

MRI and the Physical Agents (EMF) Directive

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November 2008



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Abbreviations

ALARA	as low as reasonably achievable
AV	action value
BIR	British Institute of Radiology
CNS	central nervous system
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DTI	diffusion tensor imaging
DWI	diffusion weighted imaging
DWP	Department of Work and Pensions
ELV	exposure limit value
EMF	electromagnetic field(s)
EPI	echo planar imaging
ESR	European Society of Radiology
EU	European Union
FIPRA	Finsbury International Policy and Regulatory Advisors
HPA	Health Protection Agency
HSE	Health and Safety Executive
ICES	International Committee on Electromagnetic Safety
ICNIRP	International Commission on Non-Ionising Radiation Protection
IEC	International Electrotechnical Commission
IOP	Institute of Physics
IPEM	Institute of Physics and Engineering in Medicine
MHRA	Medicines and Healthcare Products Regulatory Agency
MRI	magnetic resonance imaging
NMR	nuclear magnetic resonance
PNS	peripheral nerve stimulation
RCR	Royal College of Radiologists
RF	radiofrequency
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment)
SAR	specific absorption rate

Executive summary

Magnetic resonance imaging (MRI) is one of the outstanding developments in medical diagnosis of the past century. It is a cornerstone of modern medical practice and it continues to make new inroads as a clinical and research tool. As well as having unique imaging capabilities, MRI is free from the hazards associated with ionising radiation, and instead it acquires images using a combination of three types of magnetic field.

In 2004 the European Union (EU) adopted a directive restricting occupational exposure to electromagnetic fields (EMF), including those used in MRI. Some of the exposure limits, which are relevant to low-frequency time-varying magnetic fields, threatened to impact on the current use and future development of MRI technology. These limits are purported to be necessary to avoid known acute adverse health effects in workers, but examination of the underlying evidence shows that they are in reality based on a precautionary approach to very limited data, most of which relates to frequency ranges that are not relevant to MRI. Known adverse effects in the relevant frequency range occur at exposure levels of up to two orders of magnitude higher, and these are adequately addressed in the international standard governing the manufacture of MRI scanners.

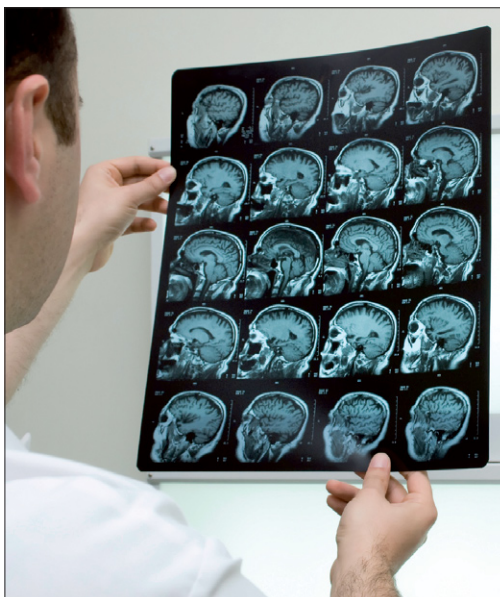
Initially unable to influence the UK and EU regulatory agencies, the MRI community began to campaign and lobby both the UK and European parliaments. This activity bore fruit in the form of research projects initiated by the UK government and the European Commission, both of which confirmed that MRI workers routinely exceed the exposure limits by a significant margin. There is no evidence that they experience ill effects as a result.

Implementation of the directive has been delayed until 30 April 2012 to allow a permanent solution to be found, which is an unprecedented move. However, the timescale is short given the political and scientific complexities of the issue. A range of possible outcomes are explored in this report. Each option has advantages and disadvantages, and a great deal of detailed discussion and negotiation will be needed over the next 1–2 years to ensure satisfactory resolution of the problem.

1: Introduction

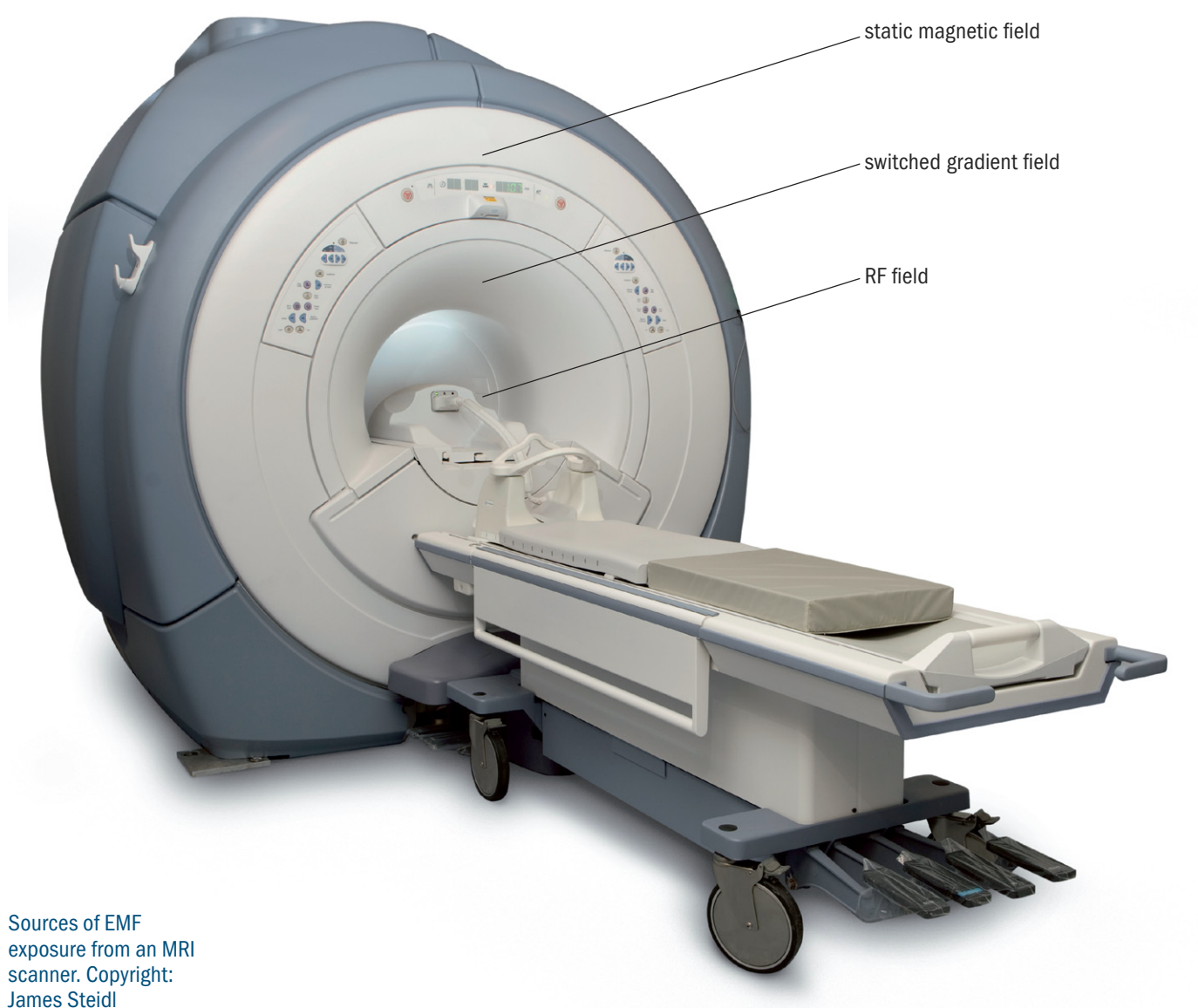
In 2004 the EU adopted a measure known as the Physical Agents (EMF) Directive, which member states are obliged by treaty to incorporate into their domestic legislation. The directive contains limits on occupational exposure to EMF that would restrict the use of MRI in medical practice and research. Following a lengthy lobbying campaign, implementation of the directive has been postponed until 2012, but a permanent solution remains the subject of ongoing debate. This report is intended as a contribution to that debate.

It begins with an overview of MRI and its applications ([section 2](#)), followed by a summary of the aims of the directive and the rationale for the stated exposure limits ([section 3](#)). [Section 4](#) outlines the impact of the directive on MRI, and it includes the results of two major research projects that have vindicated the original claims of the MRI community with regard to EMF exposure. Actions taken by the community in the UK and at EU level to address the problems raised by the directive are described in [section 5](#). The report concludes with a discussion of future options ([section 6](#)), and some general conclusions and recommendations ([section 7](#)).



A medical professional checks an MR brain scan.
Copyright: Emrah Turudu

2: What is MRI?



“The MRI process is very flexible and it is able to produce images conveying a wealth of different types of information about body structures and their mechanical and physiological properties.”

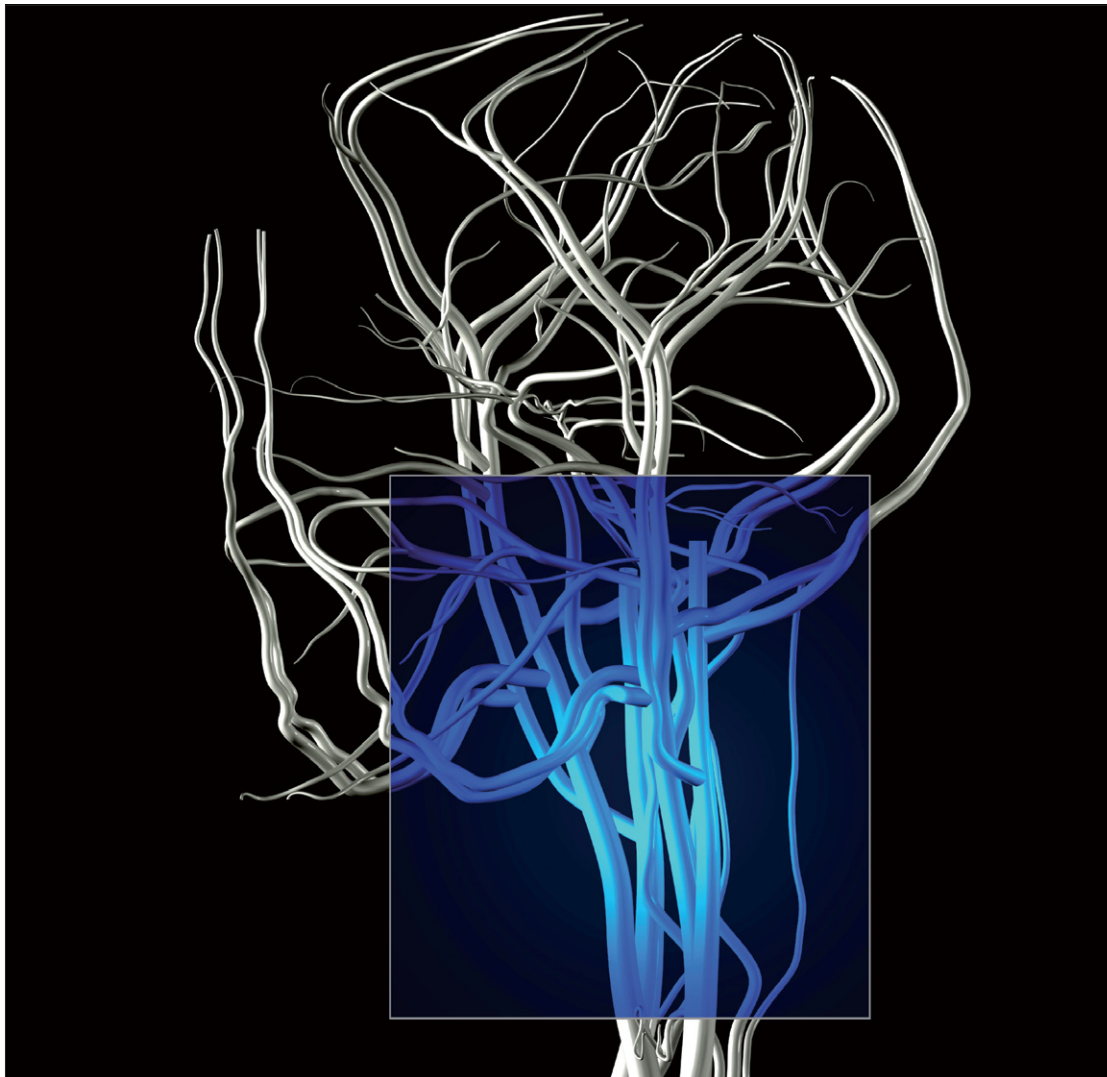
MRI is a diagnostic technique that produces images of unrivalled quality, particularly of soft tissues that are not well depicted in X-rays. The MRI process is very flexible and is able to produce images conveying a wealth of different types of information about body structures and their mechanical and physiological properties. In addition, unlike X-ray imaging it does not use ionising radiation and is thus safer for both patients and staff.

MRI is based on certain properties of the nuclei of hydrogen atoms, which are present throughout the body in water molecules. When placed in a strong magnetic field, these nuclei can absorb energy from an applied radiofrequency (RF) field and re-emit it in a way that reveals information about the interactions of the nuclei

with each other, the movement of the water molecules, and other physical and chemical properties of the tissue environment. Another magnetic field, switched on and off rapidly and varying with position inside the scanner, is used to map these properties so that an image can be formed. Thus MRI uses three types of magnetic field: a strong static field (typically 1.5–3 T), an RF field with a frequency in the 10s–100s MHz range and a magnetic field gradient that is switched on and off at a frequency of around 1 kHz during imaging.

The phenomenon underlying MRI – nuclear magnetic resonance (NMR) – was discovered by physicists in the 1940s and rapidly became a standard tool in analytical chemistry. The samples studied soon came to include

2: What is MRI?



“MRI...has generated a multibillion pound industry with an installed base of more than 20 000 scanners worldwide.”

MRI of neck and jaw arteries and veins. Copyright: Aaliya Landholt

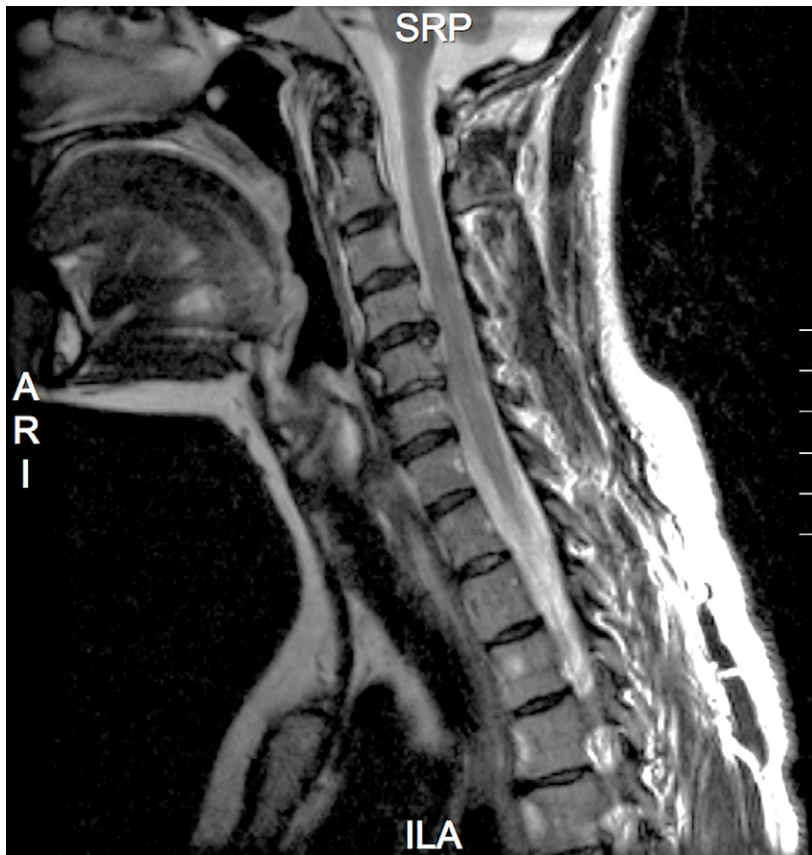
biological material, and in 1971 Raymond Damadian of the State University of New York Health Science Center at Brooklyn proposed mapping out NMR signals in the body to form images. The practical realisation of this idea came in the 1970s through the work of Paul Lauterbur at the State University of New York at Stony Brook and Peter Mansfield at the University of Nottingham. Many seminal developments in the early years of MRI took place in UK university physics departments and hospitals. The almost ubiquitous “spin warp” approach to imaging was developed by John Mallard’s group at the University of Aberdeen, rapid echo planar imaging (EPI) was another contribution by Mansfield, and the world’s first MRI head images were acquired by Ian Young and colleagues at Hammersmith Hospital. In 2003, Paul Lauterbur and Sir Peter Mansfield (by then knighted for his contributions to MRI) received the Nobel Prize in Medicine.

In the early 1980s MRI became available in hospitals, initially as a research tool. It rapidly took over as the method of choice for imaging the brain and spine,

and now it has a role in imaging almost all parts of the body. It has generated a multibillion pound industry with an installed base of more than 20 000 scanners worldwide. Around 500 scanners in UK hospitals perform more than 1 million examinations each year. No record is kept of the number of clinical MRI examinations that have been carried out worldwide, but it is probably in excess of 500 million and increasing by more than 50 million per year.

MRI is a mainstay of cancer diagnosis and treatment monitoring, with emerging molecular imaging techniques poised to make further major contributions in this area. Cardiac MRI has made huge strides in recent years. For example, it allows the functional assessment of heart muscle in heart-attack patients. Diffusion weighted imaging (DWI) allows the rapid assessment of patients in the acute phase after a stroke. Functional MRI, mapping out areas of the brain that are responsible for specific sensory and motor tasks, is making important contributions to neuroscience as well as improving the outcome of brain surgery for patients.

2: What is MRI?



MRI of the cervical spine. Copyright: Jennifer Sheets

MRI is now being used in interventional procedures that have traditionally been performed under X-ray guidance: improving image quality, providing additional information and eliminating ionising radiation. There are interventional MRI facilities at several UK hospitals, and these are responsible for a number of breakthroughs in the field. Many millions of pounds have been invested in MRI by the higher education funding councils, research councils and medical charities, as well as the NHS, and its increasing importance in preclinical research and drug development has attracted similar sums from the pharmaceutical industry.

These developments have been made possible by continuous innovation in MRI technology, which is often the result of close collaboration between industry and academia. Early scanners required the patient's entire body to be placed inside a tunnel – a daunting experience for many. Today, shorter magnets with wider bores have made MRI much more patient-friendly, and better access to the patient has facilitated new techniques, such as interventional MRI. Developments in RF technology and sophisticated mathematical algorithms for image reconstruction have resulted in split-second imaging techniques that allow real-time imaging of the beating heart. Stronger magnets, such as the 7 T system at the University of Nottingham, allow higher-resolution images and are leading the way in the development of new functional imaging techniques.

3: The Physical Agents (EMF) Directive



A radiographer monitors an MRI scan. Copyright: James Steidl

A directive is an EU legislative instrument that member states must implement in their domestic law (a process known as transposition). The Physical Agents (EMF) Directive,¹ was adopted by the EU in 2004 with a transposition deadline of 30 April 2008 (this has now been postponed; [section 5](#)). This aims to restrict occupational exposure to EMF with frequencies of up to 300 GHz because of “the risk to the health and safety of workers due to known short term adverse effects in the human body”. The wording here is crucial: the directive applies only to workers, and the objective is to prevent effects that are known, short-term and adverse. It is not intended as a precautionary measure to guard against the possibility of unknown or long-term effects, nor is it necessarily intended to prevent physiological effects that are harmless.

The directive contains exposure limit values (ELVs), which may not be exceeded under any circumstances, and supplementary action values (AVs) to ensure compliance with the limits. The ELVs and AVs are based on

exposure guidelines published in 1998 by the International Commission on Non-Ionising Radiation Protection (ICNIRP).² The scope of the directive encompasses all three types of magnetic field used in MRI. The ELVs that apply in the relevant frequency ranges are shown in [table 1](#). The data in the right-hand column of the table are discussed in [section 4](#).

There is no ELV for static magnetic fields: a proposed limit of 2 T was removed during negotiation (although somewhat paradoxically an AV of 200 mT remains). In the RF frequency range the ELV is based on the well understood phenomenon of tissue heating. Although the limit is very low (corresponding to a temperature increase of about 0.1 °C), it does not represent a major problem for MRI because worker exposure to high levels of RF is unusual and almost invariably brief, and the directive allows RF exposure to be averaged over time. The concerns of the MRI community therefore focus on the ELVs for low-frequency magnetic fields, which are expressed in terms of the electrical current density

“The objective is to prevent effects that are known, short-term and adverse.”

Table 1: Exposure limit values (ELVs) and estimated occupational exposures in MRI.

Field	Frequency	ELV	Estimated maximum occupational exposure in MRI
static magnetic field (always present for most scanners)	0 Hz	none (action value 200 mT)	3 T (clinical) 9.4 T (research)
	<1 Hz (typical) (generated by movement of subject)	current density 40 mA m ⁻² head and trunk	200–400 mA m ⁻² (CNS) ⁷ limit exceeded 0.5–1.0 m from magnet if moving at 1 ms ⁻¹
switched gradients (present only during imaging)	1 kHz (typical)	current density 10 mA m ⁻² head and trunk	>200 mA m ⁻² (CNS) ⁸ limit exceeded ≈ 1 m from end of scanner bore
RF (present only during imaging)	10–100s MHz	specific absorption rate (SAR) 0.4 W kg ⁻¹ whole body 10 W kg ⁻¹ head and trunk 20 W kg ⁻¹ limbs all SAR values averaged over 6 min, localised SAR averaged over 10 g tissue	not exceeded in normal circumstances ¹⁰

induced in the conductive tissues of the body and apply to instantaneous exposure, with no allowance for temporal averaging.

The directive states that these current density limits are necessary to avoid “acute exposure effects on central nervous system [CNS] tissues”. However, it is clear from the 1998 ICNIRP paper that the limits are based largely on the thresholds for biological effects (not adverse health effects) observed at 20–60 Hz, extrapolated over three orders of magnitude in frequency on an essentially precautionary basis. Furthermore, many of the effects described were reported many years ago, some in conference proceedings rather than full refereed papers, and they lack replication. The only specific biological effect described in the ICNIRP guidelines that has been reported at frequencies of more than 60 Hz is peripheral nerve stimulation (PNS).

PNS occurs when sensory nerves are stimulated by electrical currents induced by a time-varying magnetic field, such as the switched gradients in MRI. It results in a sensation ranging from tingling to intolerable pain, depending on the amplitude of the field, and in its severe form it is undoubtedly an adverse effect. However, the current density threshold for PNS, even in its mild form, is around 1 A m⁻² – 100 times the ELV in the directive. The International Electrotechnical Commission (IEC) standard governing the manufacture of MRI scanners³ is designed to avoid PNS in patients and workers.

Other physiological effects sometimes reported by MRI workers are transient vertigo-related symptoms and

a metallic taste in the mouth. These occur when working close to a high-field magnet – usually 3 T or more – and are due to magnetic field interactions with the organs of balance in the inner ear and the induction of currents in the tongue. They are believed to be harmless and can be minimised through worker training. There is no evidence of other acute effects due to MRI, despite the fact that hundreds of millions of patients have been exposed at levels well in excess of the ELVs in the directive.

It is perhaps worth stressing at this point that significant risks do arise in MRI due to so-called “indirect effects”, the obvious example being the possibility of ferromagnetic objects that are brought too close to the powerful magnet becoming projectiles with potentially deadly consequences. These risks are managed by means of careful safety policies and procedures. They are not within the scope of the directive, which deals only with the direct effects of human exposure to EMF.

The members of ICNIRP are internationally acknowledged experts in their fields, but the guidelines that they produced are based on the cautious interpretation of sparse data and are essentially precautionary in nature. It has since come to light that the possibility of the directive causing problems with MRI was raised by some MEPs at an early stage. However, it was dismissed because the European Commission received assurances from ICNIRP that the ELVs would not be exceeded by MRI workers. It has not been possible to determine the precise nature, timing and basis of this erroneous advice.

“Many of the effects described were reported many years ago, some in conference proceedings rather than full refereed papers, and they lack replication.”

4: Implications of the directive for MRI



“There are instances in which a member of staff remains in the examination room and close to the scanner while it is operating.”

An MRI head scan. Copyright: Luis Carlos Torres

After the draft directive was published, it soon became apparent that there would be a significant impact on MRI in both research and clinical practice.

For practical reasons, when an MR scan is performed the operator normally leaves the room and operates the scanner from a separate control room. However, there are instances in which a member of staff remains in the examination room and close to the scanner while it is operating. Examples of these situations include:

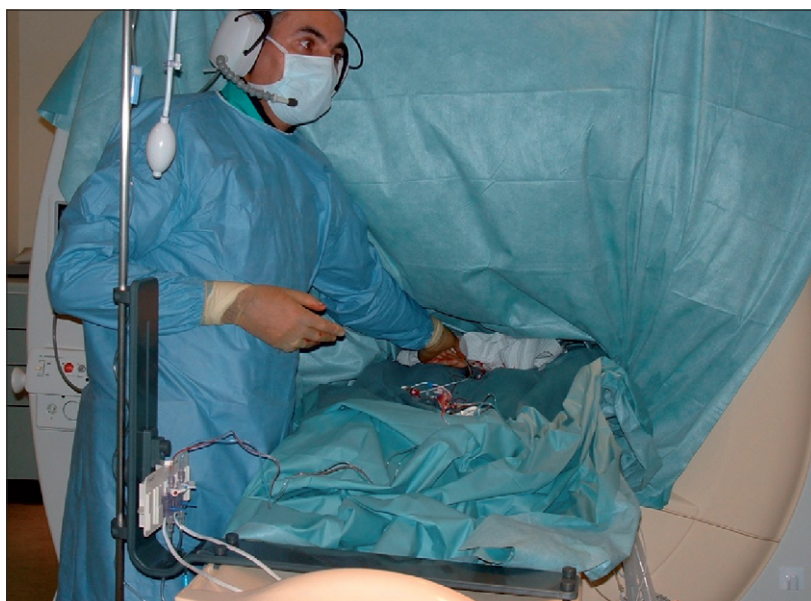
- interventional MRI, where a radiologist or other clinician may be reaching inside the bore of the magnet to carry out invasive procedures during scanning;
- some types of functional MRI, such as research studies on deaf-blind subjects where a member of staff touches the palm of the patient's hand during

scanning;

- imaging of children, where the close presence of a nurse or radiographer may avoid the need for anaesthesia to obtain satisfactory images;
- imaging of patients who are anaesthetised or require monitoring, where it is common for an anaesthetist to remain in the room and visually assess the patient during scanning;
- research applications, where a researcher may need to adjust experimental equipment during imaging.

Initial estimates showed that for workers remaining close to the magnet bore in these situations, when the switched gradients are operating, the exposure is likely to exceed the AV for 500–1000 Hz magnetic fields by a factor of around 50^{4,5} and the ELV by an order of magnitude.⁶

4: Implications of the directive for MRI



A paediatric cardiologist carrying out an MRI-guided heart procedure on a child.

This gradient exposure issue is a problem only for a limited number of procedures in which a worker must remain close to the scanner while it is acquiring images. However, there is also a more general problem. When a worker moves through the magnetic field close to the scanner, they experience a very-low-frequency time-varying field, and electrical currents are induced in the conductive tissues of the body. The directive gives exposure limits for time-varying magnetic fields; it does not distinguish between situations in which the time variation arises at source (as with the switched gradients) and those in which it arises because of movement of the subject. Indeed, such a distinction would be illogical because the situations are physically indistinguishable. Estimates have shown that movement close to a scanner at normal walking speed results in induced currents that breach the ELVs by a factor of almost 10, and that compliance would require movement no faster than 0.15 ms^{-1} close to a 3 T scanner.⁶ Most MRI scanners contain a superconducting magnet that is always on, so this problem impacts on all uses of MRI equipment, including installation, maintenance and cleaning, as well as clinical operation.

More rigorous studies have now confirmed these early estimates by the MRI community.^{7,8,9,10} The right-hand

column of [table 1](#) shows estimates of occupational exposure derived from computational modelling work by Stuart Crozier's group at the University of Queensland, commissioned by the UK Health and Safety Executive (HSE) ([section 5](#)). In another recent study, funded by the European Commission and performed by a consortium of MRI and EMF scientists from Zurich, Umeå and London, staff exposure was assessed and modelled for a range of clinical and research procedures at four MRI sites in Europe. This found that ELVs "regarding induced currents in the CNS...are violated for persons positioned next to the scanners by a factor of up to 10 and even more for movements", and that, "in the case of interventional MRI, the induced currents may exceed [the ELVs by] a factor of 50".¹⁰

As an aside, it is perhaps worth noting the difficulties implicit in assessing compliance with the directive. The ELVs are expressed in terms of quantities, such as induced current densities, that cannot be measured directly, so computational modelling must be used to assess exposure. These models have inherent uncertainties and limitations, which are amplified by ambiguities in the directive's wording. It states that the limits apply only to the CNS and that higher exposures are permissible in other tissues, but how much higher is left unclear. Exposure is to be averaged over 1 cm^2 of tissue, but there are ambiguities as to the intended shape and composition of this region.¹¹ Finally, the ELVs in the directive relate to sinusoidally varying electromagnetic waves at specific frequencies, whereas the switched gradients used in MRI are pulsed fields. There is no consensus on the assessment of exposure in this situation, and the approach recommended by ICNIRP results in significant overestimation.¹²

Despite these uncertainties, it is difficult to avoid the conclusion that a range of current and emerging MRI procedures would be rendered illegal by the directive. Some of these techniques simply cannot be performed in other ways, and in other cases the only possible option would expose both the patient and workers to ionising radiation. So, far from protecting worker health and safety, in the context of medical imaging the directive might have quite the opposite effect: a recent study found that almost 40% of interventional radiologists who perform X-ray-guided procedures have signs of radiation damage to their eyes.¹³

"Estimates have shown that movement close to a scanner at normal walking speed results in induced currents that breach the ELVs by a factor of almost 10."

5: Action by the MRI community



An MRI of the abdomen showing polycystic kidney disease. Copyright: Dean Hoch

As long ago as 1993, a proposal was published for a Physical Agents Directive limiting exposure to noise, vibration and optical radiation, as well as EMF. Concern was raised within the MRI community about the EMF element of this draft. The initiative did not proceed at that time but was revived in 1999 in the form of separate directives dealing with each of the four agents. By then the 1998 ICNIRP guidelines were available, and the proposal for an EMF directive based on these was duly published in December 2002.

In April 2003, the trade body for medical device manufacturers in Europe, the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), wrote to the European Commission to express concerns about the directive. Action by the MRI community in the UK began in July 2003, when the British Institute of Radiology (BIR) raised the issue with the HSE. The speed of these responses was remarkable, given that the community was not consulted. The directive does not specifically refer to MRI, and quite a sophisticated understanding of MRI physics is required to appreciate its impact.

A timeline of key events in the UK and at EU level is shown in [table 2](#). Regulators in both the EU and the UK were dismissive when concerns were raised. In the case of the European Commission, this was presumably because of the erroneous advice received from ICNIRP. In the UK, the view of HSE inspectors was that if ELVs were exceeded then the design and use of MRI equipment would have to change to achieve compliance. This position was maintained as late as 2005, and it subsequently became apparent that senior HSE policy staff negotiating the directive in Brussels were not made aware of the concerns being raised in the UK. In the

meantime the directive was adopted by the EU without modification, other than the omission of the proposed 2 T static field ELV.

In September 2005 a group of MRI scientists working with the charity Sense About Science issued a press release and held a press conference at the Royal Institution to make their concerns public. The ensuing media coverage was followed by a coordinated letter-writing campaign by research-funding bodies, medical research charities and individual eminent scientists. As a result, in October 2005 representatives of the Royal College of Radiologists (RCR) were invited to meet with Lord Hunt of King's Heath, who was then minister of state at the Department of Work and Pensions (DWP) with responsibility for occupational health and safety. More detailed discussions took place at a stakeholder meeting at the HSE in January 2006, attended by more than 50 representatives of professional groups, industry, government agencies and funders. Subsequent meetings with senior HSE staff and with Lord Hunt resulted in the commissioning of Stuart Crozier at the University of Queensland to model EMF exposures in MRI and to determine the extent of the problem created by the directive ([section 4](#)). The HSE began to work with the UK MRI community to bring about change in Brussels.

In parallel with this, the former House of Commons Science and Technology Select Committee launched an inquiry into the issue. Written and oral evidence was given by scientists representing the professional bodies involved in MRI, including the Institute of Physics (IOP). Members of the committee travelled to Brussels to interview European Commission officials responsible for the directive. The committee's report,¹⁴ which was published in June 2006, was critical of the HSE, the Health Protec-

"The directive does not specifically refer to MRI, and quite a sophisticated understanding of MRI physics is required to appreciate its impact."

Table 2: Timeline of activity by the MRI community and other key dates.

Date	Action
April 2003	COCIR writes to EU Social Questions Working Party expressing concerns.
July 2003 – September 2005	BIR, IPPEM and individual scientists raise concerns with HSE, HPA and MHRA in writing and in face-to-face meetings.
29 April 2004	EU adopts Directive 2004/40/EC.
20 September 2005	MR scientists and clinicians hold press conference highlighting concerns.
September – December 2005	Eminent scientists, funding bodies and charities send letters to Department of Health and HSE expressing concerns.
20 October 2005 – May 2007	RCR, Lord Hunt of King's Heath and HSE officials hold meetings.
25 November 2005	RCR writes to Lord Warner expressing concerns.
5 January 2006	Stakeholders hold meeting at HSE.
January – May 2006	House of Commons Science and Technology Committee stages inquiry. Professional bodies, including IOP, provide written and oral evidence. Report criticises national agencies and European Commission.
March 2006 onwards	ESR representatives and Commissioner Špidla hold meeting, followed by further meetings with European Commission officials.
February 2007	MRI scientists attend ICNIRP workshop to discuss EMF exposure in MRI in the context of ICNIRP guidelines.
March 2007	Alliance for MRI is established.
May 2007	ESR representatives brief European Parliament Committee of Social Affairs.
June 2007	Alliance for MRI representatives present results of Crozier study at a lunch in Brussels. Report confirms that ELVs are exceeded by MRI workers.
October 2007	European Commission announces proposal to delay transposition deadline until 2012.
February 2008	Report of contractors engaged by European Commission provides confirmation that ELVs are exceeded during a range of MRI procedures.
23 April 2008	Directive 2008/46/EC is adopted, coming into force three days later. It postpones the transposition deadline for Directive 2004/40/EC by four years.

tion Agency (HPA), ICNIRP and the European Commission, and it concluded that there was no need for the directive in the context of MRI.

Meanwhile, lobbying was also under way at EU level. In March 2006 a delegation of radiologists and scientists representing the European Society of Radiology (ESR) met with Vladimír Špidla, commissioner for employment, social affairs and equal opportunities, to discuss the difficulties posed by the directive. As a result a contact group was set up with European Commission officials and ESR representatives. This proposed a further study of EMF exposures in MRI, and an international consortium of scientists was selected to perform the work (section 4).

The Alliance for MRI¹⁵ was established in March 2007 as an umbrella group for the campaign at EU level. It consists of MEPs, professional bodies, funding agencies, patient groups and individual scientists, and has received invaluable support from FIPRA, a public affairs consultancy based in Brussels.

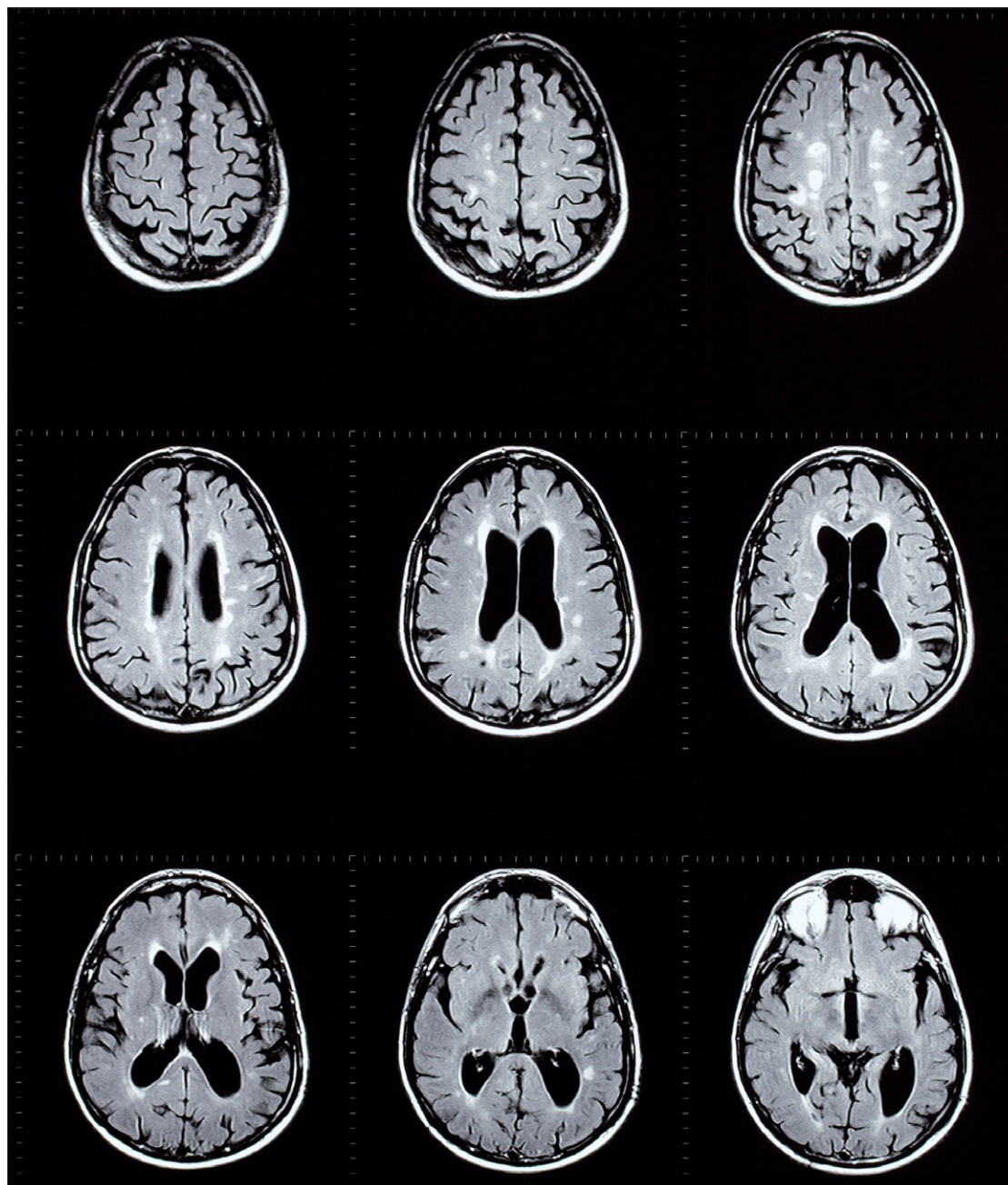
In May 2007, ESR representatives briefed the European Parliament Committee on Employment and Social Affairs on the issue, and in June 2007 the Alliance for

MRI hosted a lunch for MEPs and officials (including Commissioner Špidla) to present the results of the Crozier study, which was published by the HSE on the same day.¹⁶ These results, which are described in section 4, demonstrate that the ELVs in the directive are frequently exceeded by MRI workers.

After this presentation the European Commission indicated that a delay in the deadline for transposition of the directive might be possible. In October 2007 a four-year delay (until 30 April 2012), was proposed. This required the adoption of a new directive, which was passed using a special accelerated procedure and came into force on 26 April 2008, only four days before the original transposition deadline.¹⁷ A delay to transposition under these circumstances is believed to be unprecedented. Later in October 2007 the interim report of the European Commission's own study was received, showing that directive AVs are typically exceeded at around 1 m from an MRI scanner. The final report, which was submitted in February 2008, confirmed that the ELVs are also exceeded in a range of realistic circumstances¹⁰ (section 4).

“These results... demonstrate that the ELVs in the directive are frequently exceeded by MRI workers.”

6: Prospects for the future



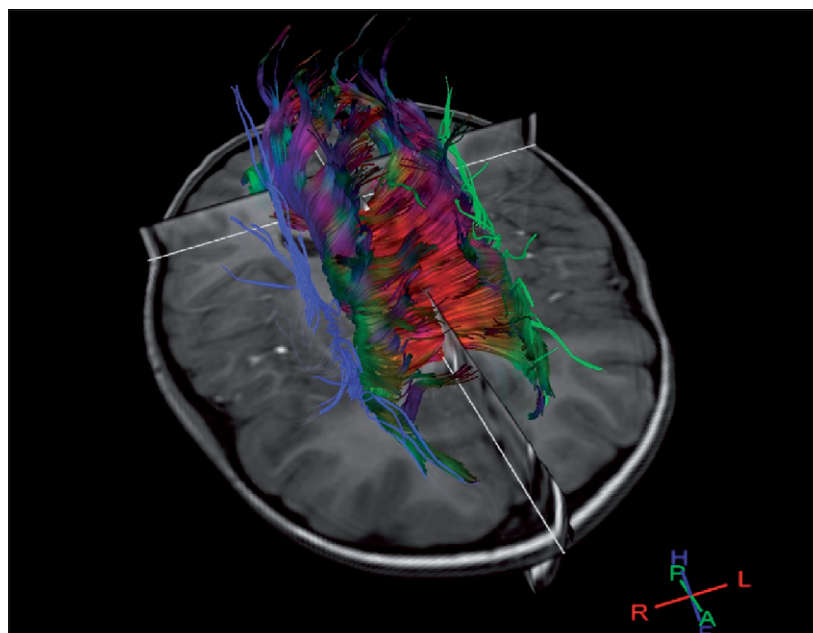
"It is sobering to remember that, so far, only the transposition deadline has changed."

An MRI series of the human brain showing multiple sclerosis plaques. Copyright: Dean Hoch

The decision to delay the transposition of the directive was motivated explicitly by the potential impact on MRI, to allow time for a substantive amendment that, according to the European Commission, would "ensure that limits will not have an adverse effect on the practice of MRI, whilst ensuring appropriate protection of personnel".¹⁸ This outcome has been warmly welcomed by MRI professionals and the media. However, it is sobering to remember that, so far, only the transposition dead-

line has changed: the legal position, until such time as there is a further amendment, is that member states are obliged to implement the existing ELVs by 30 April 2012. The community is now engaged in negotiations to find a definitive solution.

The ideal outcome, of course, would be to address the paucity of research over much of the relevant EMF frequency range so that the uncertainties underpinning the cautious approach taken by ICNIRP can be addressed.



Nerve fibre tracts in the brain, derived from MRI diffusion tensor imaging (DTI). Visualisation of these tracts allows effective and safe placement of a deep brain stimulation device to relieve the symptoms of Parkinson's disease.

Such work is in progress as far as acute effects are concerned. In addition, an HPA committee is exploring options for an epidemiological study to investigate the long-term effects of MRI exposure, which would supplement a similar study that was recently initiated by the Dutch government. However, the timescale precludes new results influencing the forthcoming amendment of the directive. There is a case to be made that the exposure of more than half a billion patients to MRI without the observation of previously unknown acute adverse effects, while not a formal scientific study in any sense, should at least contribute to a presumption against the existence of such effects. It may be sensible to proceed cautiously in the face of the remaining uncertainty, but this must be balanced against the benefits of MRI procedures that would potentially be outlawed by overcautious mandatory limits.

In July 2008 the European Commission issued a call for tenders to conduct an assessment of five different options for the future of the directive.¹⁹ The contract for this work is expected to be awarded in December 2008, with completion due by September 2009. This represents a very ambitious timescale given the size of the project, yet it leaves little time for the development of an amendment in time for transposition in 2012.

The options presented by the European Commission are summarised here as the basis for a more general discussion of possible outcomes.

1. Retention of the existing ELVs

This would not solve the problem and seems inconsistent with previous statements made by the European Commission.

MRI obviously could be brought into compliance with the existing directive by redesigning scanners and clinical practices. For example, magnet bores could be made as long as they were 15 years ago, so that exposure to the switched gradient field at the bore opening would be reduced to a level below the ELV. Alternatively, gradient amplitudes and switching rates could be curtailed. However, these would be retrograde steps in terms of the clinical utility of MRI, as described in section 2, and would prohibit developments such as interventional MRI and real-time imaging while increasing overall risk through the greater use of X-ray imaging. These sacrifices are not justified in the absence of established adverse effects, and they would also render much of the installed base of thousands of MRI scanners in Europe obsolete.

It is also true that addressing some of the ambiguities in the current directive could narrow the range of situations in which ELVs would be exceeded – for example, clarification of the volume and type of tissue over which exposure is to be averaged; agreement of a more accurate means of assessing pulsed field exposure; and clarification as to whether the time-varying field limits apply to currents arising from the movement of workers. In the absence of clarity on these issues, the worst case tends to be assumed, resulting in an overestimation of exposure.

However, while these clarifications are much needed and may improve matters at the margins, they will not solve the problem.

2. New ELVs based on the latest international recommendations

ICNIRP is expected to publish new exposure guidelines early in 2009. These are likely to be influenced by the debate around the directive and MRI, although as early as 2004 ICNIRP stated that the 1998 guidelines were “written many years ago, and [are]...now under review”.²⁰ The new guidelines are expected to include a static field exposure limit of 2 T, but with 8 T allowed in a controlled environment with appropriate working practices, which would almost certainly include MRI facilities. Changes are also expected to the low-frequency time-varying field limits, but it seems unlikely that incorporating these revisions into an amended directive will be sufficient to bring all MRI practices into compliance.

ICNIRP is the official provider of non-ionising radiation protection advice to the European Commission. However, there are alternative international recommendations that could in principle be considered as candidates for inclusion in an amended directive. The International Committee on Electromagnetic Safety (ICES) has proposed EMF exposure limits that deviate significantly from the ICNIRP recommendations,²¹ particularly in the low-frequency range. In practical terms, the ICES limits are higher than those of ICNIRP in some

“There is a case to be made that exposure of more than half a billion patients to MRI without observation of previously unknown acute adverse effects, while not a formal scientific study in any sense, should at least contribute to a presumption against the existence of such effects.”

frequency ranges and lower in others, so the implications for MRI would not be straightforward.

The exposure limits in the IEC standard on MRI equipment³ might also be considered. This standard already has a status within the EU legal framework because it is harmonised with the Medical Devices Directive, which governs the manufacture and sale of medical equipment in Europe. It has the advantage of dealing with established effects in the context of MRI specifically, rather than with largely hypothetical effects from all types of EMF exposure. The standard originally applied only to patient exposure, but in the second amendment to the current edition (not yet adopted in Europe) the limits were extended to “MRI workers”. The argument is that since exposure limits at low frequencies are based on instantaneous effects, it is appropriate to apply the same limits to both groups. This approach is not universally accepted, and some experts argue that there should be additional safety factors for workers in view of the remaining uncertainties.

3. New ELVs based on the latest international recommendations with exemptions for specific cases

This appears to leave open the possibility of a derogation to remove MRI entirely from the scope of the directive, which is the policy of the Alliance for MRI. However, there is considerable opposition to such a move in European institutions and some member state governments, and it is more likely that specific MRI practices would be made exempt – most likely interventional MRI. This would leave difficulties for other practices, such as the visual monitoring of patients by an anaesthetist, and could constrain the development of MRI in the future. A more general solution might be to introduce a higher exposure limit for workers in a controlled environment, as ICNIRP is expected to recommend in relation to static fields. Of course, a higher limit that was not based on established effects might become problematic in the future, as indeed may the proposed 8 T upper limit for the static field.

4. Non-binding action based on the latest international recommendations, possibly accompanied by good-practice guides, information campaigns, training programmes and voluntary agreements at European or sectoral level between social partners

This would restore the ICNIRP guidelines to their proper status as cautious recommendations rather than mandatory limits, and could introduce Europe-wide guidance on MRI safety that might be similar to that already in place in the UK²¹ and under development in the Netherlands.

This option also opens the way to a solution based on a framework directive supported by sectoral social partner agreements. These are agreements reached between employers and trade unions that, in this context, would set out approaches to exposure limitation



An MRI scan of a wrist. Copyright: Jennifer Sheets

that are appropriate to specific employment sectors. There could, for example, be an agreement relating specifically to MRI, perhaps based on existing national MRI safety guidelines. There could be an “exposure minimisation” approach, similar to the ALARA (as low as reasonably achievable) principle in ionising radiation protection, although here intended as a precautionary approach to guard against possible unknown effects rather than to minimise established stochastic risks.

This seems a much more sensible approach than one-size-fits-all mandatory limits, and a sectoral agreement would be easier to modify as new research results hopefully close the gap between the ICNIRP, ICES and IEC approaches to exposure limitation. It would also be consistent with the European Commission’s recommendation that precautionary approaches to regulation should be applied in a way that takes account of cost-benefit considerations.²² Such considerations are inevitably specific to a given sector.

5. Repeal of the directive

It is inconceivable that this would be acceptable, particularly to the trade unions, which are not unreasonably concerned about the protection of workers in other sectors where there are well established risks to health due to EMF exposure.

In addition to the impact assessment, proposed changes will be subject to two-stage tripartite consultation with governments, employers and trade union representatives, as is required under EU legislative procedures. They will then have to be agreed by the European parliament and council under the co-decision process. At least a year will be needed after that for national transposition. If this is to be achieved by the end of April 2012, then realistically a new draft directive is needed no later than early 2010. It is a demanding timescale, given the complexity and political sensitivity of the project.

“A more general solution might be to introduce a higher exposure limit for workers in a controlled environment.”

7: Conclusions and recommendations

“Simply amending the directive to allow marginally higher exposure limits that are still not based on established adverse effects will merely postpone the problem until developments in MRI begin to approach these levels.”

The success of the MRI community's campaign in response to the directive has been unprecedented. Starting from a position of confrontation with regulators at national and European level, the immediate threat of the directive has been deferred, with regulators in the UK working closely with the community to achieve this. The European Commission now appears to be committed to finding a permanent solution to the problem. However, the political landscape ahead is complex and the time available is short. Major potential confounding factors include the following:

- There will be elections to the European Parliament in June 2009 and a new European Commission will be appointed in November 2009. These changes may impact on links that the MRI community has developed with MEPs and in the European Commission, and a new set of relationships may need to be fostered.
 - Six member states had already transposed the directive into national law before the postponement was announced and, although some are now believed to be reversing the legislative process, others may see no need to do so. This is particularly likely in countries with less advanced MRI practices and/or a less rigorous regulatory approach.
 - On a related point, new member states in eastern Europe have historically had national EMF exposure limits that are lower than those in the directive. These countries were not members of the EU when the original directive was adopted and it may be difficult to persuade them to support an amendment containing limits that deviate even further from existing domestic legislation.
 - Trade unions have a very influential role within the EU and may oppose moves that they perceive as reducing the level of protection offered to workers generally or in specific employment sectors.
- The eventual solution should ideally be future proof: simply amending the directive to allow marginally higher exposure limits that are still not based on established adverse effects will merely postpone the problem until developments in MRI begin to approach these levels. The option that comes closest to this aim, while also having a chance of commanding the necessary support, would appear to be the sectoral social agreement approach. This is gaining ground in the UK and a report prepared for the Dutch government (currently at draft stage), while remaining agnostic as to the preferred outcome, also gives the impression that this is the most comprehensive solution.
- This situation may change and it is not yet clear that the MRI community should invest all of its efforts in a single approach. Whatever solution is pursued, a successful outcome in 2012 will depend on the engagement of the community in a number of areas:
- with MEPs and the European Commission, both before and after the changes due in 2009;
 - with politicians in the member states – the European Council, which will have to agree any proposed legislative changes, is made up of ministers from member state governments;
 - with patient groups to ensure that public pressure is kept up over the next 1–2 years as revised proposals are developed;
 - with trade unions, particularly but not exclusively with a view to promoting the sectoral social agreement model as a means of providing an appropriate level of protection to workers in each employment sector;
 - with ICNIRP to press for a clearer distinction between limits that are based on established adverse effects and those that are precautionary and should be treated as such.

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