

In June 2007, Commissioner Špidla announced that the Commission would postpone the deadline for implementing Directive 2004/40/EC by one to two years in order to consider how to amend the legislation in the light of new scientific evidence. "The Commission remains committed to the protection of the health and safety of workers. However, it was never the intention of this Directive to impede the practice of MRI. Obviously, the Commission recognises MRI as a technology offering clear benefits to patients, and continues to support MRI research financially", commented Commissioner Špidla. "Postponement of the transposition will allow time to review the current Directive and amend those provisions which have been shown to be problematic by recent scientific studies. While this review is ongoing, the Commission recommends that Member States put the transposition of the current Directive on hold."[6]

3. European Society for Magnetic Resonance in Medicine and Biology, European Union of Medical Specialists, European Federation of Organisations for Medical Physics.
4. www.hse.gov.uk/research/rrpdf/rr570.pdf
5. Capstick M *et al*, 2008. Employment, Social Affairs and Equal Opportunities DG, European Commission.
6. Press release available online at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1610

The Commission indicated in its proposal that this postponement was being introduced in order to prepare a substantive amendment to Directive 2004/40/EC. It was stated that the future amendment would aim to ensure that limits would not have an adverse effect on the practice of MRI, whilst ensuring appropriate protection of personnel. Moreover, it intended to review the situation for all sectors where personnel were exposed to electromagnetic fields while carrying out their work.

In March 2008 the European Commission proposed that the transposition deadline be postponed by four years, until 30 April 2012. This was to allow sufficient time to take into account new recommendations from relevant international bodies. The ICNIRP was at that time revising its recommendations for occupational limit values for static and low frequency EMF, while the World Health Organisation (WHO) was also revising its Environmental Health Criteria for EMF. New ICNIRP static field guidelines were duly published in 2009, and revised guidelines relating to time-varying magnetic fields were issued for public consultation later in 2009. The Commission stated that these revisions were expected to result in new, less stringent recommended limit values for occupational exposure; in fact the new ICNIRP guidelines are still unnecessarily restrictive and would still cause serious problems for MRI if incorporated into a revised Directive.

What is MRI?

MRI is an essential technique for diagnosing and treating illness, and in biomedical research. It produces detailed pictures of the inner structure and function of patients' bodies using strong magnetic fields and radio waves, and is central to important treatments and research programmes for many illnesses, in particular cancer and heart and neurological diseases.

As shown in Table 1, the origins of MRI go back more than 25 years. The technique is based on the fact that different tissues in the body react differently to magnetic fields, because the water content of individual tissues varies. In a powerful magnetic field, hydrogen nuclei within water molecules align themselves in a specific direction. When radio wave pulses of an appropriate frequency are directed at a tissue, these aligned nuclei are deflected. When the radio waves are switched off, the nuclei return to their original orientation and emit weak electromagnetic waves during this short "relaxation time". These electromagnetic waves are acquired as signals, which are used by a computer to generate high-contrast images of the tissue. Stronger magnetic fields enable stronger signals to be received, resulting in more detailed images and/or shorter total examination times.

MRI has moved to the forefront of medical imaging in recent years covering almost all areas ranging from neurological, musculoskeletal and cardiovascular imaging to imaging needed for interventional procedures. Complex, novel techniques such as diffusion imaging, perfusion imaging and functional imaging have affected our whole approach to certain diseases and patients. Advances in hardware have had an impact in applications that are still

Table 1. Brief History of MRI1[7]

1952
Nobel Prize in Physics: Felix Bloch and Edward Purcell for their development of new methods for nuclear magnetic precision measurements in bulk material such as liquids and solids.
1971
Raymond Damadian showed that the nuclear magnetic relaxation times of tissues and tumours differed, thus motivating scientists to consider magnetic resonance for the detection of disease.
1975
Richard Ernst proposed MRI using phase and frequency encoding, and the Fourier Transform. This technique is the basis of current MRI techniques.
1979
Nobel Prize in Physiology & Medicine: Allan M. Cormack and Godfrey Hounsfield for the development of computer assisted tomography.
1983
Approval from the Ministry of Health and Welfare in Japan for the first commercial MRI system.
1984
FDA approval for the first MRI scanner.
1987
Charles Dumoulin was perfecting magnetic resonance angiography (MRA), which allowed imaging of flowing blood without the use of contrast agents.
1991-1992
Functional MRI (fMRI) was developed independently by the University of Minnesota's Center for Magnetic Resonance Research (CMRR) and Massachusetts General Hospital's (MGH) MR Center. This technique allows the mapping of the function of the various regions of the human brain.
1991
Nobel Prize in Chemistry: Richard Ernst for his contributions to the development of the methodology of high resolution nuclear magnetic resonance (NMR) spectroscopy.
2003
Nobel Prize in Physiology & Medicine: Paul Lauterbur and Peter Mansfield for their discoveries concerning magnetic resonance imaging as a diagnostic tool.

7. Source: *The basics of MRI* by Joseph P. Hornak (Magnetic Resonance Laboratory. Center of Imaging Science, Rochester Institute of Technology, Rochester, New York, USA) available at http://www.cis.rit.edu/htbooks/mri/

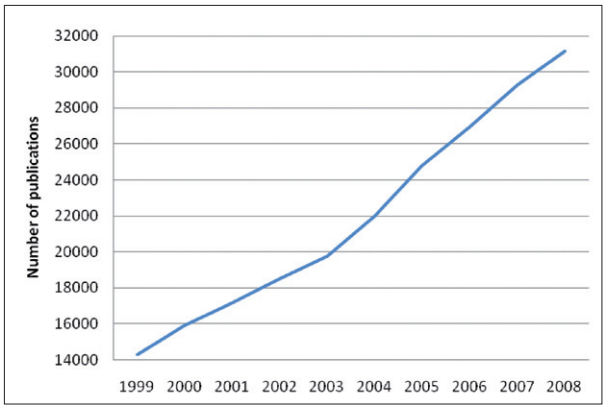

Figure 1. Number of publications relating to MRI produced annually in the past ten years.

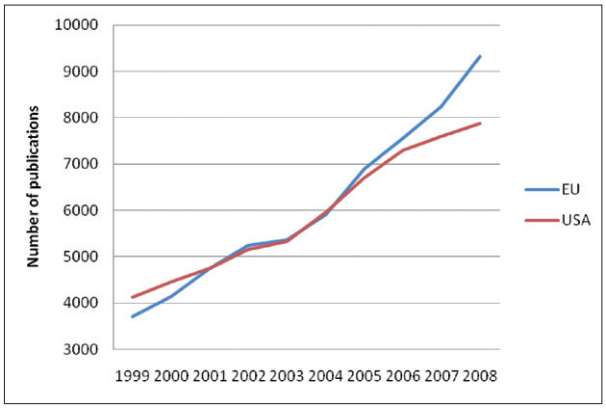

Figure 2. Number of publications relating to MRI produced annually in the past ten years in the European Union (blue) and the United States (red).

growing and maturing, such as parallel imaging techniques. These new advances could lead to a revolution in patient management and the role of MRI in diagnosis of diseases. However, these new and important applications can be developed only if further technological progress is not hampered by overly strict occupational exposure limits applicable to personnel working with MRI systems.

The clinical benefit of MRI scanners for the patient can best be illustrated by reference to the enormous amount of literature on MRI in medical and scientific journals. As shown in Figure 1 and based on searches in MEDLINE[8] (free bibliographic database of biomedical and life sciences publications compiled by the United States National Library of Medicine), the number of MRI publications has more than doubled in the last ten years. Importantly during these ten years, Europe produced more than 35% of these publications thus demonstrating its leading role in the field. This is further demonstrated by Figure 2, which shows that the trend has been moving towards increased European output. While a small proportion of these publications deals with preclinical research, the vast majority (87%) involved human subjects, proving the high clinical output of MRI.

8. Methodology and detailed results available upon request.

The number of MRI units installed worldwide is estimated to be more than 20,000, and since the introduction of MRI in 1983 around 500 million patients have been examined in the scanners.

Principles of MRI

Routine MRI is based on the magnetic characteristics of the hydrogen atom (^{1}H). The patient is placed in a strong magnetic field that is externally shielded. The typical field strength for routinely used clinical scanners is 1.5 or 3 T (tesla, the unit of magnetic field strength; to compare: a refrigerator door magnet has a strength of approximately 0.01T).

High-frequency energy in the form of radio waves is applied to the patient. This energy is then emitted by the body in specific forms and at certain intervals. An antenna (termed a coil) receives this energy, called the magnetic resonance (MR) signal. For localisation of these MR signals, low frequency magnetic pulses are applied to the patient by the 'gradient system' (see below). Using a mathematical transformation, the MR signals are converted into grey scale images. Examination of a patient may typically take 30 minutes.

Components of the MR System and EMF Exposure

Static magnetic field

The largest component in an MR system is the magnet, which creates the external magnetic field (B_0). Hydrogen nuclei in the body placed into the magnetic field align themselves, thereby enabling MR imaging. The system allows imaging over a field of view of up to 50 cm in diameter, enabling, for example, the entire spinal column to be displayed. Active magnetic shielding keeps the stray field to a minimum. MR scanners routinely apply static magnetic fields in the range from 0.2 T up to 3 T, whereby the whole body of the patient is exposed to this magnetic field. These types of scanners are commercially available worldwide. As the MRI signal increases proportionally with the magnetic field strength, there has been growing interest in so-called ultra-high-field whole-body systems, which have field strengths of up to 7 T or even 9.4 T. Systems with still higher field strength are under development, for example by the Franco-German Neurospin project, and smaller magnets operating at very high fields (up to 17 T) have already been introduced for animal research studies.

An MR operator is exposed to the field when, for example, positioning a patient, an animal or a probe in the magnet bore. Although there is no specific restriction in Directive 2004/40/EC for static magnetic fields, a worker moving through the field will experience time-varying current-flow in the body as a result of this movement, and this does conflict with the exposure limits. The issue for the *static field* from MRI systems is therefore the movement of workers through the field. Longer-duration exposure is unavoidable for medical staff when carrying out interventional MR techniques such as minimally invasive MRI-guided therapeutic interventions or during

the examination of children. It should be noted that particularly for children needing longitudinal follow up studies for therapy monitoring, MRI is extremely beneficial as it avoids the use of x-ray radiation. The magnetic field exposure values in these situations can be as high as those experienced by the patient. To date there is no evidence in the scientific literature of adverse effects due to exposure to static magnetic fields. Instantaneous effects of exposure to higher magnetic field strengths (>1.5 T) are well known and reported in the literature. These effects, which include dizziness, nausea and a metallic taste, do not require treatment, their underlying mechanisms are understood, and no lasting effects or cumulative dose-dependent effects have been observed.

Gradient system

The gradient system is the decisive component in determining imaging speed and spatial resolution. It localises the slice to be measured and encodes spatial information within this slice into the acquired signal. It consists of a power amplifier and gradient coil system. The gradient system generates low frequency (up to 1 kHz) magnetic field pulses, mostly with trapezoidal wave forms. The electrical currents induced in the conductive tissues of the body by the changing magnetic field can lead to peripheral nerve stimulation (PNS). PNS has no known long-term health consequences, but in its severe form it can be unpleasant and even painful. The amplitude and switching speed of these gradient pulses are therefore limited by scanner manufacturers to avoid PNS for the patient (and hence also for workers outside the scanner). Outside the gradient coils the pulsed magnetic field rapidly drops to negligible values, so generally MR operating personnel are not exposed to pulsed gradient fields even if they are inside the examination room during image acquisition. However, during interventional MR, when providing close clinical care to patients who are being imaged, and during some types of research study, exposure to at least part of the body cannot be avoided.

Radiofrequency system

The RF system can be separated into a transmit and a receive path. The transmit path, which consists of the RF power amplifier and a transmit antenna, creates the pulses needed to deflect the hydrogen nuclei from their alignment. The receive path, consisting of different types of receive antennae, detects the signal from the body tissue and prepares it for further processing to calculate the final MR image.

The RF power emitted by the transmit antenna causes slight heating in the patient's body tissue. The power absorbed by the patient's body is limited by manufacturers such that the body temperature does not increase by more than 1 °C. Outside the RF transmit antenna the RF field is negligible. As with pulsed gradient fields, under normal circumstances MR personnel are not exposed to the RF fields. In the case of interventional MR, exposure is limited to staff working close to the magnet bore (or between the magnet poles in the case of so-called open MR systems).

MRI Worker Exposure

Static field

ICNIRP has recently issued (April 2009) new guidelines for limiting the exposure of workers to static magnetic fields. There is no exposure limit value for static fields in the original Directive 2004/40/EC, but the expected revision may introduce the recommended limit values of 2T under normal circumstances, rising to 8T for specific work situations which would include MRI. Use of MRI systems above this limit would become impossible if 8T becomes an absolute limit in the revised Directive. ICNIRP has stated that these limits are based on lack of data on human exposure to higher fields, rather than any evidence of adverse effects. ICNIRP also acknowledges that research beyond 8T can be performed with appropriate precautionary measures. When translating the ICNIRP recommendations into legislation it is important to consider such measures so as to allow for manufacturing, maintenance and use of higher field magnets and avoid freezing innovation to the technological limits of the last millennium.

Movement in the static field

There is disagreement as to whether Directive 2004/40/EC applies to currents induced in the body as a result of movement in the static field. This would appear to be the case, since such movement results in exposure of the worker to a time-varying EMF, and such an interpretation is logical, since the effect on the body is exactly the same as that caused by a very low frequency external EMF which undoubtedly is covered by the Directive.

Work performed by Professor Stuart Crozier on behalf of the United Kingdom HSE[9] showed that current densities induced in the bodies of workers walking through the static field at a speed of 1 ms^{-1} can exceed the exposure limits at a distance of 0.5–1 m from the magnet. If working at the face of a 1.5T magnet, it would be necessary for workers to restrict their head and body movements to 0.15 ms^{-1} in order to comply with Directive 2004/40/EC. This would mean that in fact almost all MRI procedures in the EU (approximately 8 million examinations per year) would be affected, as it is normal practice that radiographers accompany patients to the magnet, position them correctly onto the examination table and move the table from the magnet opening into the isocentre of the magnet. The same would apply to injections of contrast media (which are needed in approximately 25% of all examinations) unless these are performed with a mechanical power injector, and to cleaning or maintenance of the system.

Gradient fields (low frequency EMF)[10]

Since the EMF produced by the MRI gradients do not show a sinusoidal variation in time, it is difficult to apply the frequency-dependent limits in Directive 2004/40/EC directly. One approach is to calculate a maximal rate of change of the magnetic flux density (dB/dt) in the rapid

9. Crozier S *et al. J. Magn. Reson. Imaging* 2007; **26**: 1261–1277
10. R. Stam, 2008. The EMF Directive and protection of MRI workers (RIVM Report 610703001/2008). *Bilthoven, National Institute for Public Health and the Environment.*

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 are used, the calculated maximum dB/dt value for the gradient fields is exceeded when workers are closer than half a metre from the end of the MRI magnet bore during scanning. When the maximum dB/dt value given by this simple approach is exceeded, more detailed calculations are necessary to determine whether the exposure limit value is also exceeded. Computer simulations indicate that the current density induced by the gradients fields in the central nervous system exceeds the exposure limit value in Directive 2004/40/EC when the worker's head or trunk is next to or inside the end of the magnet bore. It should be noted that the ICNIRP recommendations are based on a safety factor of 10 below perceptible, but harmless, effects. Such a safety factor may be appropriate where there is a dose-effect relationship (as is assumed in the case of ionising radiation). The nerve stimulation effects produced by low-frequency EMF, however, are threshold effects, with only small biological variations in the onset threshold between individuals. Therefore use of a safety factor is inappropriate, overly cautious, and against all experience in the practical use of MRI accumulated over the last 25 years.

Professor Crozier's study showed that occupational exposure to the gradient field can exceed the exposure limit at a distance of up to 1 m from the magnet, and by a factor of over 20 at the magnet bore itself [11]. These predictions are supported by both theoretical and experimental results in a subsequent EU-funded project [12]. These exposures to switched gradient fields would occur if workers have to be present close to the magnet during acquisition of the images. This applies to examinations under anaesthesia (mainly in children or other patients unable to cooperate – approximately 80,000 procedures per year in the EU). Moreover, close monitoring of sedated or anxious patients – a much larger group – would become impossible. Finally the emerging field of intra-operative or interventional MRI, in which surgeons or radiologists perform therapeutic procedures under MR guidance, would not be allowed under the present restrictions of Directive 2004/40/EC.

Radiofrequency field (high frequency EMF) [10]

For the MRI radiofrequency field, calculations indicate that the Specific Absorption Rate exposure limit value in Directive 2004/40/EC is not exceeded, 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 his or her 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.

Laboratory animal MRI [10]

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 are generally low. As far as can 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. However, data supplied by equipment manufacturers (see below) can be used to assess compliance with the 'action values' in Directive 2004/40/EC: more easily measurable quantities set conservatively to ensure compliance with the exposure limits themselves. Note that animal experiments are sometimes performed in clinical MRI devices, in which case the previous paragraphs apply.

The draft ICNIRP exposure limit of 2 T for head and trunk is not exceeded anywhere outside 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 about the stray fields of three commonly used types of gradient coils were available from one manufacturer. Action values in the Directive 2004/40/EC were only exceeded for one type of gradient at the very edge of the magnet bore, and exposure 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 three 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 [10]

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 Directive 2004/40/EC are not exceeded outside such spectroscopy devices, except at the moment when samples are placed in the device by a worker. 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, earlier paragraphs about whole-body human MRI apply.

Published measurements indicate that the magnetic flux density of the static field around such NMR devices

11. Crozier S *et al. J. Magn. Reson. Imaging* 2007; **26**: 1236–1254
12. http://www.itis.ethz.ch/downloads/VT2007017Final Reportv04.pdf

usually remains low, except during the short periods when samples are changed by hand. It is unlikely, however, that the 2 T exposure limit for head and trunk in the ICNIRP static field guidelines will be exceeded. Since NMR devices are closed when the radiofrequency field is active, the radiofrequency exposure limits in Directive 2004/40/EC will not be exceeded. Although magnetic resonance spectroscopy can also be applied in combination with MRI in human subjects or laboratory animals, relatively basic scanning protocols are normally used that do not increase EMF exposure above that already applied for MRI.

Why is MRI Important for Research?

Magnetic resonance is not only one of the most important scientific advances in the field of medicine in the last 25 years, but also one of the major tools in medical and biological research. The technology was mainly developed in Europe and the threat posed by the EU Directive has been recognised by Sir Peter Mansfield who was awarded the Nobel Prize for his seminal discoveries in the field of MRI.

MRI is central to fundamental brain research (the neurosciences), as well as research in areas such as cancer, cardiovascular diseases, neurodegenerative and psychiatric disorders or alterations of the loco-motor system. As a research tool, MRI allows researchers to visualise soft tissues of practically any organ with very high spatial resolution providing information on structure and morphology in both animal models and humans. Moreover, recent developments in MRI technology allow investigations of functional processes such as cardiac motion, blood flow, metabolism or brain cognition. In the newly emerging field of molecular imaging in biology and medicine, MR could play a pivotal role as the most comprehensive imaging modality combining the above mentioned capabilities of high-resolution visualisation with information at the molecular, functional and metabolic level.

The important role that MR imaging plays in fundamental and applied biomedical research has been underscored by a number of recent large European and national research projects. French Prime Minister Dominique de Villepin made clear reference to these developments on the occasion of the launch of the high-field research infrastructure project NeuroSpin in November 2006. The promotion of analytical tools and technologies for biomedical research, prediction, prognosis, diagnosis, and follow-up of diseases, for drug development, and for monitoring and guidance of therapeutic interventions, in all of which MR plays a crucial role, are also supported under the EU's 7th Framework Programme.

There are a number of other areas outside medical practice that would be affected by Directive 2004/40/EC, particularly by limitations on motion in the static field:

- *Ultra high field MR scanners.* Since the successful introduction of 3 T systems to clinical practice the attention of the research community has shifted to ultra high field systems of 7 T and higher. There are already a number of such systems in Europe, and the Franco-German Neurospin collaboration based at Saclay is currently developing the world's highest field (11.7 T) whole body MRI system. It is clear that imposition of the Directive will severely limit these developments leaving this entire area of research to be dominated by the US.
- *Cognitive neuroimaging*. European research centres play a leading role worldwide in cognitive neuroimaging which relies heavily on functional MRI (fMRI) scanning. In some experiments a scientist needs to sit close to the subject during scanning, in order to provide for example a tactile stimulus.
- *Animal scanners.* Animal MR scanners are used in research and industry, and are considered a powerful tool for reducing the numbers of animals sacrificed in drug testing and research. This is because small cohorts of animals can be scanned repeatedly in longitudinal studies, rather than taking a large cohort from which smaller samples are sacrificed at different time points.
- *Analytical NMR.* Outside the biomedical applications of MR, nuclear magnetic resonance is used in thousands of laboratories Europe-wide for chemical analysis and solid state physics.

Effect of Directive 2004/40/EC on MRI Research

The Wellcome Trust and the Medical Research Council (MRC) of the UK conducted a survey to examine the potential impact of Directive 2004/40/EC on research practice. The results suggest that the Directive could have a significantly prohibitive impact on research: more than three quarters of researchers who are present in the scanner room during operation need to work within 1 m of a scanner.

This study used a questionnaire, sent to every MRI researcher funded by Cancer Research UK, the Engineering and Physical Sciences Research Council (EPSRC), the MRC and the Wellcome Trust, to explore worker exposure to MRI in a research setting. The results revealed that 70% of respondents spend time in the scanner room while the scanner is operational. At low field strengths, researchers are most frequently present to attend to the needs of patients or to conduct interventional MRI; for higher strength scanners, researchers need to be present to monitor animal physiology. The need for researchers to provide technical support is cited across all field strengths, becoming increasingly important with higher field strength magnets. Nearly half (46%) of researchers need to reach into the magnet during imaging, mainly for technical support, patient care and interventional MRI. A further one-third (32%) are within 1 m of the scanner. Therefore, the survey found that overall more than three quarters (77%) of researchers are within 1 m of the scanner, and so could exceed the limits in Directive 2004/40/EC. The majority of respondents reported instances of several people being present in the scanner room during the scan, including technicians, carers, researchers and anaesthetists. Technicians and anaesthetists are most

likely to be standing very close to the magnet, or reaching inside, and can therefore be expected to have the highest levels of exposure.

Awareness of safety and risk assessment appears to be good among all the respondents. All units have either local safety rules for their facility or a local magnetic safety advisor or both, and the vast majority carry out a risk assessment for every research project. The reason for such safety and risk assessment is to reduce the risk to patients and workers from the attractive effects of the systems magnetic field on ferrous object carried by them and interference of the magnetic field with any implants (e.g. pacemakers, aneurism clips, etc.)

The results of this survey suggest Directive 2004/40/EC could have a highly prohibitive impact on research practice, seriously limiting the use of MRI for research purposes and prohibiting research that has clinical and public benefit. The use of new, more powerful high-field scanners in research will be particularly restricted and the Directive threatens the development of new MR methodologies and improvements in technology. Since much MRI research is performed in close collaboration with industry, implementation of the Directive would also severely impact on the ability of MRI manufacturers to undertake product development in Europe, resulting in transfer of knowledge and activities to countries outside the EU.

Problem and Solutions

New scientific research demonstrates that the impact of Directive 2004/40/EC on the use of MRI, while unintended, will have serious consequences for scientific research, healthcare provision and patient welfare.

Problems

1. It will make it impossible for healthcare staff to care for patients, such as children, the elderly or those who are anaesthetised, who need help or comfort during scans. Some of these patients may be forced to use technologies with significant proven health risks, such as X-rays. In many cases this will mean computed tomography (CT) scanning, which has much higher health risks for the patient and also for workers, such as anaesthetists, who must remain close to the CT scanner particularly in the case of children and uncooperative patients.
2. It will stop the use of MRI for interventional and surgical procedures. These procedures will revert to X-ray and CT guidance, with very high exposure to ionising radiation for workers.
3. It will curtail cutting edge research in the field of MRI, denying patients innovative treatments in the future.
4. It will interfere with careers in MRI by imposing limitations on MRI training and education.
5. It will severely interfere with the construction, installation and maintenance of research MRI systems in Europe, and with the development of new systems, often performed in collaboration with academic laboratories. European MRI manufacturers will be forced to relocate these activities outside the EU, with serious impact on European industry and research.

Risk assessment and research into safety aspects of electromagnetic fields is taken seriously by the European and international MR community. MRI scanners available on the market in Europe have to comply with the essential requirements of the Medical Devices Directive, which includes a responsibility towards the health and safety of patients and workers. This is usually achieved through compliance with International Electrotechnical Commission (IEC) standard 60601-2-33, which includes provisions relating to avoidance of peripheral nerve stimulation. In addition, MRI systems are used in a controlled environment, including access controls, safe working practice guidelines and staff training programmes. **Exemption of MRI from any limit values would therefore represent an acceptable and responsible solution for the clinical and research use of MRI, since any risk to workers can be managed in other ways.**

There is a case for adoption of harmonised standards, working practices and safety in MRI across Europe. This might include defining different working situations according to EMF exposure and level of risk. Such definitions have recently been agreed by social partners and other stakeholders as part of new MRI safety guidelines in the Netherlands. The EMRC believes that such an approach would provide a more sensible and workable solution to the issue of exposure to electromagnetic fields than the approach adopted by Directive 2004/40/EC, which will have a severely damaging impact on clinical practice and scientific research in Europe.

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