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Science and Technology Committee

Watching the Directives: Scientific Advice on the EU Physical Agents (Electromagnetic Fields) Directive

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Report, together with formal minutes, oral and written evidence

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Report

Summary

This Report is the first of three case studies under the Committee's over-arching inquiry into how Government handles scientific advice, evidence and risk in policy making. We examined this subject to test the way in which scientific advice is used by the UK Government to influence policy at an EU level, and also in response to concerns from the medical research community about the potential impact of this Directive on the use of Magnetic Resonance Imaging (MRI) equipment for diagnosis, treatment and research.

The Committee has discovered failings in the way that scientific advice was used to inform the EU Physical Agents (Electromagnetic Fields) Directive, both in Brussels and in the UK. We found that the Commission was heavily reliant on one source of advice, the International Commission on Non-Ionising Radiation Protection (ICNIRP), and was not sufficiently responsive to concerns raised by the magnetic resonance community. As a result, it is deeply regrettable that the research necessary to establish whether or not the Directive will inhibit the use of MRI scanners is only now being carried out, with a risk that it will not be complete in time to inform the implementation of the Directive, due by 2008. On the basis of the level of certainty in the available scientific evidence, we agree with the Government that there was not a strong enough case for a Directive covering MRI: existing guidelines are sufficient.

In the UK, we identify serious failings in the consultation process. In particular, we are critical of the highly disappointing response of the Health and Safety Executive and the Health Protection Agency to the concerns expressed by the magnetic resonance community about the potential impact of the Directive. This response was characterised by an instinctive and dismissive resistance rather than an attempt to engage and examine. We also find it extremely worrying that the Health and Safety Executive was giving information on its policy in the UK that was in flat contradiction to the line it had been pursuing in negotiations in Brussels.

The weaknesses of the consultation process were exacerbated by the slow reaction of the magnetic resonance community to the full potential impact of the Directive and by failings in the horizon scanning activities of Government and the Research Councils. We have suggested improvements to the way in which the Government and scientific communities can interact on European legislation.

Finally, we used this case study as an opportunity to examine how the precautionary principle is applied in practice. Unfortunately, we found no clear evidence as to how it was applied in the context of this Directive, nor any satisfactory definition of the principle or explanation of how it should be applied.

1 Introduction

1. The Committee launched a major inquiry into the Government's handling of scientific advice, risk and evidence in November 2005.[1] In addition to taking evidence on these issues at a general level, we decided to further inform our work by undertaking three case studies. This Report on the UK's involvement with, and response to, the EU Physical Agents (Electromagnetic Fields) Directive (referred to hereafter as "the Directive") represents the outcome of the first such case study.[2] We chose to examine this subject partly in order to test the way in which scientific advice is used by the UK Government to influence policy at an EU level, and partly in response to concerns from the medical research community about the potential impact of this Directive on the use of Magnetic Resonance Imaging (MRI) equipment for diagnosis, treatment and research. This case study also gave us an opportunity to examine how the precautionary principle is used in practice.

2. The Directive was adopted on 29 April 2004 and must be enshrined in law in Member States by April 2008. Implementation in the UK can be achieved through secondary legislation under the Health and Safety at Work Act 1974. The Directive is subject to a review in 2009, when Member States are required to report to the Commission on the practical implementation of the Directive.

3. As part of this inquiry we received 15 memoranda of written evidence: from Government and its agencies; the medical and research communities; and from industry. We undertook a brief visit to Brussels in which we held meetings with the UK Deputy Permanent Representative at UKREP, Anne Lambert, and the official responsible for negotiations on the UK side, Mr Kevin Dench; the Director General of the Social Affairs and Equal Opportunities Directorate at the Commission, Mr Van der Pas; and a British member of the European Parliament Committee which considered the draft Directive, Liz Lynne MEP. We also took formal oral evidence from two officials from the Social Affairs and Equal Opportunities Directorate, Mr Bernhard Jansen and Mr José Ramon Biosca de Sagastuy. They subsequently made it clear that the views expressed were personal, rather than those of the Commission. However, Mr Biosca de Sagastuy has been the lead official on the Directive since 1997 and his views are therefore a useful gauge of the approach taken in the Commission. The following week we took evidence from representatives from the medical resonance (MR) community and the Chief Executive of the Medical Research Council (MRC), Professor Colin Blakemore. The views of the MR community were represented by Dr Stephen Keevil, Head of Magnetic Resonance Physics, Guy's and St Thomas' NHS Foundation Trust. He was speaking on behalf of the joint submission of evidence from the five organisations whose members stand to be the most affected by the Directive in terms of MRI: the Royal College of Radiologists (RCR), the British Institute of Radiology (BIR), the Institute of Physics (IOP), the Institute of Physics and Engineering in Medicine (IPEM), and the British Chapter of the International Society for Magnetic Resonance in Medicine (ISMRM). This evidence is referred to as the "joint submission" throughout this Report. Finally, we took evidence from the Minister responsible for the Health and Safety Executive (HSE), Lord Hunt of Kings Heath, together with the Chief

1 www.parliament.uk/parliamentary_committees/science_and_technology_committee/scitech091105.cfm.

2 The other two case studies are on the *Classification of illegal drugs* and the *Technologies supporting identity cards*.

Executive of the HSE, Mr Geoffrey Podger, and two representatives of the Health Protection Agency (HPA), Dr Alastair McKinlay and Dr John Stather. We are extremely grateful to all those who contributed written and oral evidence to this inquiry and to all those whom we met in Brussels.

2 Background

Current use of MRI

4. MRI scanners have been in increasing use throughout Europe and the rest of the world over the last 20 years. They provide a powerful tool for use in diagnosis, treatment and research, and have been widely recognised as the most significant development in medical imaging since the X-ray machine. The scanners provide well-defined images of internal organs of the body, which can be used for diagnostic purposes and also for guiding invasive surgery and other interventional procedures. MRI involves non-ionising radiation. As such, it is, in principle, a safer modality than those that use X-rays, which are ionising radiation. Ionising radiation has well established adverse health effects and its use is governed by exposure limits agreed at EU level.[3] MRI scanners are also more expensive than X-ray machines, both in terms of the costs of manufacture and of usage. Most current scanners operate at a level of 0.5—1.5 tesla (T),[4] but new, more powerful MRI scanners capable of producing higher resolution images are being developed and manufactured for use in the UK and elsewhere. For example, the MRC is funding a number of 3 T whole body scanners dedicated to research and a new 7 T machine being installed at Nottingham University is one of only two such facilities in Europe.[5] MRI is beginning to be used at several UK hospitals instead of X-ray for interventional procedures.[6] Such usage is likely to increase. The NHS recently purchased 100 new MRI scanners, at nearly £1 million apiece, as part of its Cancer Plan, making the UK a leader in MRI usage as well as research.[7] The extent to which use of these new machines will be affected by the limits imposed by the Directive is a matter of current debate. If, as has been suggested, usage of the machines will be affected by the Directive, its impact would be particularly keenly felt in the UK.

Box 1: Definition

Magnetic Resonance Imaging (MRI) is a medical imaging technique that uses magnetic fields and radio waves to produce detailed images of the body.

It uses electromagnetic fields (EMF) in three frequency ranges:

- Static magnetic field;
- Time-varying magnetic fields in the order of 100–1000 Hertz (Hz); and
- Radiofrequency (RF) fields in the order of 10–100 MHz).

3 Q 851; X-ray exposure limits in the UK are governed by the Ionising Radiation (Medical Exposure) Regulations 2000, which implement the European Directive 97/43/Euratom (The Medical Exposures Directive).

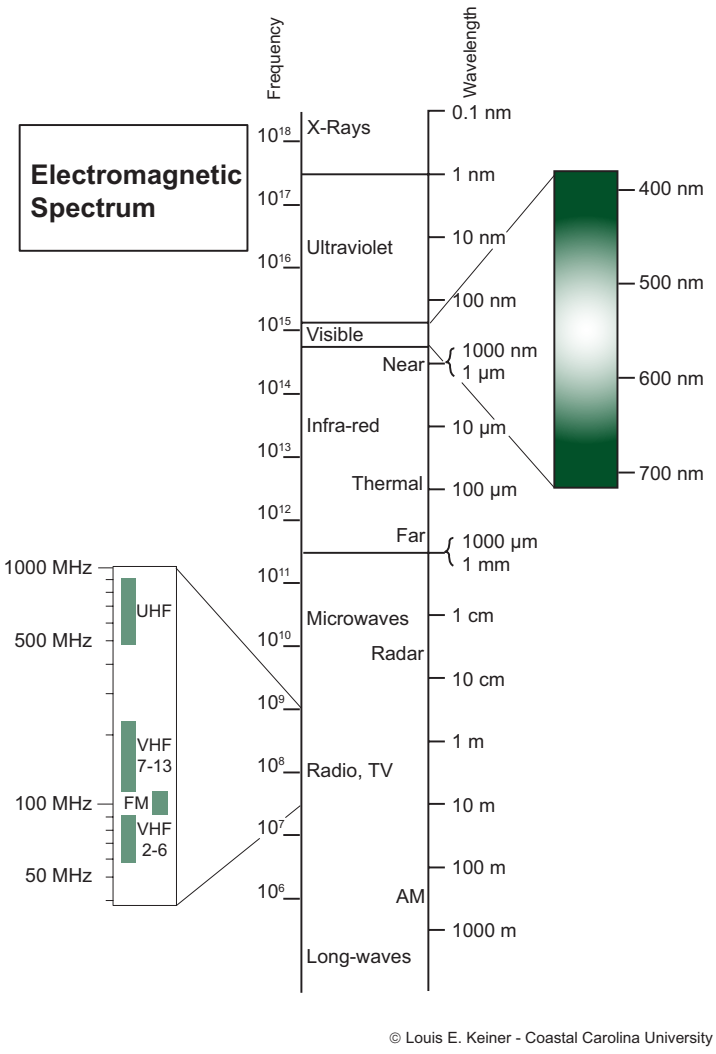
4 The tesla is the unit of magnetic flux density. It is a unit to define the intensity (density) of a magnetic field.

5 Ev 58, Q 813

6 Ev 41

7 As above

Figure 1: Electromagnetic Spectrum



This diagram indicates where radio frequency fields are in relation to X-ray

Existing regulatory regime

5. Several organisations are involved in the provision of safety guidelines for the use of MRI (see Box 2). In the UK, the Health Protection Agency (HPA) and its predecessor the National Radiation Protection Board (NRPB)[8] has issued guidance on exposure to Electromagnetic Fields (EMF) since 1993 which have been widely accepted by Government, professional bodies and industry. These guidelines have tended to follow very closely the guidelines issued by the International Commission on Non-Ionising Radiation Protection (ICNIRP). Guidance on static magnetic fields was issued by ICNIRP in 1994 and on time-varying fields in 1998, in place of earlier advice dating from 1988.[9] ICNIRP guidelines are thought to be in use in some 30 countries. (Italy is one of a few

8 The NRPB became the Health Protection Agency in April 2005.

9 NRPB, Volume 10, No. 2, *1998 ICNIRP Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic and Electromagnetic Fields (up to 300 GHz): NRPB Advice on Aspects of Implementation in the UK*

countries which use more restrictive exposure limits than the Directive and the NRPB states that the limits set there "do not consistently draw on the scientific evidence".[10]) Both NRPB and ICNIRP contribute to World Health Organisation (WHO) work on harmonising approaches to establishing EMF exposure limits. This work is due to be completed in 2007. Manufacturers of MRI equipment follow guidance on safety standards produced by the International Electrotechnical Commission (IEC), in particular IEC 601-2-33. This standard stipulates requirements for equipment design to enable safe use and traditionally this has led to a focus on protecting patient wellbeing rather than occupational health hazards. These standards are currently being reviewed, partly in order to include occupational exposure. The Institute of Electrical and Electronic Engineers (IEEE) is also a recognised developer of standards in the areas of telecommunications, information technology and power generation. The IEEE has developed standards covering EMF exposure which are relevant to the Directive. In the US, and other countries, these IEEE standards can be used for guidance on occupational exposure. In the UK, employers are bound by the provisions of the Health and Safety at Work Act 1974. The Health and Safety Executive expects employers to abide by NRPB/HPA guidance on EMF exposure.

Origins of the Directive

6. The origins of the Directive lie in an umbrella health and safety Directive adopted in 1989 and the implementation of the Community Charter of the Fundamental Social Rights of Workers.[11] This general Directive led to a series of more detailed measures covering different sectors. One such measure was a Physical Agents Directive. This was first proposed in 1993 and included four elements or agents: noise, vibration, EMF and optical radiation. This Directive was based on a study of the impact on health of EMF commissioned by the Commission, to which the NRPB contributed. The proposals came at a time when there was increasing public concern and pressure group activity on the safety of mobile telecommunications. However, there was not a consensus on EMF safety in the EU at that time and the proposal made no progress for six years.[12] In 1999, the original proposed Directive was revived but split into four separate measures, each of which has now been adopted in an individual Directive. The EMF Directive was the third of the four to be taken forward; the draft proposals were first published in December 2002 under the Danish Presidency.

10 NRPB, *Summary of comments received on the May 2003 Consultation Document and responses from NRPB*, NRPB-W59, July 2004, pp 19 and 27

11 Directive 2004/40/EC of the European Parliament and the Council, 29 April 2004

12 Q 884

Box 2: Key organisations

International Commission on Non-Ionizing Radiation Protection (ICNIRP)
ICNIRP is the leading source of international guidance on EMF exposure. ICNIRP's principal aim is to disseminate information and advice on the potential health hazards of exposure to non-ionizing radiation to everyone with an interest in the subject. ICNIRP's information and advice covers all of the non-ionizing radiations including the optical radiations (ultraviolet, visible and infrared—and lasers), static and time-varying electric and magnetic fields, radiofrequency (including microwave) radiation, and ultrasound.

The World Health Organisation (WHO)
The WHO seeks to harmonise internationals standards and co-ordinate research efforts on EMF. It sponsors research and issues advice on EMF, based upon international research, including that undertaken by ICNIRP.

International Electrotechnical Commission (IEC)
The IEC produces safety standards for MRI equipment manufacturers. These focus on patient health rather than occupational health.

The European Committee for Electrotechnical Standardization (CENELEC)
This body is in the process of establishing harmonised European standards for all assessment and calculation of exposure levels.

The Institute of Electrical and Electronic Engineers (IEEE)
The United States based IEEE is a recognised developer of standards in the areas of telecommunications, information technology and power generation. The IEEE has developed standards covering EMF exposure which are used for guidance in many countries.

Health and Safety Executive (HSE)
The HSE is a non-departmental public body with specific statutory functions in relation to health and safety. It reports to the Health and Safety Commission (HSC). The HSE receives scientific advice on matters of radiation protection from the Radiation Protection Division of the Health Protection Agency.

Health Protection Agency (HPA)
The HPA was established as an Non Departmental Public Body to replace the National Radiation Protection Board (NRPB) in April 2005. The HPA Radiation Protection Division (RPD) provides advice to Government and other agencies on radiation protection, including protection from EMFs.

Purpose and scope of the Directive

7. The principal aim of the Directive is to provide a minimum standard of protection for those working with EMF across the EU and to ensure that industry is competing on an equal basis. The Directive applies to time-varying electromagnetic fields with frequencies between 0 and 300 GHz. It seeks to deal with the risk to workers due to "known short-term adverse effects on the human body" caused by the circulation of induced currents and energy absorption. It does not apply to static magnetic fields, which are a major

component of exposure from MRI equipment. (A provision for static fields was removed from the proposed Directive during negotiations, but is to be reconsidered when the Directive is reviewed in 2009.)[13] The Directive does not address potential long-term effects of EMF exposure, due to the absence of evidence of such effects. The main sectors affected by the Directive are the electricity generating and telecommunications industries, where workers are in close proximity to power lines and mobile phone masts respectively. The use of navigation and broadcasting equipment, along with various industrial processes, may also be affected.

8. The Directive sets "exposure limit values" for EMF in terms of induced current densities for frequencies less than 10 MHz and specific absorption rate (SAR) for frequencies greater than 100 kHz. It also sets "action values", expressed in terms of measurable field quantities such as magnetic field strength, magnetic flux density and power density.[14] These action values may be exceeded, but when this occurs employers are required to undertake a risk assessment in order to ensure compliance with the exposure limits. Such a risk assessment would involve the measurement and calculation of exposure levels and the taking of appropriate remedial action such as altering the layout of work stations and changing working patterns to limit the duration and intensity of exposure. Employers are also required to undertake health surveillance: medical examinations are to be made available for workers when certain limits are exceeded. In this case study we have focussed on the impact of the Directive on MRI use, but it is important to bear in mind that it was intended to cover all occupational exposure to EMF—it was not aimed at specific industries or practices. The attempts made by the Commission to gauge the impact of the Directive on all sectors are discussed in chapter 3 of this Report.

13 See paragraph 21 below.

14 Health Protection Agency, *MRI Information sheet on EC Physical Agents Directive*

3 Scientific basis of the Directive

Introduction

9. Both the scientific basis of the exposure limits set out in the Directive and their impact on MRI usage have been questioned. This chapter looks at the strength of the scientific evidence that informed the establishment of the exposure limits set in the Directive. It then looks at the evidence and scientific advice underpinning the debate on the impact of these exposure limits on the use of MRI in diagnostics and in research. Both factors need to be taken into account in considering the justification for the Directive, or at least its inclusion of MRI.

Box 3: Timeline of key events

Date	Event
1993	Original proposal for catch-all Physical Agents Directive
1994	ICNIRP publishes guidelines on static magnetic fields
1998	ICNIRP publishes guidelines on time-varying fields
1999	Proposal for Physical Agents Directive to be separated into four separate measures
December 2002	Danish Presidency publishes proposals for EMF Directive
26 February—2 September 2003	EU Social Questions Working Party considers Directive
17 September 2003	Political agreement reached in European Council on Directive. Static field limits withdrawn
August 2004	Revised ICNIRP guidelines on MR procedures published
March 2004	Consideration of Directive in European Parliament
29 April 2004	Directive adopted

Sources of advice to the Commission

10. The exposure limits established by the Directive are based on those contained in the ICNIRP guidelines of 1998.[15] They are based on an extensive review of all available scientific evidence, which is clearly summarised in the document. As part of its preparation of the Directive, the Commission provided support to international research on the health effects associated with EMF exposure in the late 1990s.[16] Commission officials cited a number of studies, peer reviewed and published, by different European organisations, including the NRPB, that also informed the limits set out in the Directive.[17] In addition, a

15 Q 673

16 Q 886

17 Q 712

seminar of experts in Luxembourg in September 2002 discussed whether there was sufficient scientific evidence of potential health risks of EMF to justify legislation. There was agreement here on a number of potentially acute health effects resulting from powerful EMF and other sources.[18]

11. Since the proposals for a Physical Agents Directive were first published in 1993 the Commission has relied upon ICNIRP to inform its work on the Directive. Dr McKinlay, who chaired ICNIRP between 2000 and 2004, provided a list of ICNIRP's publications throughout the 1990s and also of its meetings with the Commission in 2003.[19] However, he made it clear that ICNIRP did not advise regulators on how to use their guidelines: "It is up to governments and super-national governments to decide about regulations. We do not lobby on this. We do not have a view about it, but we do provide scientific advice.".[20]

12. Dr McKinlay also stressed that ICNIRP does not provide guidelines on individual applications: "We do not concern ourselves [at ICNIRP] with exposure to the particular device with a particular frequency".[21] ICNIRP's role is to provide independent and science-based guidelines and recommendations on protection from non-ionising radiation exposure.[22] He told us that, in terms of specific advice to the Commission on MR, there was "None specifically on occupational exposure and little in general on MRI can be recollected."[23] We believe that Dr McKinlay is underplaying ICNIRP's work here. Whilst the 1998 ICNIRP guidelines cover the full range of EMF exposure, ICNIRP has provided specific guidance on medical MR procedures, for both time-varying and static fields. In April 2003 a draft statement of guidance was circulated by ICNIRP to some experts in the MR community.[24] These largely concern patient safety but also include some reference to occupational exposure. These guidelines were eventually published in August 2004. They state that "concerning open or interventional MR devices with field strengths below 1.0 T, staff operating such devices are not exposed at levels higher than the currently recommended limits for occupational exposure. However, there are only limited data on the exposure of surgeons at open MR devices."[25] Nothing is included about the use of machines with field strengths of above 1.0 T, which are now beginning to be used interventionally. These guidelines demonstrate that ICNIRP was well aware that the Directive might have an impact on MR usage, even if it did not have access to the necessary evidence or expertise to establish the extent of this impact.

13. We accept Dr McKinlay's point that it is not the job of ICNIRP to advise on specific devices or applications, and is therefore not in a position to advise on the impact of the Directive. However, the Commission did have had the opportunity to draw on the advice of ICNIRP in order to ensure that it assessed the full potential impact of the Directive. Equally, given its work on the subject, ICNIRP had the opportunity to suggest that possible

18 European Parliament, *Procedure file*, COD/1992/0449C, www.europarl.eu.int/oeil/file.jsp?id=215622

19 Dr McKinlay was also Vice-Chair from 1996–2000; ev 77

20 Q 889

21 Q 887

22 ICNIRP, *The Global Focus for Non-Ionising Radiation Protection,* www.icnirp.org

23 Ev 79

24 ICNIRP, *Medical MR Procedures: Protection of Patients, Volunteers and Staff*, April 2003 *[not published]*

25 ICNIRP, *Medical Magnetic Resonance (MR) Procedures: Protection of Patients*, 2004, Health Physics 87, p 197

consequences for MR, including the future development and use of MRI technology, should be fully explored with the MR community. We accept that it was the Commission's responsibility to assess the impact of the Directive and we discuss its efforts in this respect later in this chapter. **We conclude that the Commission was right to go to the established international authority, ICNIRP, for advice on which to base its proposals. However, we believe that the Commission did not seek to obtain the maximum benefit from the work undertaken by ICNIRP by exploring the potential impact of the Directive on MRI. Equally, ICNIRP should accept that, if its guidelines are being used as the basis of the Directive, it has some duty to advise, to the best of its knowledge, on those potentially affected by the Directive, to enable the Commission to consult appropriately. This detailed advice does not appear to have been given.**

14. There were further opportunities for advice to be taken during the passage of the Directive through the European Council and European Parliament under the co-decision procedure.[26] The Social Questions Working Group at the European Council considered the Directive during 2003 and suggested some amendments. Following political agreement of a common position on the Directive in September 2003, the Directive was considered by the European Parliament in the first three months of 2004. The Committee considering the Directive proposed some minor amendments, which were accepted. Some concerns about its impact on MRI procedures were raised by the medical equipment manufacturers' representative body, COCIR.[27] This organisation wrote to the Social Questions Working Party in April 2003 to warn that the proposed Directive "could have the effect of restricting or even preventing the use of MRI scanners used in health care" and proposed that MRI equipment be excluded from its scope.[28] When asked about the extent of criticism of the Directive, officials at the Commission eventually acknowledged that "some letters" were received, but we did not get the impression that these were given serious consideration. Passage of the Directive through the European Parliament was swift. The proposal for an exemption in the Directive for MRI equipment was raised in the relevant European Parliament Committee, but was defeated. We note that the European Parliament does not have the time or the resources to conduct a full scientific appraisal of the Directive. Nonetheless, the scientific basis of the Directive was considered in detail by the European Council and one important change was made to it during negotiations, as we set out below in paragraph 21. We discuss in paragraphs 27–40 the extent to which the impact of the Directive was considered.

Strength of the evidence base

15. We have received contradictory views on the strength of the science underpinning the ICNIRP 1998 guidelines. Dr McKinlay stood by them although, as we have seen, he was keen to emphasise that "they are guidelines" and that ICNIRP did not have a view on their use in regulation.[29] Officials from the Commission rejected any notion that the ICNIRP guidelines had been criticised. Mr Biosca de Sagastuy told us that "the ICNIRP guidelines

26 The co-decision procedure requires the European Council and European Parliament to agree on legislation.

27 COCIR is the European Co-ordination Committee of the Radiological Electromedical and Medical IT Industries.

28 COCIR, Letter to Social Questions Working Party, 11 April 2003

29 Qq 866

are not contested anywhere in the world. They are the world authority in this field."[30] He pointed to a number of studies by international organisations, including the NRPB, which he said supported the limits set out in the Directive. He drew a distinction between the agreed position of the scientific community, set against the "opinions" of MR manufacturers and medical personnel: "The medical community might have a different opinion but they are not the experts in this field."[31] He drew a parallel with the opposition of the medical community to any restrictions on the use of X-rays until the dangers were identified.

16. This level of certainty was disputed by the MR community. Dr Keevil acknowledged that there was a large body of published research on EMF exposure but asserted that it "reveals a wide margin of uncertainty rather than agreement".[32] Much of the published work on EMF was carried out or commissioned by the NRPB. Following its production of a report on the potential impact of the original 1993 proposals for a Directive, the NRPB carried out a further review for the HSE in 2001 in anticipation of an EMF Directive that year. A report was published in 2002. [33] The NRPB consulted again in 2003. As a result of this work, in 2004 it confirmed that the 1998 ICNIRP guidelines on which the Directive is based should be followed in the UK. The joint submission of evidence describes these 1998 guidelines as being based on a "cautious interpretation of sparse scientific evidence".[34] A recent academic paper reviewing the evidence concludes that the "scientific basis for the exposure levels is incomplete and inconclusive".[35] The quality of the science, as well as the quantity of data available, has also been questioned. A report to the MRC on a meeting of UK stakeholders in January 2006 records that the ICNIRP committee member present accepted that the science underpinning the 1998 guidelines was "poor", although he stood by the limits set. This report also records that there was agreement among the international and national bodies present that some of the ICNIRP guidelines that formed the basis of the Directive were "flawed".[36] These questions are reflected in the HSE-commissioned report of this meeting. One HPA representative is reported as suggesting that "the science is moving faster than the guidance".[37]

Evidence of adverse health effects

17. The strength of the NRPB-commissioned evidence has also been questioned. One aspect of the debate is over the extent to which safe exposure limits can accurately be extrapolated from the available evidence on adverse health effects from exposure. The Chief Executive of the MRC, Professor Colin Blakemore, expressed surprise that his work in 2001 on the Weak Electric Fields Group of the NRPB had been cited as evidence in

30 Q 801

31 Qq 678, 744-45

32 Ev 66

33 Ev 34

34 Ev 42

35 Hill DLG, Keevil SF, *Impact of electromagnetic field exposure limits in Europe: is the future of interventional MRI safe*? Acad Radiol (2005)12: 1135–1142

36 EMF Workshop, 5 January 2006, Note by Professor Derek Hill and Professor Jo Hajnal

37 Galson Sciences Ltd, *EU EMF Physical Agents Directive EC/40/2004 Implementation into UK National Legislation, Report of Roundtable Discussions*, 5 January 2006, p 4

favour of the proposed exposure limits and therefore of the Directive.[38] He argued that the existence of measurable effects need not imply that these effects were harmful. The group had been asked to speculate about the possible levels of field strength at which there were detectable effects on the body and found that, while it was conceivable that there could be adverse health effects, there was no hard evidence of such effects or that the limits indicated a hazard.[39] He argued that if the current knowledge about radio frequency (RF) fields had been known at the time of the Stewart Report on mobile phones and health in 2000, it would have been difficult for ICNIRP and NRPB not to adopt limits so low as to stop the development of radio frequency telecommunication technology. He said that it was only the uncertainty surrounding clearly agreed thresholds that prevented there being "similar, inappropriate, extremely cautious limits set for radio frequencies".[40] Dr Keevil said that "we are in a grey area, where really there are not proven adverse health effects at these levels of these frequencies".[41] He makes the distinction between biological effects, such as magneto-phosphenes or peripheral nerve stimulation, which are well established, and adverse health effects, which are not, and interprets the Directive as seeking to avoid the possibility of any kind of effect. [42]

18. Some have pointed to the fact that MRI equipment has been in use now for over 20 years and there has been no evidence of any adverse health effects resulting from EMF exposure alone. According to evidence provided by the Medicines and Healthcare Products Regulatory Authority (MHRA), there have been two reported cases of physiological effects being experienced as a result of MRI exposure. (It is not clear how long these effects lasted.) The adverse incidents reported—some 144 since 1995—are primarily due to accidents or failings in the procedures that have resulted in contact burns, damage from projectiles or from internal medical devices. There are generally over five times as many radiology adverse incidents as there are MRI incidents each year, although this in part reflects the current availability of each type of equipment.[43] Commission officials confirmed that the incidents of adverse health effects were caused by accidents rather than exposure.[44] The ICNIRP guidelines are not designed to cover the prevention of such accidents: these are already covered by established stringent safety procedures in hospitals, which medical practitioners have a responsibility to enforce, as Mr Biosca de Sagastuy acknowledged.[45] Mr Biosca de Sagastuy explained that there was no evidence of adverse health effects due to exposure because the levels of exposure experienced by medical workers were lower than those contained in the Directive.[46] In response, Dr Keevil argued that "hundreds of millions of patients have been exposed to MRI over the past 25 years, at gradient field amplitudes up to 100 times the occupational exposure limit, with no evidence whatsoever of harm." He acknowledged that this exposure is to patients rather

38 Q 833

39 Q 840, ev 59

40 Q 840

41 Q 819

42 Ev 66, Q 825

43 Ev 61

44 Qq 727-32

45 Q 690

46 Q 733

than workers, but contended that there is no reason to assume differences in the susceptibility to exposure between the two.[47]

19. The Directive refers to the "risk to the health and safety of workers due to known short-term adverse effects in the human body".[48] The MR community argues that these known short-term health effects of EMF are not necessarily adverse. It is asserted that the data provided by experiments and animal research have been used to make extrapolations to excessively high levels of exposure which can be considered safe. The joint submission observed that that the "leap from cautious, guarded statements in the ICNIRP guidelines to 'known adverse health effects' in the Directive would certainly not have survived objective scientific review."[49] Professor Blakemore also questioned the link between biological effects and adverse health effects: "It would be very unfortunate if MRI, with all its proven benefits, were to be curtailed, simply because thresholds for biological effects can be defined, but without clear evidence that such effects are hazardous."[50] The British Institute of Radiology states that "The proposed limits were based on hypothetical rather than established adverse effects on health, yet the effect would be an increase to both staff and patients exposure to the well-established hazards of ionising radiation from alternative, X-ray based imaging techniques."[51] Another witness engaged in operating clinical MRI equipment, Dr Calverd, agreed: "The supposed basis of the Directive's exposure limits to time-varying magnetic fields is an arbitrary multiplier applied to a reported threshold for some subtle, transient physiological effects."[52] The joint submission asserted that "the limits are not presented in the Directive as precautionary values, but as established thresholds for onset of adverse effects."[53] The Wellcome Trust complained that "The limits are absolute—there is no scope for time averaging, or for less restrictive limits for brief exposures."[54] In short, there was widespread support in the MR community for Dr Keevil's assertion that the premise on which the Directive is based—that there are known adverse health effects—is a false one.[55]

20. The Directive is based upon the provision of "protection against known adverse health effects". This description, as we have seen, can be taken as implying that these effects occur at the limits set out. This impression has been encouraged by some statements from the Commissioner with ultimate responsibility for the Directive, Commissioner Spidla, who said in November 2005 that "The Directive is designed to protect workers against excessive exposure to MRI and EMF which scientific experts agree is dangerous for health".[56] This interpretation was not the intention of the Commission and officials did not agree with this

47 Ev 65

48 Directive 2004/40/EC of the European Parliament and of the Council, Official Journal of the European Union L 159 of 30 April 2004, Article 1, para 2

49 Ev 44

50 Ev 60

51 Ev 40

52 Ev 38

53 Ev 44

54 Ev 52

55 Q 819

56 Press notice, 18 November 2005, www.esmrmb.org/hauptframe.php?pid=409

statement.[57] Rather, the limits are intended to be precautionary: the exposure levels are set so as to ensure that workers are protected from any possibility of adverse health effects, even though these are not necessarily proven. A precautionary approach, which we discuss in detail in chapter 4, is used when there is uncertainty in the scientific evidence currently available. There is also an assumption implied in this approach that steps will be taken to accumulate the necessary evidence and level of certainty to inform a review of decisions reached. **The lack of available evidence of adverse health effects at present is not reason in itself to avoid taking preventative action, but it should require a convincing scientific case to be made in favour of statutory regulation, including a balancing of the risks of harm against the costs, pending the establishment of a fuller evidence base.**

Static fields

21. ICNIRP published guidelines on exposure to static electromagnetic fields in 1994. The Directive proposed in 2002 included limits for static fields which were based in part upon these guidelines. Representations made to the Commission during 2003, notably the COCIR submission, focussed upon the impact of the provisions relating to static fields. In September 2003 ICNIRP informed the Commission at an informal meeting that these guidelines were to be reviewed in the near future and that static fields should therefore not be included in the Directive.[58] The Commission accepted this advice, as did the European Council, in which a number of Member States, including the UK, had argued for their withdrawal. The provisions relating to static fields were withdrawn during negotiations in Council on 17 September 2003.[59] Dr McKinlay said that the advice from ICNIRP to the Commission was that static fields should be excluded on the grounds of an imminent review. The implication here is that the existing evidence base was insufficiently strong, or reliable, to be the basis of a Directive. Indeed, it was the lack of evidence, rather than an impending review, that was cited by Council as the reason for withdrawal.[60] We understand that this was an issue of some controversy: the removal of static fields was, to some, an unfortunate weakening of the protection to workers afforded by the Directive. A review of the science on static fields has now been carried out and ICNIRP is currently considering revised guidelines. The introduction of limits for static fields will be considered again in the 2009 review of the Directive.[61] **We find it puzzling that static fields were included in the initial proposed Directive when the principal source of scientific advice for the Commission, ICNIRP, was about to review its own guidelines and advised against using existing guidelines as a basis for the Directive. This suggests that communication between the two organisations was not as effective as it could have been, but it does demonstrate that the legislative process was responsive to new scientific advice.**

57 Q 753

58 Q 888, ev 78

59 Ev 70

60 European Parliament, *Procedure file*, COD/1992/0449C, www.europarl.eu.int/oeil/file.jsp?id=215622

61 As above

Time-varying fields

22. The exposure limits in the Directive for time-varying fields were based upon more recent guidance. The 1998 ICNIRP guidelines provide a comprehensive review of available evidence on the health effects of time-varying fields which is used to inform the limits set for public and occupational exposure. They summarise the evidence of biological effects and the potential for adverse health effects from exposure to EMFs at a range of frequencies up to 300 GHz. In line with other safety guidelines, ICNIRP takes a measurable exposure level which is known to cause an effect, and divides this level by a factor in order to provide an exposure limit which is safe. The argument is over whether, as the International Electrotechnical Commission and others maintain, this factor is too great.

23. We have referred above to the questions raised about the science underpinning these 1998 guidelines. In setting out the evidence base, the 1998 guidelines do acknowledge some degree of uncertainty:

> "In establishing exposure limits, the Commission [ICNIRP] recognises the need to reconcile a number of differing expert opinions. The validity of scientific reports has to be considered, and extrapolations from animal experiments to effects on humans have to be made. The restrictions in these guidelines were based on scientific data alone; currently available knowledge, however, indicates that these restrictions provide an adequate level of protection from exposure to time-varying EMF."[62]

The guidelines also state that:

> "There is insufficient information on the biological and health effects of EMF exposure of human populations and experimental animals to provide a rigorous basis for establishing safety factors over the whole frequency range and for all frequency modulations. In addition, some of the uncertainty regarding the appropriate safety factor derives from a lack of knowledge regarding the appropriate dosimetry."[63]

The guidelines make clear that the limits will be periodically reviewed in the light of further advances in identifying adverse health effects. In 2004, ICNIRP acknowledged that its 1994 and 1998 guidelines were "written many years ago, and they are now under review."[64]

24. We asked what advice ICNIRP gave to the Commission on the certainty of the scientific basis for the 1998 guidelines. In response, Dr McKinlay referred to uncertainties surrounding the interpretation of scientific data and the selection of "safety factors", which were discussed at numerous seminars and conferences. He also referred to the caveats contained in the guidelines (such as those quoted above) but did not indicate that any specific advice was given to the Commission regarding levels of certainty.[65] The reason that ICNIRP made no recommendation for withdrawal in respect of time-varying fields is that

62 *ICNIRP Guidelines,* Health Physics, 74, No. 4, 1998, pp 494-5

63 As above, p 509

64 ICNIRP (2004), Health Physics 87, p 197

65 Ev 77

the revision of variable fields "seemed rather a long way off".[66] Dr McKinlay was reluctant to accept any role in advising the Commission on the suitability of available evidence for a Directive on time-varying fields on the grounds that this was a matter for the regulators. This contrasts with the position on static fields, when ICNIRP did advise on the reliability of the available evidence. It is, of course, for the Commission to take decisions upon what to include in a Directive, but, in making this decision, it relies upon the advice of ICNIRP to assess the level of certainty in the evidence base. ICNIRP is well placed to advise the Commission on the strength of the evidence base, rather than just the date of the next review. **Having advised on the exclusion of static fields from the Directive, it would be inconsistent and slightly disingenuous of ICNIRP to evade all responsibility for advising the Commission on the strength of the evidence base regarding time-varying fields.**

International standards

25. At an international level, different standards are in operation, as set out in Box 2. The IEEE sets standards for EMF exposure. Mr Biosca de Sagastuy argued that ICNIRP and the IEEE use different models of the human body to calculate maximum exposure limits but that "they follow the same basic restrictions as ICNIRP" and "there is very little difference" between the two.[67] Dr Keevil argued that, in the frequency range relevant to the MR community, the basic restrictions are expressed in different ways and that the limits differ "by a factor of almost 20".[68] Furthermore, manufacturers and users of MRI equipment follow the different International Electrochemical Commission standard (IEC 601–2–33), which includes specific requirements for the safety of magnetic resonance equipment for medical diagnosis. This standard is currently being amended to include occupational exposure to EMFs in the frequency ranges relevant to MRI. We understand that the occupational exposure limits adopted by IEC will be somewhat different to those of ICNIRP.

Conclusions on evidence base

26. We are not in a position to evaluate the validity of the evidence base on which the 1998 ICNIRP guidelines are based, to compare them with other international guidelines, nor to assess whether the limits are excessively cautious. However, we have found that significant uncertainties around the scientific basis of the guidelines exist. Indeed, the ICNIRP guidelines themselves describe a number of studies which offer conflicting evidence or are inconclusive. There is undoubtedly a large and growing evidence base on EMF exposure and the MR community agrees that the NRPB literature review carried out in 2004 is widely regarded as a definitive summary of the state of the science.[69] It should also be observed that ICNIRP and NRPB/HPA have highlighted uncertainties in the evidence base, and the need for further research, particularly on any long term effects of exposure to static fields.[70] The ICNIRP guidelines also acknowledge a degree of uncertainty that was

66 Q 893

67 Q 804

68 Ev 67

69 Ev 44

70 eg NRPB-W24, September 2002 & NRPB-W59, July 2004, ICNIRP (2004), Health Physics 87, p 211

not relayed to us by the Commission. It may be that officials were concerned that they gave a misleading impression: the witnesses from the Commission submitted a note of clarification following our visit which acknowledges "differences in some details" amongst various published international assessments whilst asserting that, in respect of established health effects, there was no scientific evidence to challenge the underlying concepts adopted by ICNIRP and the Directive.[71] **We welcome the fact that the scientific advice on which the Directive is based is all published: this transparency has assisted debate. However, officials we met at the Commission misrepresented the level of certainty in the scientific evidence underpinning the Directive. This approach was unhelpful, and can only undermine confidence in the way in which scientific evidence was used by the Commission to support the Directive.**

Impact of the Directive

27. There is also considerable debate over the impact of the Directive on the usage of MRI for medical research and for diagnostic purposes. The views we heard in the Commission on this were diametrically opposed to those of the MR community. The uncertainty is caused in part by the difficulty in measuring the extent to which current usage of MRI actually exceeds the prescribed exposure limits. The Directive prescribes action limits, which when exceeded require monitoring to be carried out to check compliance with exposure limits. This requires detailed calculation in each individual case. It can be difficult to measure what values have been exceeded in MRI as an MRI scanner involves the combination of three different EMF, as set out in Box 1. The exposure of a worker will depend on many factors including: the design of the MRI equipment; the strength and frequency of all the EMF fields used in the system; the precise location of the worker relation to the EMF fields; the speed of motion of the worker; and the sequences that the scanner is running (scanners have different sequences for different medical applications which switch the time-varying fields on and off at different rates).

Impact and risk assessments

28. The other main cause of uncertainty stems from the failure of impact assessments, at both EU and UK levels, to identify the full range of sectors that might be affected and to examine in detail the extent of this impact.

EU Commission

29. The Commission published a risk assessment in 1993 when the original Directive was first proposed. This did not identify any implications for MRI. When the new proposed Directive came before Council some ten years later the UK asked for a new risk assessment to be carried out. At the time, this was not mandatory. (Since 2004 there is a commitment for all major policy defining documents and legislative proposals to be accompanied by impact assessments.[72]) This 1993 assessment was not thought in all quarters to be of great quality. It was criticised by a manufacturers' representative body as "insubstantial and does

71 Q 715, see footnote

72 See www.ec.europa.eu/governance/impact/docs/progress_report_council_sec_1377.pdf

not bear close examination nor take into consideration [existing] product related legislation …".[73] The request for a new assessment was rejected by a majority at the European Council: Member States believed that existing risk assessments could be extrapolated easily to reassess costs and that national assessments had already been carried out to evaluate the impact.[74] Mr Jansen from the Commission argued that it was impractical to have another impact assessment, which takes one year to complete, each time amendments were made while the proposals were before Council and the European Parliament.[75] This misses the point. It was not a case of looking at the effects of minor amendments to the original proposals: the Directive was firmly based on guidelines that were published in 1998, some five years after the original proposals on which the initial assessment was made. It was essentially a different piece of legislation. In the ten years since 1993 the technologies supporting medical imaging, as in many other areas, progressed significantly. Machines became more powerful and the potential medical benefits as well as potential negative health effects rose accordingly. Commission officials agreed, but said that the need for a new assessment was "only to show that there are even bigger risks than was originally thought."[76] Of course the potential for harm might increase with ever more powerful machines, but we find this response revealing and indicative of a mindset in the Commission that could not envisage any adverse consequences of the Directive. **We were alarmed to discover that the European Council was prepared to rely on a ten year old risk assessment to inform legislation in an area of rapidly developing science and technology. We welcome the moves taken to ensure that new proposals are accompanied by new impact assessments, as long as these are taken to include revived Directives such as this one.**

The UK

30. In the UK, the HSE commissioned the NRPB to produce a report on the potential impact of the 1993 proposals for a Physical Agents (EMF) Directive. In response to an anticipated revival of the proposal for a single Directive on EMF the HSE then commissioned a further review of the published evidence by NRPB in 2001. This report concluded that "many of the exposure measurements that are reported complied with the relevant reference levels, however a number of devices and applications have been identified where the reference levels or basic restrictions may be approached or exceeded".[77] However, MRI equipment was not listed among the sources of EMF in question. The report called for further work in some areas.

31. The Regulatory Impact Assessment (RIA) on the Directive produced by HSE in November 2003 stated that its only knowledge of EMF over-exposure was as a result of very infrequent accidents or incidents and that the effect of the Directive on such incidents was likely to be minimal. It noted that the RIA was "unable to identify any health and safety

73 WEM/ORGALIME Position Paper, *Draft Directive for the protection of workers from exposure to electro-magnetic fields and waves (EMF)*, 20 March 2003, p 2

74 Q 696

75 Q 701

76 Q 704

77 NRPB-W24, September 2002

benefits from the Directive".[78] This in itself is a fairly damning assessment of the case made for the Directive as a whole. The RIA estimated that around 250 pieces of equipment and 1250 workers were potentially affected by the Directive.[79] In spite of the fact that the RIA estimates that between 200 and 500 organisations concerned with MRI equipment would be affected, no representative organisation of MRI equipment manufacturers, the medical or research communities is listed among those consulted.[80] The focus was primarily on the cost implications for major industries.

32. The RIA carried out by the HSE, having identified that MRI equipment would be affected by the Directive, failed to explore any further, in spite of the fact that concerns about its impact were being raised with HSE in the four months prior to the publication of the report (see paragraphs 56–60). The Chief Executive of the HSE, Mr Podger (who was not in post at the time), acknowledged its failings: "The truth is that that regulatory impact assessment was done very quickly because, as you know, the proposal only suddenly appeared out of the blue in September 2002".[81] We do not accept that the proposal "came out of the blue": it had been known that it was forthcoming since 1999 when the original all-encompassing proposed Directive was divided into four parts, one of them being EMF. We have noted that the HSE itself commissioned the NRPB in 2001 to undertake work on the exposure limits covered by the Directive. The HSE also was aware of the Directive in 2001 through its membership of the Interdepartmental Liaison Group on non-ionising radiation.[82] **We conclude that the HSE did not apply the necessary expertise to its assessment of the impact of the Directive. We recommend that the Health and Safety Executive ensures that regulatory impact assessments on EU proposals are conducted in a comprehensive manner, on a sector by sector basis, with care being taken to address the broader impact, rather than just the costs, of the legislation.**

Views of the MR community

33. The views of the medical community on the impact of the Directive on MRI can be summarised as follows:

- "It will be difficult to monitor patients requiring close supervision during imaging - e.g. anaesthetised or sedated children, very sick patients and uncooperative psychiatric patients - since staff will not be able to stand close to the scanner. (It is suggested that the limits will be exceeded if a worker stands within 1–2 metres of the bore during imaging.[83])

- Movement of staff near the scanner may be restricted even when it is not operating. The static magnetic field is present at all times, and movement through it will

78 Health and Safety Executive, *Proposal for a Physical Agents (Electromagnetic Fields) Directive*, Regulatory Impact Assessment, November 2003, para 16

79 As above, para 20

80 As above, para 12

81 Q 879

82 This is discussed further in paragraph 71.

83 Note on EMF Workshop, 5 January 2006, Professor Derek Hill & Professor Jo Hajnal

expose staff to a time-varying field that may breach the relevant limit. This will also affect testing of magnets during manufacture and maintenance of installed systems.

- Most interventional MR procedures will become illegal, as clinicians will not be permitted to stand close enough to the scanner to perform them.
- Some functional MRI studies will become impossible—e.g. studies on deaf-blind subjects, where staff 'sign' into the palm of the patient during imaging;
- There is likely to be an increase in X-ray and CT imaging in place of MRI, resulting in increased radiation risk to staff and patients, where the risks are known."[84]

Dr Keevil told us that "It is true to say that the vast majority of clinical diagnostic MR imaging would not be directly affected" but that there were whole new areas, such as interventional MR, which would be "effectively blocked by this".[85] He states that there are a growing number of cases (some 40,000 in the UK each year) in which staff are required to remain in the vicinity of the scanner during imaging. This is typically necessary for some children and particularly anxious or seriously ill patients.[86]

34. Manufacturers also believe that there will be an adverse impact of the Directive. Siemens state that the limits contained in the Directive are "in conflict with MR practice and equipment design".[87] The European medical equipment manufacturers' Committee, COCIR, has said that the limits contained in the Directive "severely hamper the normal installation, use and maintenance of MRI equipment."[88] At a European Congress of Radiology in March 2006 Mr Hans Engels, Head of Safety at Philips, said that the new limits would hamper several specific situations in the hospital and interventional MR. It would also affect the manufacturing process of the MR community.[89]

Views from the Commission

35. At the Commission, officials giving evidence rejected any idea that there could be the impact described above. Mr Biosca de Sagastuy told us repeatedly that in their view, and that of the scientific experts, the Directive would have no impact on the continued use of MRI in hospitals.[90] He told us that the machines used for surgery were very low powered and that for invasive procedures, MRI machines were only used "for a very limited amount of time, a maximum of five minutes and no more."[91] Mr Biosca de Sagastuy assured us that magnetic resonance was discussed at length in Council, with experts present, and that no

84 Ev 44

85 Q 808

86 Dr S F Keevil, *Impact of the Physical Agents (EMF) Directive on medical magnetic resonance imaging*, 2006, [*not published*].

87 Ev 63

88 COCIR position paper on the Council Common Position on the EMF Directive, 2003

89 Presentation given at ECR 2006, Session on Safety, Considerations in MR (European Radiology Supplements A-286)

90 Qq 691, 717, 739

91 Q 691

problems for health personnel were foreseen.[92] Officials had been satisfied in visits to hospitals that there would be no impact on current use of MRI equipment.[93]

36. Officials did acknowledge a potential impact on maintenance work and research. Mr Biosca de Sagastuy said that the Directive "could have an impact on the maintenance procedures, yes", for example in the testing by technicians of equipment.[94] There could also be consequences for the use of some of the newer, more powerful machines being developed for research, but this would require further investigation.[95] Professor Blakemore did not dispute that there may be an impact on clinical practice but thought that research was likely to be most directly affected. He also observed rightly that, in time, research has a tendency to translate into clinical practice.[96] This was not a point that was acknowledged by officials from the Commission, who agreed with the suggestion that the impact of the Directive had been greatly exaggerated by the MR community.[97]

37. The views we heard in Brussels were evidently new to many in the MR community. Dr Keevil expressed astonishment at the evidence we heard and told us that he found it "amazing those individuals could say that there is no impact".[98] He informed us that there were two 1.5 T interventional MR systems in use in the UK—far more powerful than the 0.4 T machines that Mr Biosca de Sagastuy referred to, and that his measurements suggested that his team were over the relevant action value in the Directive "by a factor of about 40".[99] He argued that in interventional procedures there is continuous use of machines for "up to around 20 minutes" rather than the five described by Mr Biosca de Sagastuy.[100] He reports that movement of staff through a static field exposes them to a slowly time-varying field which induces currents that "almost certainly" exceed the limits at 3 T and "quite possibly" also at 1.5 T.[101] **We can only express alarm that, two years after the adoption of the Directive, officials responsible for the detailed work on it have an understanding of the use of MR equipment that is so far removed from that of the practitioners themselves.**

Conclusions on impact

38. In reaching firm views on the impact of the Directive, the Commission relied on the views of the scientific experts, primarily ICNIRP. As we have seen, ICNIRP has no responsibility to advise on the impact of their guidelines on medical practice and its advice on MR procedures has been limited as far as occupational exposure is concerned. Part of the reason why it would have been difficult for any impact assessment to make

92 Q 715

93 Q 779

94 Qq 736-37

95 Q 692

96 Q 813

97 Q 693

98 Q 806

99 Qq 808, 810, ev 68

100 Ev 69

101 Ev 65, 69

authoritative judgments about the effects of the Directive is the lack of published research specifically directed at this issue. Dr Keevil told us that "the MR community believes that there is substantial evidence that exposure in MRI exceeds the limits".[102] He submitted to us a paper summarising this evidence which is awaiting peer review and publication.[103] He also referred to current research being undertaken at Royal Marsden Hospital on 0.5 T scanners. However, he could not point to a body of peer reviewed, published research confirming the views of the MR community.[104]

39. It is difficult to reconcile the substantial differences of opinion on the impact of the Directive between the Commission officials we took evidence from and medical practitioners. There is general agreement that there will be an impact on maintenance procedures and on future research involving more powerful machines, although the extent of this impact remains uncertain. There are strong suggestions from MR practitioners to suggest that the limits established in the Directive will affect the conduct of existing MRI procedures. This evidence is not strong at present: the necessary research has not been conducted to provide an authoritative view. This in itself is not surprising, as this type of research could only be expected to be carried out at the request of regulators.

40. In the light of this paucity of evidence, we were surprised by the sometimes dismissive attitude we found in Brussels towards the views of the medical practitioners. The need for more evidence on the potential impact has now been acknowledged by the Commission, as we record in chapter 7. However, the fact that there is such uncertainty over the Directive's impact some two years after its adoption of the Directive reflects poorly on the influence of scientific advice in the policy making process in Brussels. This uncertainty was caused partly by the failure of the Commission to conduct a proper, up-to-date impact assessment, and partly by the Commission's reluctance to take seriously and investigate the concerns of the MR community when they were raised. Alternative views were ignored or dismissed rather than investigated and confronted by further evidence. As a result, the research necessary to determine the impact of the Directive on MR use is only now beginning to be undertaken. **It is deeply regrettable that the impact of the Directive on MRI procedures was not established before the Directive was adopted. This case study illustrates the potential consequences of the failure of policy makers to seek comprehensive scientific advice early in the policy formulation process and to commission the necessary research to inform this process where uncertainty or gaps in knowledge exist.**

Justification for a Directive

41. The rationale for the Directive was to provide uniform health and safety standards for workers across Europe which could also be used to inform manufacturers and promote fair competition. Some Member States argued that existing guidelines were sufficient and that a Directive would increase administrative burdens on employers. For the MR community, the disadvantage of enshrining exposure limits in a Directive are that the limits are absolute and to be enforced inflexibly, regardless of the circumstances. The question as to whether

102 Ev 68

103 Dr S F Keevil, *Impact of the Physical Agents (EMF) Directive on Medical Magnetic Resonance Imaging*, 2006, [*not published*].

104 Q 812

the advantages outweigh the disadvantages is ultimately a political judgment, but it is one that depends to a certain extent on scientific advice.

42. ICNIRP guidelines are already widely accepted and followed. It is up to individual countries to use them as a basis for national guidance and to enforce them. Similarly, there are internationally agreed IEC guidelines for equipment manufacturers. As far as MR is concerned, we have seen no evidence that the absence of a Directive was either distorting the competitive environment or leading to adverse health effects. The UK Government argued against a Directive from the outset. The Minister, Lord Hunt, confirmed the view of the HSE: "we felt that there was no need for the directive because we already had these guidelines".[105] While internationally respected guidelines can be, and are, reviewed and updated regularly in line with a growing evidence base, an EU Directive is a far less flexible tool. We share the view of the Stewart Report on mobile phones and health of 2000, which stated that: "We are not convinced of the need to incorporate ICNIRP guidelines into statutes. We believe that they are liable to change as more scientific information on possible health effects becomes available."[106] On the impact of EMF exposure on health, the science is in places uncertain and is being updated all the time. The reasonable demands of health and safety officers for precise, measurable limits based on scientific certainty do not sit easily with the normal scientific discipline of learning by constant evidence gathering and review. Guidelines that can be readily updated when necessary are a useful tool for uniting these two strands. We acknowledge the desire of the Commission to put EMF exposure limits on an equal footing throughout the EU and we have not examined the full scope of the Directive and its impact. However, **for MRI at least, we do not believe that there was a strong enough case for enshrining exposure limits in a Directive. We agree with the Government that existing guidelines are sufficient. The Directive will, at best, impose burdens on employers and, at worst, inhibit the use of valuable diagnostic procedures and important research.**

105 Q 902

106 Independent Expert Group on Mobile Phones, *Mobile Phones and Health*, May 2000 [The Stewart Report], para 6.36

4 The precautionary principle

Definition

43. We identified the precautionary principle in the terms of reference of our overall inquiry into the handling of scientific advice, evidence and risk, and used this case study to examine its application in practice. The European Council resolved in 1999 "to be even more determined to be guided by the precautionary principle in preparing proposals for legislation."[107] Although the precautionary principle is frequently invoked by the Commission and has been used as an approach to regulation at EU level since the early 1990s, nowhere is it defined for general use by Treaty. It is only cited (and it is not defined) in the 1992 Maastricht Treaty, for use in environmental policy. The term is often used to support the arguments of those cautioning against the introduction of new technologies and at times has been prayed in aid by both sides in debates. The term has been frequently cited in EU courts but only once defined, as follows: "the precautionary principle implies that where there is uncertainty as to the existence of risks to human health, the institutions may take precautionary measures without having to wait until the reality and seriousness of those risks become fully apparent."[108]

44. In order to address the lack of clarity, the Commission published a communication on the precautionary principle in 2000. It sought to outline its approach to using it and to establish guidelines for its application. It stresses that the principle applies far more widely than the environmental field, to cover:

> "those circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection."[109]

The paper goes on to set out when the principle should be invoked and how it should be applied. Critics argue that it "fails to articulate clear, usable factors or criteria to determine when the precautionary principle applies and when it does not" and that it fails to define when risks are acceptable.[110] Academic studies have, according to the Director of the King's Institute for Risk Management, found up to 19 different formulations for the principle.[111] It is also argued that the EU courts have invoked and applied the precautionary principle in an inconsistent and *ad hoc* manner. We find the Commission paper on the precautionary principle helpful in taking forward the debate, but not sufficient in itself. In essence, it is a check-list of issues to be considered in situations of scientific uncertainty within an overall

107 EU Commission, *Communication from the Commission on the Precautionary Principle*, COM (2000) 1, 2 February 2000

108 As above, p 33

109 As above, p 10

110 Gary Marchant and Kenneth Mossman, *Arbitrary and Capricious, The Precautionary Principle in the EU Courts*, 2005

111 Ragnar E. Lofstedt, *Risk Communication and management in the Twenty-First Century*, International Public Management Journal, 7 (3), pp 335-346, 2004

approach to risk management. It does not provide a detailed explanation as to how the precautionary principle should be applied in practice to decision making.

Use of the precautionary principle in the Directive

45. We sought to establish whether the Directive was based on the precautionary principle, as understood in the Commission. The ICNIRP guidelines which underpin the Directive are based, according to Dr McKinlay, on a "cautious approach in the interpretation of the science" rather than a "precautionary" approach.[112] The difference between the two has been defined by the NRPB as follows:

- "'caution' and 'cautious' are used strictly to describe the approach taken in evaluating scientific data and in particular the uncertainties associated with these data and in making judgements as to their relevance to exposure restrictions.
- 'precaution' and 'precautionary' are used strictly in relation to possible additional measures that might be considered in the light of the uncertainties with the evidence of long-term adverse effects of exposure."[113]

By this definition, the Directive, which excludes long-term health effects, could be said to be cautious in its approach rather than precautionary. However, the Commission definition does not include the above distinction. It does provide some guidance on application. This requires decision makers to apply general principles of risk management, including an "examination of the benefits and costs of action or lack of action".[114] Such benefits include economic, socio-economic and, in certain circumstances, non-economic considerations such as the protection of public health. The guidance goes further, and confirms the implications of European Court case law that consideration of public health should "undoubtedly be given greater weight than economic considerations."[115] This elaboration does not help decision-makers establish how to proceed in respect of the EMF Directive, when the economic costs of regulation as well as any other potential adverse impacts need to be weighed against the avoidance of health risks associated with occupational exposure to EMF.

46. The potential health risks were certainly given a higher priority than economic factors in this case, but there was no evaluation of the potential negative impacts on medicine and research. It could be argued that, by failing to give due consideration to the potential benefits afforded by MRI diagnosis and treatment that might be lost under the Directive, the Commission did not follow its own guidelines on applying the precautionary principle. Professor Blakemore referred to the "intransigence" of the Commission in dealing with the concerns expressed in a manner which infringes the principles outlined in the Commission's paper.[116] The Directive does not allow for an overall risk-benefit assessment to be made on a case by case basis, taking into account the benefits for the patient in using

112 Q 918

113 NRPB-W59, July 2004, p 17

114 *Communication from the Commission on the precautionary principle*, COM(2000) 1, p 18

115 As above, p 20

116 Q 850

MRI, for example instead of X-ray, and setting these against a slightly higher exposure level for health workers. Mr Biosca de Sagastuy explained this position: "With a patient you can balance risks against benefits but with a worker you cannot. There is an obligation under general health and safety legislation to eliminate the risk or reduce it to the lowest achievable limit … You cannot cure one person and injure the health of another one".[117] We find this approach both simplistic and out of step with reality. It is certainly not in line with the type of risk-benefit analysis demanded by the precautionary principle. **While there should be an obligation to reduce risks to a reasonable level, to actually pursue the "lowest achievable limit" would entail health and safety practices which most would consider unnecessary and economically unviable, if not counter-productive in certain circumstances. Risks need to be balanced against gains, rather than necessarily minimised.**

47. It is well established that workers may be required to subject themselves to a higher degree of risk than the general public in order to achieve some wider benefit, whether economic, health or other. Indeed, the health risks of the hospital environment itself are greater than many other working environments. The International Society for Magnetic Resonance in Medicine states that "In health employment it is common to accept certain hazards, whilst controlling these very carefully, for the benefit of the individuals treated".[118] The 1998 ICNIRP guidelines themselves set different lower exposure limits for the general public than for workers. The 2004 ICNIRP guidelines recommend that the medical practitioner should be responsible for assessing the need for an MRI scan and for the safety of the patient."[119] This is entirely sensible. Equally, employers have duty of care towards employees, and are required to make judgments on the basis of the latest available guidelines, taking into account the role that employees are fulfilling. At present, employers and physicians have the flexibility to make these judgements; under the Directive, they will not.

48. The Commission's own guidelines on the precautionary principle include provision for some account to be taken of the benefits as well as the costs of the action in question. The Directive considers only the health and safety of workers. Because the impact assessment for the Directive did not identify any potential impact on MRI usage, any health benefits lost as a result of implementation were not considered. We discuss in chapter 7 the steps the Commission is now taking to explore further the impact of the Directive on MRI procedures. **Regardless of the impact on current MRI procedures, any attempt to consider the health of workers in isolation from all other factors would be against the spirit of the precautionary principle, as set out by the Commission. We hope that the agreement of the Commission to undertake further work on the potential impact of the Directive indicates a willingness to accept the need for a wider risk-benefit analysis.**

49. We found no evidence in Brussels that these arguments on the application of the precautionary principle were rehearsed in relation to this Directive, either in its formulation or its consideration in Council and Parliament. Indeed, we were given no clear response at all to questions to officials on the use of the precautionary principle in the

117 Qq 762-63

118 Ev 39

119 ICNIRP (2004), Health Physics 87, p 207

formulation of the Directive.[120] Whilst one official asserted that the precautionary principle was "not used at all", [121] another told us that the Directive, like other EU legislation, was based on it. This lack of clarity highlights the inadequacy of the current definition and application of the principle. We accept that there are no straightforward answers. Indeed, it is difficult to see how any definition or general guidance could provide definitive instruction in a situation in which the potential but uncertain adverse health effects on a relatively small number of workers has to be weighed against the potential but uncertain loss of techniques known to be of significant benefit to relatively large numbers of patients. In this situation, as in most others, there is a scientific but also a political judgment to be made. No principle can obviate the need for such difficult decisions. **We have found no explanation as to how the precautionary principle was, or was not, applied to the development and agreement of the Directive. The fact that such confusion remains confirms our view that the Commission's guidelines on its application are of limited practical use, even if there were a desire to refer to them.**

A precautionary approach

50. In the UK, there is no legal recognition or Government definition of the precautionary principle. Witnesses in our over-arching inquiry have shown little enthusiasm for existing definitions or usage of the precautionary principle. Professor Blakemore, for example, argued that "there are serious problems with the precautionary principle because of the variety of interpretations of it" and that a "serious piece of work" on it would be very helpful.[122] The Government Chief Scientific Adviser prefers to talk of a precautionary *approach* rather than a principle. According to the Government, such an approach applies where "the scientific evidence is incomplete or inconclusive, and there is the possibility of severe and irreversible consequences."[123] This approach is similar to the one adopted by the Stewart Report. It elaborates on the precautionary approach as follows:

> "The precautionary approach is not all or nothing in nature. Rather, it is a matter of degree. In essence, it requires that before accepting a new development we should have positive evidence that any risks from it are acceptably low, and not simply an absence of convincing evidence that risks are unacceptably high."[124]

In the case of mobile phones, it recommended that this precautionary approach be adopted "until much more detailed and scientifically robust information on any health effects becomes available."[125] It recommended that ICNIRP guidelines be adopted for mobile phone frequencies.

51. The Government's definition of the precautionary approach does not provide any explanation of how it should be applied in any given set of circumstances. Rather, it provides for a further judgment to be made, alongside other risk management principles

120 Ev 64

121 Q 750

122 Q 851

123 Government memorandum, para 39 (to be published in HC 900-II, Session 2005-06)

124 Stewart Report, para 6.16

125 Stewart Report, para 6.40

such as consistency, proportionality and cost-benefit analyses. We believe that it is more realistic and less misleading to frame the debate in terms of an "approach" rather than a "principle", to indicate that it provides another factor to consider when managing risks rather than a precise formula to be applied in any given situation. In fact, this is very close to what the Commission's guidance provides. Like the principle defined by the Commission, the precautionary approach is at present ill-defined and certainly unsatisfactory as a tool for practical use. There is, as Lord Hunt acknowledged, a balance to be struck between the desirability of maintaining some flexibility in application, and a very precise definition of a principle.[126] Similarly, the Head of the Government Economic Service, Sir Nick Stern, doubted whether risk analysis could be reduced to one particular principle or rule.[127] The nature of this balance and the means by which it might be achieved is not easily identified, and still less easily agreed. We will draw on the whole evidence we take in our over-arching inquiry to consider the desirability and nature of further action to elaborate on how a precautionary approach could be usefully defined and applied in practice. In the meantime, **we recommend Government and its agencies desist from using the term "precautionary principle" in order to explain policy decisions or judgments. We also urge Ministers to propose a similar approach in discussions in the EU Council.**

126 Q 916

127 Q 1054 (to be published in HC 900-II, Session 2005-06)

5 Engagement with scientific community

Guidelines on scientific advice

52. One of the roles of the Government Chief Scientific Adviser (GCSA) and his colleagues at a departmental level is to ensure that the GSCA's guidelines on how scientific advice should be used in policy making are followed. Consultation with relevant experts is a key component of the scientific advisory process. The *Guidelines for Scientific advice and policy making* that were current at the time of the Directive's adoption stress that departments, when identifying the need for scientific advice, should draw on "a sufficiently wide range of the best expert sources, both within and outside Government". They specifically mention Research Councils, industry, academia, professional bodies and learned societies.[128] In the updated guidelines of November 2005, this advice is maintained, along with an emphasis on obtaining a broad spectrum of advice. The guidelines state that:

> "When deciding which external experts sources to seek advice from, departments should encourage those responsible for individual issues to cast their net wider than their traditional contacts and continually establish new networks in order to capture the full diversity of good evidence-based advice.".[129]

The 2005 update provides sensible elaboration on the need for a broad basis for scientific advice, but this principle was well established during the period in which the Directive was under consideration.

Sources of advice

53. One of the aims of our over-arching inquiry is to examine the impact that the departmental Chief Scientific Advisers (CSAs) are having on the policy making process. In this case study, we have found no evidence of any involvement from either the Chief Scientist at the HSE or departmental Chief Scientific Adviser at the Department of Health (DH) in the provision of advice on the Directive. The Chief Executive of the HSE, Mr Podger, told us that on these types of specialist issues, "you would not normally expect to ask the Chief Scientist or the Chief Scientific Advisers … In general terms, specialist issues on directives would be considered by HSE with the relevant public bodies, which was done by colleagues in the HPA, and it would also be considered with the relevant stakeholders."[130] Ministers delegated responsibility for policy on the Directive to the HSE and the NRPB without ensuring that there was an alternative scientific input, or any challenge, from a CSA, to the views put forward by these bodies. In view of the expenditure committed by the DH on new MRI scanners, it was especially remiss of the Department not to obtain appropriate advice on the potential consequences of the Directive for MRI use.

128 OST, *Guidelines 2000, Scientific advice and policy making*, July 2000, para 12

129 OST, *Guidelines on Scientific Analysis in Policy Making*, October 2005, para 13

130 Q 921

54. Departmental Chief Scientific Advisers should be responsible for ensuring that policies are properly informed, where necessary, by scientific advice and that the scientific advice obtained is sufficiently comprehensive and based upon a strong evidence base. They cannot perform this function if they are not involved in policy advice. It should be for the Chief Scientific Advisers and equivalents to determine whether there is a scientific element that needs to be considered in any policy development. This case study demonstrates clearly that the impact of science and on scientific research of a policy is not necessarily easily identified. **We are surprised that neither the Chief Scientific Adviser at the Department of Health nor the Chief Scientist at the Health and Safety Executive was involved at any stage in providing advice on the Directive, particularly in view of the high levels of expenditure on MRI equipment at DH. If they are not involved in the policy making process on a subject with such a heavy reliance on science, it is difficult to see how they were operating effectively. We recommend that the DH and the HSE take steps to ensure that their respective chief scientists are actively and routinely involved in the provision of advice informing policy.**

55. The Government relied on the HSE and the NRPB/HPA to advise and to negotiate on the Directive during the legislative process. The Minister with responsibility for the HSE, Lord Hunt, explained that while he has overall responsibility, "I take advice from the Health and Safety Commission and they, in turn, are advised by the Health and Safety Executive. In the question of the scientific issues that are under discussion, formal advice is received from the Health Protection Agency."[131] The HSE has responsibility for monitoring and enforcing controls on occupational exposures to EMFs,[132] but receives advice on radiation protection from the Radiation Protection Division of the Health Protection Agency, as well as from other sources.[133] The HSE Chief Scientist is responsible for ensuring that its policies are based on the best available scientific advice and, like departmental CSAs, that the Government Chief Scientific Adviser's Guidelines on *Scientific Analysis in Policy Making* are followed. The HSE reports that this monitoring indicates "good compliance with the Guidelines."[134] On the subject of the Directive and MRI, the HSE states that, "regular discussions have taken place between HSE, DH and the MHRA. This has ensured the consistent and effective application of scientific advice, and HSE's development of policy has taken OGD's [other Government departments] views fully into account."[135] The evidence we have collected does not fully support this assertion, as we set out below.

Engagement with MR community

56. The Government followed its established system for obtaining the necessary scientific advice on the Directive by relying upon the HSE for advice on the Directive. For further advice on the suitability of the limits contained in the Directive, the HSE relied upon the NRPB. The NRPB conducted its own consultations on its guidance, which informed its

131 Q 860

132 Ev 37

133 Ev 42

134 Ev 73

135 Ev 34

advice to the HSE. The successful operation of this arrangement for securing scientific advice depends upon the HSE and then the NRPB securing the necessary breadth of scientific advice, as set out in the GCSA's guidelines. It also requires these bodies to relay to Ministers an indication of the degree of certainty in the advice provided. As we have noted, responsibility for advice on the Directive was delegated to the HSE, which appears to have the necessary expertise to be able to advise properly on the full impact of the Directive, or at least to understand when further specialist advice was needed. It has 76 people with expertise in medical science, nine radiation technical specialists, two of whom have expertise in electromagnetic fields.[136] We note that the HSE has made "limited use of external science" because of the difficulties experienced by outside experts in making regulatory judgments, but welcome the fact that this position is being reviewed at present.[137]

57. There were two strands to the consultations on the Directive. The HSE had a responsibility to identify all sectors of the workforce affected by the Directive and the NRPB/HPA was responsible for the provision of scientific advice on the exposure limits proposed and their potential impact. Mr Podger explained that specialist issues in the Directive were referred to the NRPB/HPA to consult with relevant public bodies and stakeholders.[138] The HSE commissioned the NRPB to identify the industrial sectors likely to be affected by the Directive as early as 2001, and there was no mention of the impact on medical MR applications and research in its findings. Early attempts to publicise and explain the impact of the Directive were directed mainly at the electricity and mobile telecommunications industries, the principal ones affected. This emphasis is reflected in the list of organisations consulted by the HSE in producing its Regulatory Impact Assessment and in attendance lists of various international conferences and events held to discuss the Directive. It appears that the MR angle was first considered during 2002: the MRI equipment manufacturers were first informed of the Directive towards the end of that year. The Institute of Physics and Engineering in Medicine confirms that "the commissioning of the Directive is unlikely to have been promoted as a major benefit for the 'healthcare industry'. Hence it is possibly not surprising that the passage of the Directive has seemingly bypassed the healthcare industry…".[139] The NRPB had done a substantial amount of work on EMF, including in the medical field, and should have ensured that it pro-actively consulted appropriate medical practitioners and scientists at the cutting edge of MR research and use, rather than relying on a website consultation. Equally, as we have seen, the HSE had identified in its Regulatory Impact Assessment the fact that MR equipment would be covered, but failed to ensure that appropriate direct consultations took place.

58. Having failed to consult all those affected by the Directive in the first instance, the HSE and NRPB still had an opportunity to revise their advice in response to representations made during and after consultations on the Directive. The table in Box 4 was provided in the joint submission and provides a detailed account of engagement on this issue between

136 Ev 73

137 Ev 33

138 Q 921

139 Ev 54

the medical/research community on the one side and Government, HSE and NRPB on the other. Neither the HSE nor the Government have disputed the content of this record.

Box 4: Outline of activities of MR community[140]

Date	Action	Outcome
July 2003	British Institute of Radiology (BIR) writes to HSE expressing concerns.	HSE response Issues about limits should be directed to NRPB.
August 2003	BIR writes to NRPB expressing concerns as part of consultation on new guidance.	No response—concerns not addressed in guidance.
August 2003	HSE inspector visits MRI research centres to discuss concerns.	Comments by inspector HSE's hands tied by NRPB and ICNIRP limits. Manufacturers and users must redesign scanners and practices to comply.
19 September 2003	Meeting of MR scientists with HSE.	Static magnetic field limit dropped from Directive as ICNIRP have withdrawn that part of guidance. HSE will still seek to enforce this limit in the UK because it is in the NRPB guidance.
29 April 2004	Directive adopted	
June 2004	IPEM[141] writes to MHRA expressing concerns about consequences for ionising radiation protection.	Issues will be discussed at forthcoming HSE stakeholder meeting.
27 July 2004	HSE stakeholder meeting covering all affected employment sectors.	HSE position Static field limit should not have been removed—HSE will seek to enforce it in UK because it is in NRPB guidance. Concerns of the MR community are 'esoteric and of no interest to anyone else in this room'. Implementation group established with input from MR community.
October 2004	IPEM raises concerns about consequences for ionising radiation protection with HSE contacts.	HSE ionising radiation inspectors believe risk-benefit analysis is needed.
October 2004	Letter to MHRA raising concerns about conflict with Ionising Radiation (Medical Exposure) Regulations in intervention.	Reply from Department of Health No conflict will exist, as MR technique will be illegal. Subsequent apology from DH and offer to involve community in stakeholder group. Stakeholder group subsequently abandoned
October 2004	IPEM meeting on EMF attended by HSE.	HSE position Manufacturers and users must redesign scanners and practices to comply.

140 Ev 14-16. The table has been edited for inclusion in this Report.

141 Institute of Physics and Engineering in Medicine

Date	Action	Outcome
6 June 2005	Debate with HSE at UKRC conference.	HSE position No case for medical staff to be treated differently from other groups. HSE will seek to include 2T static field limit in UK legislation. 96% of audience support motion that Directive will be detrimental to clinical services and research.
20 September 2005	Group of eminent scientists write to Health Secretary raising concerns.	DH response Directive not onerous, as limits follow existing guidance. Data on acute effects 'well established'. Stakeholder meeting will be held.
20 September 2005	MR scientists and clinicians hold press conference highlighting concerns.	European Commission response[142] Experts agree excessive exposure to MRI dangerous to health. Risk is to those exposed regularly, not patients. HPA response '…there is a lack of evidence for deleterious effects'. But need to be cautious in case there are long-terms effects.
20 October 2005	Meeting of Royal College of Radiologists (RCR) with Lord Hunt of King's Heath and HSE	HSE will explore options for renegotiation or amendment of Directive. Need further research to establish exact extent of the problem for MRI. Directive will be a low priority for enforcement.
25 November 2005	RCR writes to Lord Warner expressing concerns.	Lord Warner concerned about impact on clinical MRI.
5 January 2006	Stakeholder meeting at HSE.	Agreement that further work is needed.
24 January 2006	Meeting of RCR with Lord Hunt and HSE.	Further work discussed.
9 March 2006	Delegation meets Commission.	Agreement to establish Working Group to review impact of Directive.

59. Communication between the HSE and research/medical communities has been a central issue: both HSE and NRPB/HPA are accused by the MR community of not taking their concerns sufficiently seriously until September 2005.[143] A consultation document on revised guidelines was published by NRPB on 1 May 2003, inviting comments by the end of July. It was not until June 2003 that the MR community in the UK noticed the potential impact on MRI use. The British Institute of Radiology first wrote to the HSE and then the NRPB, in July and August 2003 respectively, expressing concerns about the proposed new guidance. No direct response was received until March 2004, when all respondents to the consultation were sent an acknowledgment letter along with the NRPB's current advice. A further letter was sent on 30 July 2004 with the summary of responses to the consultation, some 12 months after the initial deadline for responses.

142 www.esmrmb.org/index.php?pid=409&SID=cf56847d32bff904b5a31433eff64982, with response from European Society for Magnetic Resonance in Medicine and Biology (ESMRMB).

143 Q 837

60. During this time there was contact between the MR community and the HSE. In meetings between HSE staff and MR scientists in August and September 2003 the HSE took the line that the NRPB guidelines, which were essentially those of ICNIRP, being included in the Directive would be enforced by the HSE and that users and manufacturers would need to make the necessary alterations to equipment and working practices in order to comply. This was at a time when the European Council was still in the process of agreeing a common position on the Directive, and there were opportunities to seek amendments. There was no undertaking to explore these concerns further or to relay them to negotiators in Brussels. The attitude adopted by the HSE was not to take the concerns particularly seriously, according to the MR community. The Institute of Physics states that its "bewilderment" at the introduction of the Directive "is exacerbated by the HSE and HPA ignoring the deeply held views of the scientific and medical community … and ignoring the overwhelming scientific advice that has been offered to them."[144] The joint submission states that the concerns of the MR community were described by HSE at a stakeholder meeting in July 2004 as "esoteric and of no interest to anyone else in this room".[145] This statement, which has not been disputed by HSE, suggests a degree of arrogance and disdain which is extremely disturbing to find in what is a generally well respected public body. It was not until Ministers became directly involved with the issue that the HSE began to fully engage with the MR community, in September 2005 (see paragraph 63, below). **Given that the concerns raised about the Directive in 2003 coincided with its consideration in the European Council, and that they came from medical practitioners well placed to provide advice, we find the response by the HSE and NRPB/HPA to them highly disappointing. This reaction was characterised by an instinctive and dismissive resistance rather than an attempt to engage and examine. Both organisations acted in contravention of the guidelines laid down by the Government Chief Scientific Adviser.**

Confusion at the HSE

61. The HSE also repeatedly gave wrong information about its intentions on static fields. UKREP worked—under the instruction of HSE—with other Member States in Brussels to have the static fields limits removed from the Directive. This was achieved on 17 September 2003. Yet in a meeting on 19 September 2003 HSE staff in the UK told MR scientists that HSE would still seek to enforce this limit because it was in the NRPB guidance. This commitment by the HSE to go beyond the terms of the Directive to impose tighter restrictions was then repeated at a meeting in July 2004. Here, HSE staff said that the static field limit should not have been removed, in spite of the fact that the HSE had argued since mid-2003 in favour of its removal! When asked for an explanation for this, the Minister acknowledged that the information given at the UK meeting by HSE staff was wrong and that what was said "is not our policy".[146] As late as June 2005, the HSE repeated that it would seek to introduce static field limits in the UK legislation.[147] We have had no explanation as to why this wrong information was being given repeatedly. **It is extremely**

144 Ev 48

145 Ev 45, Q 837

146 Q 905

147 Ev 46

worrying that the HSE managed to outline a policy to the MR community in the UK which was the precise opposite of the one it had been pursuing in Brussels during negotiations. That the HSE could be contradicting itself for such a long period suggests some quite astonishing failings in management and internal communications. We recommend that the HSE seeks to discover how this situation could persist for so long, and takes appropriate steps to ensure that there can be no repeat.

Acknowledgement of failings

62. The Minister, Lord Hunt, acknowledged the failings by the HSE in its consultations on the Directive. He said that the issue "has not been fully considered by the Government, and clearly something went wrong with the process".[148] Specifically, he described the failure of the HSE to go to the medical royal colleges when it initially consulted as a "glaring omission" although he suggested that "it may well be … that the colleges might have been more active.[149] He told us that "I do think that the HSE should have consulted more widely with the medical field, yes".[150] This was endorsed by the Chief Executive of the HSE, who explained "What was not realised at all was that there were these minority of clinical interventions … we had not appreciated it by September 2003."[151] He explained the reasons for the failings in consultation were "that we had consulted with manufacturers and technicians and we had some clinical engagement, although certainly with the benefit of hindsight insufficient—and I would be the first to say that.".[152] **We welcome the frank admission of the failings in consultations on the Directive by the Minister and, more pertinently, by the Health and Safety Executive.**

63. As well as failing to give proper consideration to the views expressed to it, the HSE failed to communicate these concerns to Ministers until far too late to affect the content of the Directive. On 20 September 2005, the MR community held a press conference to publicise its concerns. This gained significant and sympathetic coverage in many national newspapers and journals over the following few days. It was following concerns raised directly with Ministers by clinicians that the Minister, Lord Hunt, requested a note from the HSE, which was provided on 27 September 2005. The Minister then agreed to meet the Royal College of Radiologists on 20 October and discussed further action (see paragraph 76). Lord Hunt subsequently set up a general meeting for all stakeholders on 5 January 2006 to discuss further action. A report of this meeting has been published. Lord Hunt also met the RCR and HSE later that month. In evidence to us, the Minister regretted that it took so long to be brought to his attention. He told us that "if the issue had come to Ministers before then, a similar kind of process [of action] could have been undertaken".[153] This is not doubted by the MR community. Dr Keevil told us that "It became a different story when we started to engage at Government level" and that the Government was now working with the MR community to find a solution.[154] We acknowledge the Minister's

148 Q 909

149 Qq 908-09

150 Q 909

151 Q 872, ev 72

152 Q 872

153 Q 862

154 Q 838

positive response when finally informed of the concerns being expressed about the impact of the Directive. We also welcome his willingness to learn from this episode. He states that "The key lesson is to listen and work with all stakeholders and not become complacent that existing networks are sufficient".[155] We note that it was only when the HSE was asked by the Minister for advice on the concerns raised directly with him that the HSE responded. Without such a direct approach to Ministers, there is little to suggest that the HSE would have taken any action at all.

Conclusions on HSE and NRPB consultation

64. Both the HSE and the NRPB failed to consult sufficiently widely to ensure the impact on MRI was given full consideration. The HSE identified that MRI workers and equipment would be affected by the Directive but then did not consult the MR community on its impact. It relied completely for advice on the NRPB. For its part, the NRPB was more aware of the potential impact of EMF limits on MRI, having contributed to and reviewed much evidence on the subject, particularly from 2001 onwards. It too failed to consult the MR community and thus its advice to the HSE was incomplete. **The Government was badly let down by the HSE and NRPB, not only by their failure to consult sufficiently widely but also by their failure to advise Ministers on the concerns being raised. When informed of these concerns, Ministers acted with commendable speed to investigate further. We welcome the commitment by the Government to rectifying these earlier failings by working closely with the MR community.**

Engagement of MR community

65. The failings in engagement activities are not all those of the HSE and NRPB/HPA. There were deficiencies in the time it took the MR practitioners and their professional bodies and research sponsors to identify the potential implications of the Directive and in the way they communicated with their research community and with policy makers.

66. It took the medical practitioners six months from the publication of the Directive to express concerns or seek clarification from the HSE. Dr Keevil, who was in the forefront of activity on this front, became aware of the issue "sometime in the middle of 2003".[156] When medical practitioners and scientists did mobilise, their focus was solely on the proposals on static fields, which were removed in September 2003. UK organisations did not identify the limits for time-varying fields as a potential problem until June 2004, when the Institute of Physics and Engineering in Medicine (IPEM) wrote to the Medicines and Healthcare products Regulatory Authority. The issue was discussed at a stakeholder meeting with HSE the following month.[157] The only evidence we have found of time-varying fields being raised during the negotiations was the letter from COCIR of April 2003 to the Social Questions Working Party considering the Directive. However, the focus of their concerns was also on static fields and the Government reports that the presenters of this paper "appeared content with the removal of static field values only".[158] The HSE was

155 Ev 70

156 Q 837

157 Ev 65

158 Ev 71, Q 3

consequently allowed to believe that the MR community was content once static fields had been removed from the Directive.[159] There was still time, in early 2004, for the UK to influence the content of the Directive as it was considered by the European Parliament. Yet the British MEP who was seeking to have MRI removed from the Directive told us that she heard nothing from the UK medical community, or indeed from UKREP in Brussels.[160] IPEM acknowledges that "the scientific community must take responsibility for not bringing matters to government attention in a timely way …" and suggests that there "may be hesitation" in alerting Ministers when concerns are not being addressed.[161] This Committee has sought to promote increased political awareness and engagement in all sections of the scientific community. Unfortunately, the potential benefits of such political acumen were not enjoyed in this case. It is regrettable that the issue of time-varying fields was only raised as a major problem after the Directive had been agreed. **We conclude that the MR community in the UK was very slow to consider the impact of time-varying fields and failed to raise it early enough to influence the negotiations on the Directive.**

67. This case study has also suggested that there is a disconnect between the MR community and the mainstream medical research community, and, more generally, between medical scientists and the clinicians. In spite of the efforts of the medical practitioners in 2003 and 2004, eminent scientists working on MR remained unaware of the Directive some two years after concerns began to be aired. We were surprised to discover that a leading MR researcher, Professor Ray Dolan, Head of the Wellcome Department of Imaging Neuroscience at University College London, only found out about the Directive in summer 2005 and was then formally notified in October that year.[162] Equally, we find it odd, to say the least, that individual medical scientists knew about the Directive while key funders of MR research such as the Wellcome Trust and the Medical Research Council did not. Given its own research interests and its financial commitment to new MRI equipment, the MRC might have been expected to maintain an interest in a Directive covering EMF. The Chief Executive of the MRC, Professor Blakemore, told us that he did not know about the Directive until around September 2005. The Wellcome Trust became aware around a similar time. In spite of his work with the Weak Electric Fields Group, Professor Blakemore was, surprisingly, not specifically consulted by the NRPB.[163] When it did finally hear about the issue, the MRC was responsive and immediately raised strong concerns with the HSE.[164]

68. The failings in communication throughout the medical research community were threefold: horizontal, across medical practitioners and researchers; top down, from professional bodies and research sponsors; and also bottom up, from practitioners to policy influencers. This comprehensive failure of communication meant that the medical research community was unable to exert any political influence until it was far too late to be effective. **We conclude that the professional bodies, the Wellcome Trust, and the MRC**

159 Qq 868, 874

160 Private meeting with Liz Lynne MEP, 11 May 2006

161 Ev 55

162 Q 834

163 Q 843

164 Ev 27, 29

were insufficiently pro-active in identifying the implications of the Directive and informing their communities, and politically ineffective in communicating these concerns in Westminster and Brussels. We recommend that the professional bodies and research funders re-examine the development of their links with each other and explore ways in which they can work together to improve their political effectiveness.

Horizon scanning

69. The failure of the medical research community to pick up on the Directive for so long suggests a lack of effective horizon scanning activities, in Government and among research funders. The GCSA's guidelines on scientific advice require departments to have adequate horizon scanning mechanisms in place and ensure that the evidence obtained is appropriately considered and, when necessary, acted upon.[165] We have not considered the full range of Department of Health or Government horizon scanning activities here but have focussed on the mechanisms that are in place to detect issues of interest at an EU level and also on non-ionising radiation specifically.

70. The HSE identifies forthcoming proposals from the Commission by developing its own links with relevant officials there and by liaising with UKREP.[166] We explore its links with UKREP in chapter 6. For non-ionising radiation, there is an Interdepartmental Liaison Group, established in 1994, with specific responsibility for ensuring effective discussion of cross-departmental interests on this subject. It consists of officials from a number of Government departments, including the Department of Health, the HSE, the HPA and the MRC. This Group first noted the possibility of a Directive in June 2001 and was given further updates at subsequent twice-yearly meetings, at which the possible impact was discussed. The Government states that "The MRI issue was mentioned to the group in June 2003 but no action agreed".[167] This group has a sufficiently broad membership to be capable of ensuring that the right organisations were consulted when the Directive was first discussed. It did not identify the potential impact on MR for two years. Even when it did, the Group failed to ensure that key organisations such as the HSE, DH and the MRC fully considered the implications of the Directive and developed a coherent cross-departmental approach to this issue. The Government has in place, in the Interdepartmental Liaison Group on non-ionising radiation, a mechanism for advising on measures such as those contained in the Directive. In this case, the Group failed to identify all departments and agencies affected by the Directive and to consider further the extent of its impact. **We recommend that the Department of Health and the Medical Research Council review their representation on the Interdepartmental Liaison Group on non-ionising radiation to ensure that the Group is provided with the necessary breadth of expertise and that they give due consideration to the issues raised by the Group.**

71. In addition to its membership of the Interdepartmental Liaison Group, the MRC had the opportunity to become aware of the impact of the Directive through the presence of the UK Research Office (UKRO) in Brussels. This is part-funded by the Research Councils and was set up to provide advice and information on EU research programmes to organisations

165 OST, *Guidelines on Scientific Analysis in Policy Making*, para 9

166 Ev 74

167 Ev 73

in the UK. It is well placed to keep an eye on proposed Directives which might impact upon the UK research community and advise accordingly. We were surprised to discover that UKRO seems to make no attempt to provide this service for the Research Councils. RCUK told us that UKRO has "very limited horizon scanning activities" and that it "would not have been expected to pick up on this particular EU Directive".[168] Whilst its focus might naturally be on providing information about funding opportunities to its subscribers, the Research Councils which also fund it might nonetheless expect to see some return in terms of information about EU legislation relevant to their respective communities. We believe that the Research Councils stand to benefit from providing the necessary resources to enable it to fulfil this function.

72. We have identified failures in the horizon-scanning activities of the Government and its agencies, the Research Councils which contributed to the late reaction of the UK MR community to the Directive. The Directive was well over the horizon before the medical research community, led by the MRC, reacted to its potential consequences. There are bodies in place which should, or could, perform this horizon-scanning function, both for the issue of non-ionising radiation and for developments in the EU of interest to the UK research community. That they are not specifically charged with this responsibility is indicative of the low priority given to this important role, which, in turn, results in an absence of established links for feeding this advice and information into the policy making process. **We recommend that the Office of Science and Innovation reviews its horizon scanning activities in respect of EU legislation, in consultation with the Research Councils. We believe that there is a strong case for the UK Research Office to perform a horizon scanning function on behalf of the Research Councils.**

6 Role of UKREP in using scientific advice

73. The UK Permanent Representation to the European Union (UKREP) represents the interests of Government departments in negotiations on EU business. It also provides up-to-date advice on the progress of Commission proposals and acts as a link between Whitehall and Brussels. Its staff are organised around the subjects of different specialist Councils. It has no dedicated scientific staff but relies on the responsible Government departments to obtain the necessary scientific advice in support of policy. During the negotiation of this Directive, UKREP took its instructions exclusively from the HSE. As we have noted, the UK was not in favour of the Directive in principle. As the Directive was subject to Qualified Majority Voting and given that it was supported by the majority of Member States, the Government was right to engage in negotiation and to seek to dilute the more onerous requirements.

74. We heard that the concerns of the HSE during negotiations in 2003 were around the burdens imposed by health surveillance requirements and about the approach to risk management which did not distinguish between cumulative and acute risks. From mid-2003 UKREP, under instruction from the HSE, argued in support of other States for the removal of static fields from the Directive. This pressure, as we have seen, was successful. However, officials at UKREP told us that no attempt was made to seek to remove time-varying fields from the Directive. This reflected the focus of the representations being made to the HSE during the latter half of 2003. An attempt by the UK and other Member States in May 2003 to seek a derogation for those working with MR in the medical sector was rejected on the grounds that medical staff were not expected to be present in the area when patients were exposed to MR.[169] We were surprised that this attempt by the UK was not mentioned in the Government evidence to us nor highlighted by UKREP staff during our visit to Brussels. Taken in the context of the HSE's mixed messages in the UK and Brussels, we take this as further evidence of the lack of clarity in Government policy on this issue.

75. UKREP was reliant on one source of advice during the passage of the Directive. It was therefore not aware of the representations being made by COCIR directly to the Commission during negotiations in April 2003.[170] This preceded the involvement of the UK MR community. There is a weakness in a system in which UKREP has no means of direct engagement with scientific advice but is completely reliant on the sponsoring department. The Wellcome Trust comments on the difficulty of following the progress of Directives through the EU, a problem exacerbated, in its view, by the fact that more than one Commission Directorate can be involved and that there is no single source of information.[171] In this case, UK policy might have benefited from earlier detection of the concerns being raised in Brussels and from a capability at UKREP to receive representations directly from stakeholders. Such a capability would have provided an opportunity for the HSE to discover that it was giving two different messages in the UK and in Brussels. Some form of scientific capability, even just a dedicated contact point for

169 Council of the European Union, *Outcome of proceedings of the Social Questions Working Party*, 2 September 2003, Section IV, footnote 22. The other Members States were Germany, France, Austria, Portugal and Finland.

170 Ev 71

171 Ev 53

scientific issues, would provide a useful backstop for any failures in the UK consultation process, particularly in cross-departmental issues where a wide spectrum of scientific interests may be involved and affected. It would also provide the research community with a straightforward method of obtaining information about relevant developments in Brussels. **We recommend that UKREP reviews its channels of communication with the scientific community in the UK and considers developing some capability for direct links, on a systematic basis, or at least on an *ad hoc* basis in response to the introduction of proposals.**

7 Further work on implementation of the Directive

The UK

76. The concerns of the MR community have now been recognised in London and Brussels and further work is in the process of being established to assess the potential impact of implementation of the Directive. Following the meeting between the HSE and stakeholders on 5 January 2006, the Government agreed a programme of research in order to assess the extent and nature of the impact the Directive may have on MRI procedures. This will be overseen by a working group of the HSE. It is funding research which is due to be completed in summer 2007. Further work is being funded by MRC, which may report in a shorter timescale.[172] The Minister said that he "was hopeful that that will produce some hard evidence on which we can then go forward".[173] **We welcome the commitment of funds from the HSE and the MRC to a programme of research on the potential impact of the Directive on MRI procedures. In the meantime, we recommend that the Government does not prioritise the Directive for implementation through secondary legislation.**

The Commission

77. The Commission is also sponsoring further research. On 9 March 2006, an international group (including Dr Keevil) representing the European radiology, medical physics and MRI communities met with Commissioner Spidla and Mr Biosca de Sagastuy in Brussels. The delegation argued for the exclusion of MRI from the Directive. Commissioner Spidla said that he was open to re-evaluation but only if there was clear evidence that the Directive would restrict the use of MRI so as to reduce patient benefits and limit the evolution of the discipline. It was agreed that a working group of representatives of the radiology and scientific communities and Commission representatives be formed in order to measure the exposure levels produced using current equipment and test the claims of the medical community.[174] Some members of the HSE working group are expected to serve on this group. The group was due to meet for the first time in June 2006. The mandate of the group, Mr Biosca de Sagastuy told us, was "not to propose amendments to the regulations" but it could "make recommendations" for the Commission to consider.[175] No deadline has been set for concluding its work. Mr Biosca de Sagastuy clearly was of the view that there was no evidence that could persuade him of any need to amend the Directive because "the scientific community says no".[176] He also believed that, even if the group were to recommend any changes, these could not be implemented before the Directive is due to come into force in 2008. The Director-General

172 Ev 72

173 Q 877

174 Ev 64

175 Qq 784-85

176 Q 794

of the Directorate preferred not to speculate on the conclusions of this work: the question of modification of the Directive remained "a hypothetical one."[177] We were not convinced by the commitment shown at the Commission to the re-opening of discussions, if necessary, on a Directive that had so recently been agreed by Member States.

78. **We welcome the establishment of the joint working group by the Commission to examine new evidence and hope that it is a genuine attempt to inform the implementation of the Directive rather than simply a device to mollify the critics. We urge the UK Government to ensure that this work is well informed by the further research in the UK, and is completed in time for decisions on the implementation or amendment of the Directive to be taken before April 2008. If new research demonstrates a clear need for the Directive to be amended, for example to exclude MRI from its scope, the UK Government should seek this solution, rather than relying on non-enforcement. At the very least, the Government should press for a full impact assessment when the Directive is reviewed in 2009.**

177 Ev 64

8 Conclusion

79. We sought in this case study to examine how scientific advice is used by the Government to inform and advise on legislation emanating from the EU. Of course, individual departments are responsible for taking the lead on relevant Directives and for seeking appropriate advice. To this extent, many of our conclusions about the way in which advice was sought and handled are focussed on the HSE, HPA and the medical research community. We have found flaws in their processes for providing advice on EU legislation. Similar failures in consultation at the Commission resulted in the need for further research to inform policy being identified far too late in the legislative process, and not acted upon with sufficient speed. Without the benefit of this research, we have seen no evidence to justify the inclusion of MRI in the scope of the Directive: existing guidelines are sufficient and provide the flexibility to cope with any unintended negative impacts on MR procedures.

80. There are some general lessons which we identified. The importance of securing the necessary breadth of scientific advice and for giving appropriate consideration to dissenting voices is clear, although in this case the MR community was also slow to appreciate the full potential impact of the Directive. This inquiry has emphasised the need for horizon-scanning of EU activities to be carried out, but also to be ingrained into the policy making process. We have identified a need for the Research Councils to improve their mechanisms for identifying when the interests of the UK research community may be affected. Finally, we have found that the precautionary principle is not yet sufficiently well defined to be of real practical use to policy makers. We will return to some of these issues in our final Report, having assimilated the lessons of our other two case studies and further evidence.

Conclusions and recommendations

Sources of advice to the Commission

1. We conclude that the Commission was right to go to the established international authority, ICNIRP, for advice on which to base its proposals. However, we believe that the Commission did not seek to obtain the maximum benefit from the work undertaken by ICNIRP by exploring the potential impact of the Directive on MRI. Equally, ICNIRP should accept that, if its guidelines are being used as the basis of the Directive, it has some duty to advise, to the best of its knowledge, on those potentially affected by the Directive, to enable the Commission to consult appropriately. This detailed advice does not appear to have been given. (Paragraph 13)

Strength of evidence base

2. We find it puzzling that static fields were included in the initial proposed Directive when the principal source of scientific advice for the Commission, ICNIRP, was about to review its own guidelines and advised against using existing guidelines as a basis for the Directive. This suggests that communication between the two organisations was not as effective as it could have been, but it does demonstrate that the legislative process was responsive to new scientific advice. (Paragraph 21)

3. Having advised on the exclusion of static fields from the Directive, it would be inconsistent and slightly disingenuous of ICNIRP to evade all responsibility for advising the Commission on the strength of the evidence base regarding time-varying fields. (Paragraph 24)

4. We welcome the fact that the scientific advice on which the Directive is based is all published: this transparency has assisted debate. However, officials we met at the Commission misrepresented the level of certainty in the scientific evidence underpinning the Directive. This approach was unhelpful, and can only undermine confidence in the way in which scientific evidence was used by the Commission to support the Directive. (Paragraph 26)

Impact of the Directive

5. We were alarmed to discover that the European Council was prepared to rely on a ten year old risk assessment to inform legislation in an area of rapidly developing science and technology. We welcome the moves taken to ensure that new proposals are accompanied by new impact assessments, as long as these are taken to include revived Directives such as this one. (Paragraph 29)

6. We conclude that the HSE did not apply the necessary expertise to its assessment of the impact of the Directive. We recommend that the Health and Safety Executive ensures that regulatory impact assessments on EU proposals are conducted in a comprehensive manner, on a sector by sector basis, with care being taken to address the broader impact, rather than just the costs, of the legislation. (Paragraph 32)

7. It is deeply regrettable that the impact of the Directive on MRI procedures was not established before the Directive was adopted. This case study illustrates the potential consequences of the failure of policy makers to seek comprehensive scientific advice early in the policy formulation process and to commission the necessary research to inform this process where uncertainty or gaps in knowledge exist. (Paragraph 40)

Justification for a Directive

8. For MRI at least, we do not believe that there was a strong enough case for enshrining exposure limits in a Directive. We agree with the Government that existing guidelines are sufficient. The Directive will, at best, impose burdens on employers and, at worst, inhibit the use of valuable diagnostic procedures and important research. (Paragraph 42)

Use of the precautionary principle in the Directive

9. While there should be an obligation to reduce risks to a reasonable level, to actually pursue the "lowest achievable limit" would entail health and safety practices which most would consider unnecessary and economically unviable, if not counter-productive in certain circumstances. Risks need to be balanced against gains, rather than necessarily minimised. (Paragraph 46)

10. Regardless of the impact on current MRI procedures, any attempt to consider the health of workers in isolation from all other factors would be against the spirit of the precautionary principle, as set out by the Commission. We hope that the agreement of the Commission to undertake further work on the potential impact of the Directive indicates a willingness to accept the need for a wider risk-benefit analysis. (Paragraph 48)

11. We have found no explanation as to how the precautionary principle was, or was not, applied to the development and agreement of the Directive. The fact that such confusion remains confirms our view that the Commission's guidelines on its application are of limited practical use, even if there were a desire to refer to them. (Paragraph 49)

A precautionary approach

12. We recommend Government and its agencies desist from using the term "precautionary principle" in order to explain policy decisions or judgments. We also urge Ministers to propose a similar approach in discussions in the EU Council. (Paragraph 51)

Sources of advice

13. We are surprised that neither the Chief Scientific Adviser at the Department of Health nor the Chief Scientist at the Health and Safety Executive was involved at any stage in providing advice on the Directive, particularly in view of the high levels of expenditure on MRI equipment at DH. If they are not involved in the policy making process on a subject with such a heavy reliance on science, it is difficult to see how

they were operating effectively. We recommend that the DH and the HSE take steps to ensure that their respective chief scientists are actively and routinely involved in the provision of advice informing policy. (Paragraph 54)

Engagement with MR community

14. Given that the concerns raised about the Directive in 2003 coincided with its consideration in the European Council, and that they came from medical practitioners well placed to provide advice, we find the response by the HSE and NRPB/HPA to them highly disappointing. This reaction was characterised by an instinctive and dismissive resistance rather than an attempt to engage and examine. Both organisations acted in contravention of the guidelines laid down by the Government Chief Scientific Adviser. (Paragraph 60)

15. It is extremely worrying that the HSE managed to outline a policy to the MR community in the UK which was the precise opposite of the one it had been pursuing in Brussels during negotiations. That the HSE could be contradicting itself for such a long period suggests some quite astonishing failings in management and internal communications. We recommend that the HSE seeks to discover how this situation could persist for so long, and takes appropriate steps to ensure that there can be no repeat. (Paragraph 61)

16. We welcome the frank admission of the failings in consultations on the Directive by the Minister and, more pertinently, by the Health and Safety Executive. (Paragraph 62)

17. The Government was badly let down by the HSE and NRPB, not only by their failure to consult sufficiently widely but also by their failure to advise Ministers on the concerns being raised. When informed of these concerns, Ministers acted with commendable speed to investigate further. We welcome the commitment by the Government to rectifying these earlier failings by working closely with the MR community. (Paragraph 64)

Engagement of MR community

18. We conclude that the MR community in the UK was very slow to consider the impact of time-varying fields and failed to raise it early enough to influence the negotiations on the Directive. (Paragraph 66)

19. We conclude that the professional bodies, the Wellcome Trust, and the MRC were insufficiently pro-active in identifying the implications of the Directive and informing their communities, and politically ineffective in communicating these concerns in Westminster and Brussels. We recommend that the professional bodies and research funders re-examine the development of their links with each other and explore ways in which they can work together to improve their political effectiveness. (Paragraph 68)

Horizon scanning

20. We recommend that the Department of Health and the Medical Research Council review their representation on the Interdepartmental Liaison Group on non-ionising radiation to ensure that the Group is provided with the necessary breadth of expertise and that they give due consideration to the issues raised by the Group. (Paragraph 70)

21. We recommend that the Office of Science and Innovation reviews its horizon scanning activities in respect of EU legislation, in consultation with the Research Councils. We believe that there is a strong case for the UK Research Office to perform a horizon scanning function on behalf of the Research Councils. (Paragraph 72)

Role of UKREP in using scientific advice

22. We recommend that UKREP reviews its channels of communication with the scientific community in the UK and considers developing some capability for direct links, on a systematic basis, or at least on an *ad hoc* basis in response to the introduction of proposals. (Paragraph 75)

Further work on implementation of the Directive

The UK

23. We welcome the commitment of funds from the HSE and the MRC to a programme of research on the potential impact of the Directive on MRI procedures. In the meantime, we recommend that the Government does not prioritise the Directive for implementation through secondary legislation. (Paragraph 76)

The Commission

24. We welcome the establishment of the joint working group by the Commission to examine new evidence and hope that it is a genuine attempt to inform the implementation of the Directive rather than simply a device to mollify the critics. We urge the UK Government to ensure that this work is well informed by the further research in the UK, and is completed in time for decisions on the implementation or amendment of the Directive to be taken before April 2008. If new research demonstrates a clear need for the Directive to be amended, for example to exclude MRI from its scope, the UK Government should seek this solution, rather than relying on non-enforcement. At the very least, the Government should press for a full impact assessment when the Directive is reviewed in 2009. (Paragraph 78)

Formal Minutes

Tuesday 20 June 2006

Members present:

Mr Phil Willis, in the Chair

Dr Brian Iddon Dr Desmond Turner

Draft Report (Watching the Directives: Scientific Advice on the EU Physical (Electromagnetic Fields) Directive, proposed by the Chairman, brought up and read.

Ordered, That the Chairman's draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 80 read and agreed to.

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Wednesday 21 June at nine o'clock.

Witnesses

Written Evidence

Reports from the Science and Technology Committee

Session 2005-06

First Report	Meeting UK Energy and Climate Needs: The Role of Carbon Capture and Storage	HC 578-I
Second Report	Strategic Science Provision in English Universities: A Follow–up	HC 1011
Third Report	Research Council Support for Knowledge Transfer	HC 995-I
First Special Report	Forensic Science on Trial: Government Response to the Committee's Seventh Report of Session 2004-05	HC 427
Second Special Report	Strategic Science Provision in English Universities: Government Response to the Committee's Eighth Report of Session 2004-05	HC 428
Third Special Report	Meeting UK Energy and Climate Needs: The Role of Carbon Capture and Storage: Government Response to the Committee's First Report of Session 2005-06	HC 1036

Oral evidence

Taken before the Science and Technology Committee

on Thursday 11 May 2006

Members present:

Mr Phil Willis, in the Chair

Dr Evan Harris
Bob Spink
Dr Desmond Turner

Witnesses: **Mr Bernhard Jansen,** Director for Social Dialogue, Social Rights, Working Conditions, Adaptation to Change, and **Mr José Ramon Biosca de Sagastuy,** Head of Health, Safety & Hygiene at Work Unit, Employment, Social Affairs and Equal Opportunities Directorate, European Commission, gave evidence.

Q671 Chairman: First of all, can I thank you very, very much indeed, Mr Jansen and Mr Biosca, for agreeing to see us this morning for us to take formal evidence from you for our inquiry. If I can just set the scene. Our inquiry is a broader inquiry looking at the way in which the Government uses scientific advice to inform policy and assess risk. Within that broad inquiry we are looking at a number of case studies, one of which is this particular Directive, the 2004 Directive, which is looking basically at the use of limits on electromagnetic fields with particular reference to MRI scanners, which is where our concern is. Given the limited time, as a Committee we are anxious to ask you as many questions as we can. Can I please assure you that we are interested only in looking at the process and we are not accusing you of any skulduggery or anything else as far as Europe is concerned, though one of my colleagues is particularly supportive of the European project and you will find out who he is along the way. Could I start off by asking you, Mr Jansen, what or who were the driving forces behind this Directive? What was wrong that needed fixing?

Mr Jansen: Thank you for coming here and addressing us on these matters. Let me say by way of introduction that I have been in charge of these matters since 2001. The Commission's proposal, however, goes back to 1993. It is important to know that there has been a debate on this Directive for longer than ten years, which is quite some time. I participated in the last run-up to the decision-making but not when the original proposal was made, so it is always a little bit difficult to reconstruct what has happened. My colleague, Mr Biosca, has been dealing with these matters for longer than I. I think he started in 1997, if I am right, although he may have to correct me. He knows more than I do but, again, he was not here in 1992 when this all started. Perhaps it is interesting for you to realise how long a period of debate on European legislation may last. In fact, in the original proposal the Commission had combined what we call the physical agents, meaning noise, vibration, electromagnetic fields and optical radiation. All four aspects today have been covered by European Directives. The last one on optical radiation was approved and published in the *Official Journal* about a fortnight ago. This is an extended process, all the elements have been considered and what we can say is when the proposal was made in 1992 it was felt that the coverage of physical agents, perhaps with the exception of noise which had already been covered at that time, was variable in different Member States. One of the concerns which is important for us is the protection of workers, of course, but also trying to get a level playing field for the industry so that competition will not take place on the basis of who is the most unconscientious about the risks which workers are exposed to. In a member country where there is no legislation—there are a few on electromagnetic fields—there may be ways in which the industry can work which would not be possible in those Member States where there is such legislation.

Q672 Chairman: I can understand in 1993 when everything was basically lumped together within the same area there was a need to differentiate between different levels of risk with different areas, but once you started looking at electromagnetic fields, what were the perceived benefits of this Directive, because we cannot find any? What is it trying to do?
Mr Jansen: We are really surprised that you say that.

Q673 Chairman: Why?
Mr Jansen: Because there is scientific evidence which is based on international findings by an organisation which is called the International Commission on Non-Ionising Radiation Protection—ICNIRP—which is a Geneva-based institution working with the World Health Organisation which has published large books, parts of which we have brought here, in which these risks are described in detail. They have carried out experiments on dead bodies to show that electromagnetic fields influence—

Q674 Chairman: They are at huge levels of exposure in the ICNIRP guidelines and the research which they presented and the World Health Organisation

presented. Our Health and Safety Executive in the UK could find absolutely no benefits from this Directive at all.
Mr Jansen: We have a report from the UK authorities here.
Mr Biosca de Sagastuy: Your comment is very surprising when the UK authorities supported the Directive in Council. How about the report of the National Radiological Protection Board of the UK on proposals for limiting exposure to electromagnetic fields? You said—

Q675 Chairman: But they are the guidelines, Mr Biosca, they were not hard and fast rules.
Mr Biosca de Sagastuy: That was a proposal for setting limits to exposure and it covered the public and workers as well. You stated that you do not see any benefits but maybe you should go and visit a steel mill where they have induction furnaces—

Q676 Chairman: I am talking specifically about MRI scanners.
Mr Biosca de Sagastuy: I am talking about electromagnetic fields. The Directive does not focus on magnetic resonance imaging only.

Q677 Dr Tuner: We are concerned about the impact on MRI.
Mr Biosca de Sagastuy: We are not talking about magnetic resonance imaging.

Q678 Chairman: I would not disagree with you in terms of steel mills because the level of exposure can be absolutely massive, but in terms of MRI scanners, which is what we are particularly interested in, there does not seem to be any evidence from the medical community or any evidence from research which has come to the Commission which says that working with MRI scanners in a hospital setting doing invasive procedures is harmful, and yet all this will be removed.
Mr Biosca de Sagastuy: That is not the opinion of the scientific experts worldwide. There are limitations even by the Food and Drugs Administration in the USA on the use of magnetic resonance scanners on patients and on medical personnel. People are concerned about exposures coming from magnetic resonance scanners. The medical community might have a different opinion but they are not the experts in this field. They could be experts in medical issues but not on magnetic exposure. To draw a parallel: a long time ago the medical community did not want any restriction on the use of X-rays until it became very apparent that they were having cancers. They reacted at that time against limiting exposure to X-rays and now the same thing is happening. Nevertheless, the Commission had a meeting with the European Radiological Association in order to hear their concerns about it and they claimed that in positioning the patient and accompanying a sedated, very young patient in the machine they would get exposures that go over the limit values. We checked that with ICNIRP and the answer we got was, "No. In no circumstances do medical personnel with currently installed magnetic resonance equipment in hospitals, which goes up to three teslas, get exposures over the limit values".

Q679 Chairman: They will not get them?
Mr Biosca de Sagastuy: That is what they are saying. However, they acknowledge that there are machines which are used for testing, experimental machines, up to seven teslas. One is going to be installed in Norfolk, I think. They recognise that these machines could give exposures which go much beyond the limit values and they say that does not mean they are safe to use. In fact, we have checked with American OSHA (Occupational Safety and Health Administration) because in America there are two magnetic resonance machines up to eight teslas. They said the restrictions on using these machines are so great they could never be commercially available. They gave us an example. They are doing experiments with volunteers and in order to walk the room with the patient—it is a room like this—they had to spend 20 minutes because if you move fast within the magnetic field you get induced currents in the body and you have disturbances in the brain because there is a migration of calcium ions in the neurons and you become really, really sick and you can fall. You have to walk very, very slowly to the cell. The problem with that is that life saving equipment has to be readily available beside the machine because if a volunteer, in this case, has a coronary problem he might have fibrillation of the heart.

Q680 Chairman: Is there any evidence to demonstrate that in terms of personnel working with MRI scanners at up to three teslas or, indeed, over three teslas with known equipment, there have been any permanent health risks to any worker in any European country in any piece of research?
Mr Biosca de Sagastuy: No. Up to now there are no permanent health risks, but do not forget that the Directive covers health and safety. If you enter any metallic material in any magnetic field it gets attracted, does it not?

Q681 Chairman: Yes.
Mr Biosca de Sagastuy: So you could have flying objects. You could have induced currents in the body, induced charges in the body, and when you touch a grounded object you get a very painful shock. If you are handling something else, like a patient, the immediate reaction is to let that go so the patient could fall. There could be accidents due to that.

Q682 Chairman: This Directive is basically saying that health workers will not be able to work for more than a certain period of time using this equipment.
Mr Biosca de Sagastuy: No. First of all, the Directive does not refer to health workers but to workers in general, in all sectors of activity who are exposed to—

Q683 Chairman: Specifically we are looking at workers with MRI scanners.

Mr Biosca de Sagastuy: Basically, what the directive says is, "Employers, if you have workers working in an electromagnetic field, whose strength is above the action levels specified in the directive, which are directly measurable parameters in terms of electrick field strength, magnetic field strength, magnetic flux density and power density, you have to undertake a risk assessment to see whether the limit values are exceeded. In that case, you will have to take measures, either technical or organisational measures, like limiting the time the person will be there, in order to eliminate or reduce exposure to a minimum". In the case of magnetic resonance equipment, of course you have not got any permanent health effects so far with the current machines because the electromagnetic field strengths are not exceeding the action values. If there is no exposure above the specified action values, there is no adverse health effect. There are two types of effect. There are the biological effects when exposure to EMF causes some detectable psychological damage in a biological system, but that does not necessarily mean an adverse effect. An adverse effect occurs when the body cannot respond to that biological change, which is outside the normal range for the body compensation, and this leads to some detrimental health condition. That is exactly what happens with magnetic resonance equipment: there are biological effects but no adverse health effects because exposures are lower than the limit values specified in the directive. Nevertheless, in a recent meeting between Commissioner Mr Spidla and the European Radiological Society it was agreed to constitute a working group of the European Radiological Society, the Commission's services and an independent body like the National Radiological Protection Board, a scientific body, because we want to clarify the situation once and for all. We want to go and measure in hospitals, follow the procedures that the medical personnel are following and measure the real exposures. Then we will see who is right because scientific experts on one side tell us there is no problem but medical doctors say there is a problem. In my view, manufacturers have not said anything at all, they are very happy with the Directive so far.

Q684 Bob Spink: Very happy?
Mr Biosca de Sagastuy: So far, nobody from Siemens nor Philips have expressed any concern. We do not have any complaints to the Commission so far from manufacturers of magnetic resonance equipment.

Q685 Chairman: Just before I pass you on to my colleagues. You are saying you have now set up a piece of research which is looking at—
Mr Biosca de Sagastuy: We are going to.

Q686 Chairman: You are going to. When is that coming in?
Mr Biosca de Sagastuy: We are going to have our first meeting with the European Radiological Society in order to constitute that working group in June.

Q687 Chairman: So the MR community will be involved in that piece of research?
Mr Biosca de Sagastuy: Of course.

Q688 Chairman: If, in fact, it demonstrates our thesis that there are no significant risks, is there a likelihood that before the 2008 implementation of the Directive there could either be changes or a derogation for MRI equipment? Would you support that?
Mr Biosca de Sagastuy: The Directive contains provisions to allow for technical amendments in line with technical progress and new scientific findings concerning EMF. Even contains a specific invitation of the legislator to the Commission to review the health effects especially as regards static magnetic fields.

Q689 Chairman: You have removed static fields from this.
Mr Biosca de Sagastuy: For the moment. If something proves that there is no health or safety risk—both—then we will proceed to remove it, but if there are health or safety risks then the Directive will stay.
Chairman: Thank you very much indeed.

Q690 Dr Turner: Can I get some absolute clarity here. You are saying that there will not be any impact on the use of MRI equipment, at least such as is currently in routine use in hospitals and laboratories, as a result of the Directive. Are you saying that the imaging departments in hospitals can go on as before, as at present, without any interference?
Mr Biosca de Sagastuy: I would say so. If you follow the procedures in magnetic resonance departments of hospitals you will see that they have already in place very stringent procedures to go in and position the patients and everything.[1] The time that medical personnel are allowed to be there is very, very limited, not only because of magnetic resonance but also because of noise. Levels of noise are around 120 dBs and occupational exposure limit for noise is 87 dBs.

Q691 Dr Turner: The concern is not so much with the straightforward scanning of a patient but the use of MRI equipment in invasive procedures, neurosurgical procedures which are carried out using MRI equipment, so naturally people will have to be exposed to radiation for much longer than simply taking the scan of a patient. Do you envisage that those procedures would be affected?
Mr Biosca de Sagastuy: No. I will tell you why. In the operating theatre the machines that are used for brain surgery or heart surgery are very low powered machines, a maximum of 0.4 teslas. You can easily verify this with the manufacturers and hospitals. Secondly, there are machines that when they are permanently installed in operating theatres they are

[1] *Note by the witness:* We do not expect that the implementation of the directive will impose more stringent procedures or medical protocols than the ones already in place.

hidden below the table and when the doctor needs to see an image after doing a certain operation it comes out from under the table and it is switched on. There is very limited exposure. Do not ever think that the doctors in operating theatres use the machines continuously throughout the whole operation because that is not true. They use it for a very limited amount of time.

Q692 Dr Turner: Do you envisage any impact on medical applications involving the use of newer machines of higher power?
Mr Biosca de Sagastuy: With the newer machines of higher power we will have to investigate more. The ICNIRP, the Institute of Electrical Engineers and FDA in the US and other specialised organisations, are looking into the health effects of exposure to such high fields because of the potential risks for patients as well.

Q693 Dr Turner: You would say that the concerns which have been expressed to us about the impact of the Directive on the medical community have been greatly exaggerated?
Mr Biosca de Sagastuy: In our view, yes. The only way to clear this up is to set up this working group and perform measures in hospitals by a recognised body.

Q694 Chairman: Is there a deadline for when it will finish its work?
Mr Biosca de Sagastuy: We do not know because we will have to place a contract with the National Radiological Protection Board in the UK in order for them to perform the measures.[2]

Q695 Chairman: Before 2008?
Mr Biosca de Sagastuy: We have to have the first meeting to constitute the group and then we are going to set up a timescale.

Q696 Dr Turner: We are curious that before the Directive was enacted in 2004 there was not a fresh impact assessment undertaken because the old one was ten years old and likely to be quite out of date. Why did the Commission refuse to undertake a fresh assessment?
Mr Biosca de Sagastuy: The Commission was asked by the UK Representation in Council to update the risk assessment and we said that the existing risk assessment could be extrapolated later to the costs and that could be done easily. In any case, the debate on the proposal had already started in Council and the rest of delegations considered that a new impact assessment, at this point in time, would be of little added value since Member States had done their own impact assessments and knew very well the socio-economic impact at national level. For instance, the Health and Safety Executive had done that.

[2] *Note by the witness:* The group of experts have to be constituted, its mandate has to be jointly defined with the European Radiology Association, a contract will need to be placed with a specialised body for performing the measures and then a time schedule would be defined.

Chairman: They have and they have found no problems.

Q697 Dr Turner: They found no risk.
Mr Biosca de Sagastuy: No, because that was not the position of the UK during the negotiations. They found risks. If they did not find risks why did they produce a 200 page long document?
Dr Turner: I can quote from what they said which was that they were "unable to identify any health and safety benefit from the Directive".

Q698 Chairman: That is a direct quote from them.
Mr Biosca de Sagastuy: That is an opinion of the Health and Safety Executive. Anyhow, they did not take this line in Council as far as I know, and I was President. Sorry, what was the original question?

Q699 Dr Turner: The original question was why did you not undertake a new risk assessment?
Mr Biosca de Sagastuy: Because to undertake an impact assessment takes one year and at that time the discussions had already started in Council and there was no time. We had an impact assessment after. It would not enlighten discussions in Council.

Q700 Dr Turner: It was not a question of convenience, was it, because I believe in 2004 Senor Prodi insisted that all Directives should be accompanied by fresh impact assessments?
Mr Jansen: On what would the impact assessment have been based? The Commission had made its proposal and that proposal was on the table. The Council was discussing adaptations to the proposal all the time, which is normal procedure. It is a moving target. An impact assessment needs to be done on the proposal of the Commission, which had not changed, and the only thing that could be done was to extrapolate the costs. It is not possible for the Commission, it has nothing to do with Mr Prodi or any other such—

Q701 Chairman: Important person.
Mr Jansen: In the area of health and safety the Commission had a longstanding practice of having impact assessments done before it became the general practice of the Commission. That is not an issue here. We cannot see how we could have had an impact assessment during the debate in the Council when things were changing with time passing. Also, the Parliament has a role to play because this is co-decision. We are not in a position to have an impact assessment each time another suggestion is made concerning the original proposal of the Commission and we do not know whether it will be approved in the end. It is not possible to do that.

Q702 Chairman: To be fair, Mr Jansen, the 1993 impact assessment that was done by the Commission, the Commission agreed was unsatisfactory.

Mr Jansen: What do you mean?
Mr Biosca de Sagastuy: Who said that?

Q703 Chairman: We literally heard that this morning.
Mr Jansen: I am sorry, I have never heard anything of that sort.

Q704 Chairman: From the UK Representation, that it was unsatisfactory and there was a need because science has moved on immeasurably in a period of ten years.
Mr Jansen: Only to show that there are even bigger risks than was originally thought.

Q705 Chairman: There are now greater risks?
Mr Jansen: Yes.
Mr Biosca de Sagastuy: Greater risks and less costs because of technological advances. To give you an example: when the proposal from the Commission was issued in 1993 we got a big reaction from the BBC and broadcasters because they said that maintenance operations could be impaired by the Directive. There is no reaction whatsoever now. Why? Because they have changed their procedures and the technology has changed, so people do not need to be exposed during maintenance operations.

Q706 Bob Spink: I just want to pursue this risk assessment issue while we are on it. Is it accepted that the UK asked for a new risk assessment in 2003 because they thought the 1993 risk assessment was not adequate? Do you accept that the UK asked for that new risk assessment and was refused?
Mr Biosca de Sagastuy: It was asked for and was discussed in Council and the Council, the majority of delegations, rejected that.

Q707 Bob Spink: Thank you. You have also accepted that it is a moving target, that since 1993, and we are thinking specifically not about the BBC or anything but just MRI technology, imaging technology for medical purposes, the technology and the understanding in that particular branch of science has moved on tremendously fast and there have been massive changes in that area. Do you accept that?
Mr Jansen: Please, could I—

Q708 Bob Spink: I am sorry, could you answer my question.
Mr Jansen: There is a misunderstanding. You asked about risk assessment but we are talking about impact assessment, which is not the same thing. We need to be clear on this.

Q709 Bob Spink: We are talking about impact assessment or cost benefit analysis. Do you accept that the understanding and the technology of the industry in imaging for medical reasons has changed since 1993, it has changed dramatically?
Mr Biosca de Sagastuy: Yes.

Q710 Bob Spink: Yet still you went ahead without a new impact assessment in 2003 even though you accept that things have changed dramatically.
Mr Jansen: The Council and the European Parliament went ahead, I hope that is clear.

Q711 Bob Spink: The scientific evidence in 1993, I guess, was based on ICNIRP and nothing else, there was no internal research, no external research commissioned, it was just the ICNIRP guidelines.
Mr Biosca de Sagastuy: No, that is not true.

Q712 Bob Spink: What was it based on?
Mr Biosca de Sagastuy: The Commission launched a study, as early as 1991, about the health effects of occupational exposure to electromagnetic non-ionizing radiations. It was commissioned from the experts from the National Radiological Protection Board in the UK, the Federal Office of Radiological Protection in Germany and the Instituto Superiore di Sanita in Italy. The experts were asked to perform a critical analysis of scientific literature on the health effects of emf's and to propose basic exposure restrictions based on the scientific evidence found. The results were published in *Physica Medica- Vol. VII, N2, April-June 1991*. That was done in collaboration with ICNIRP. When negotiations started in Council an update was performed on the studies undertaken by the German Institute, the Finnish Institute, the Health Council of the Netherlands—a study commended by the Government of the Netherlands—whose concern was the relationship between electromagnetic fields and health, including potential carcinogenic effects and covered occupational exposure as well as public exposure.

Q713 Dr Harris: These are all peer reviewed and published?
Mr Biosca de Sagastuy: These are published.

Q714 Dr Harris: Peer reviewed and published in medical journals?
Mr Biosca de Sagastuy: Yes.

Q715 Dr Harris: That is quite a bundle of paper that you have.
Mr Biosca de Sagastuy: What I have here is critical analyses of all published scientific literature in the world in the field and in the "references" part of these analyses, including in the guidelines of ICNIRP, all the scientific studies considered are listed. We followed, in addition, the studies done by the American conference of governmental industrial hygienists (ACGIH) and the Institute of Electrical Engineers (IEEE).[3] During the discussions in Council every delegation was accompanied by its own experts. There were experts from all Member

[3] *Note by the witness:* We also followed more recent published assessments of expert panels of different countries: UK, NL, S, CDN, AUS, NZ etc. Although there are differences in some details, the conclusions of all these assessments generally agree: There is no evidence of current scientific knowledge, in view of established health effects, to challenge the scientific assessment underlying the protection concepts of ICNIRP and those of the directive.

States, high level experts. After the first discussion in Council a workshop was organised by the Commission in Luxembourg where all social attachés of the Permanent Representations were invited and Members of the European Parliament in order for ICNIRP and other relevant societies to give an update on the evolution on the scientific knowledge of the health effects of electromagnetic radiation between 1993 and then and what was the impact on the values put forward by the Commission at the time. We received technical/scientific information and magnetic resonance was discussed extensively in the Council. It was an issue that was raised by several delegations and the conclusion of the experts, as I told you before, was that there was no problem for health personnel but where it could be a problem was with maintenance personnel. That is the reason why they should be protected, because they are exposed to very high levels with very adverse effects.

Q716 Bob Spink: So this research or literature-based trawl took place between 1993 and 2003 and that formed the basis of the limits that were set in 2003 for the Directive. That is true, is it not?
Mr Biosca de Sagastuy: Yes.

Q717 Bob Spink: At any stage was there any balancing of the impact of this Directive on overall benefits to society, ie whether it would prevent or inhibit the use of MRI scanners in any circumstances?
Mr Biosca de Sagastuy: No, because at the time the experts said that it would not impact on the use of MRI scanners.

Q718 Chairman: Including the British delegation, there were no concerns raised from the MR community?
Mr Biosca de Sagastuy: No. Before the discussion in Council an industrial organisation organised a meeting with the manufacturers and medical personnel. It was attended by all social attachés at the time, if I remember correctly, and the Commission. Later on, during parliamentary discussions, there was an invitation from medical associations to visit MRI equipment in Louvain University Hospital, so parliamentarians knew about it.

Q719 Chairman: And nothing was raised?
Mr Biosca de Sagastuy: Nothing was raised. It was raised but—

Q720 Chairman: But nobody had a major concern at that time?
Mr Biosca de Sagastuy: No.

Q721 Bob Spink: I would like to come back to press you on the fact that it seems to us the actual limits in the Directive are based very much on the ICNIRP original guidelines.
Mr Biosca de Sagastuy: That is correct.

Q722 Bob Spink: They seem to follow those.
Mr Biosca de Sagastuy: That is correct.

Q723 Bob Spink: So all this research that you did simply confirmed that the ICNIRP guidelines were the ones that you should use?
Mr Biosca de Sagastuy: Yes.

Q724 Bob Spink: The ICNIRP guidelines were based on a massive safety factor built in.
Mr Biosca de Sagastuy: I would not say a massive safety factor.

Q725 Bob Spink: What then?
Mr Biosca de Sagastuy: It was based on a safety factor which varies depending on the range of frequency. It varies from two to ten.[4]

Q726 Bob Spink: At any time during this period before the Directive was passed in 2004, was there any research done on the adverse health effects suffered by workers from MRI usage?
Mr Biosca de Sagastuy: No.

Q727 Bob Spink: Do you know how many people in the medical industry, how many workers, have been adversely impacted in terms of health by using or working with MRI scanners?
Mr Biosca de Sagastuy: In terms of health, no, but in terms of safety there have been quite a few accidents.

Q728 Bob Spink: Are these incidents the result of accidents or of routine operation or maintenance of the scanners?
Mr Biosca de Sagastuy: Sorry?

Q729 Bob Spink: Where you say there have been a number of incidents that have been reported—we will come on to what they are in a moment—are they the result of accidents, you called them accidents, or was that a slip of the tongue and were they the result of routine operation or routine maintenance of the equipment?
Mr Biosca de Sagastuy: No, it was because of medical personnel operating.

Q730 Bob Spink: It was just routine operation?
Mr Biosca de Sagastuy: Yes.

Q731 Bob Spink: Can you tell us what the incidents were or where we can see a record of those incidents so we can see the evidence to support this?
Mr Biosca de Sagastuy: You can look at the web page of the Food and Drugs Administration of the US and you will find several examples there. You will see chairs and medical equipment which flew off into the machine and in some cases killed the patient. In some cases there were scissors that had injured

[4] *Note by the witness:* The rationale for their choice is explained in the ICNIRP guidelines. The safety factors are a matter of scientific judgement and compensate for uncertainties about exposure-effect thresholds, including extrapolation of animal data to effects on humans, differences in the psychological reserves of different peoples and in the dose-response function.

medical personnel. You can look at the Food and Drugs Administration web page, which is www.fda.org, and you will see those pictures.

Q732 Chairman: Are these not just accidents?
Mr Biosca de Sagastuy: These are accidents but this is a health and safety Directive.

Q733 Chairman: But you would never have a car on the road, would you?
Mr Biosca de Sagastuy: As I told you before, how can we see health effects in medical personnel if exposure levels of the medical personnel are lower than the limit values which are set there in order to ensure that there is no health effect so you cannot see them? That is why we maintain our position that the Directive will not have an impact on magnetic resonance imaging equipment that is already there, but in the future we do not know.

Q734 Chairman: We take that point.
Mr Biosca de Sagastuy: This is a question that—

Q735 Chairman: You are quite definite about that. We are very grateful to you for putting that on the record. You have stated quite clearly that as far as the Directive is concerned there should be no impact in terms of the use of this equipment as it is currently being used within our hospitals for routine MRI scans or, indeed, for interventional procedures.
Mr Biosca de Sagastuy: If medical personnel follow the protocols they already have in place there should be no impact.

Q736 Bob Spink: Could I press you on that. Would there be an impact on the maintenance of that equipment which would equally prevent it being used?
Mr Biosca de Sagastuy: It could have an impact on the maintenance procedures, yes.

Q737 Bob Spink: What would that impact be? Potentially would that restrict the use of that equipment?
Mr Biosca de Sagastuy: You cannot test the equipment without the presence of the technician. The technician should be in the control room after doing the adjustments. He does the adjustment, he goes back to the control room and checks the results, then switches off and goes in.

Q738 Bob Spink: So this is going to establish better working procedures?
Mr Biosca de Sagastuy: Safer working procedures.

Q739 Bob Spink: It is not going to in any way restrict or threaten the continued use of the equipment in hospitals?
Mr Biosca de Sagastuy: In our view, no, and that is the view of the scientific experts also.

Q740 Bob Spink: When you turn on a huge magnetic field ferrous objects are attracted to it, did the Commission not feel that there was an easier way of improving health and safety than this Directive to prevent scissors and chairs flying around? Did they not think that there was an easier way to achieve that aim without this Directive?
Mr Biosca de Sagastuy: Again, you are thinking that this Directive was for the use of magnetic resonance equipment, and it is not. It is a Directive for protection of the health and safety of workers against the risk of exposure from electromagnetic fields.

Q741 Bob Spink: I am aware that MRI equipment could have been excluded and any dangers that were there from high magnetic fields could have been covered in other and more relevant regulations by member nations, for instance. The Health and Safety Executive have rules to protect workers from this in our country anyway.
Mr Biosca de Sagastuy: You might have rules to protect your workers in your country but we have to ensure that equivalent rules are set up across the Community.
Chairman: We understand. We are not going into that area.

Q742 Dr Harris: On this issue of your belief that it is not going to have an effect, as we have heard you say, on the use of MRI equipment according to protocol currently in existence, COCIR, which is the industry body, say in a statement of 6 April 2006: "The EMF Directive contains limit values that will negatively impact the use of MR equipment and may prevent its use." Not only that, but they claim they put in a paper to the Commission expressing similar concerns in April 2003 yet you say you did not hear any complaints from industry, so we will have to get to the bottom of that.
Mr Biosca de Sagastuy: I did not say that. I said we had a meeting with the industry and social attachés had a meeting with the industry and MEPs had a meeting with the industry and medical personnel.

Q743 Chairman: You said there was no problem.
Mr Biosca de Sagastuy: This was issue was discussed extensively at Council and all of the experts said the same thing, that the impact from magnetic resonance equipment of non-ionising radiation on health personnel would be negligible because the levels of exposure are below the limit values set out by the Directive.

Q744 Dr Harris: That was the expert advice, opinion, of the people of the Council with their experts, I understand that. But I am asking you whether you were aware of the view of industry, COCIR, which is Siemens and Philips and so forth, where they say that it will—not may—negatively impact the use of MR equipment and may prevent its use.
Mr Biosca de Sagastuy: That is an opinion, like my opinion or his opinion.

Q745 Dr Harris: I understand that. I just want to clarify what you said earlier. Whether you were aware of what I said just now? I am a little confused, and I will have to look at the record, but I want to

give you the chance to make it clear. I got the impression that you said you had not heard until now at least, certainly not during the passage of the Directive, of any concerns by industry in relation to the impact on correct use of MR equipment. I am a little confused about whether what you are saying reflects what was in meetings or in documents?
Mr Biosca de Sagastuy: Okay. Of course we received letters in the Commission when the discussions were raised in Council, so did all delegations in the Council and Members of the European Parlianment. We received letters from manufacturers, industry associations, medical personnel, and that was the reason why this subject was discussed in Council and in the European Parliament. I feel that you are putting questions to the Commission that do not belong to the Commission, they belong to the legislator and the legislator is the Council and Parliament.

Q746 Dr Harris: Understood. I can assure you that certainly I will be putting the same questions to them. You said that the Commission had not heard complaints?
Mr Biosca de Sagastuy: That is not true. I never said that.
Dr Harris: Okay, I am sorry.

Q747 Chairman: We misunderstood you and it is important that we have corrected that because that was not what we understood.
Mr Biosca de Sagastuy: We received letters from manufacturers and we had a meeting at the beginning of the discussions in Council with the social attachés. We met with COCIR, Siemens, Philips, medical personnel in our offices in Luxembourg several times.

Q748 Chairman: And they had concerns?
Mr Biosca de Sagastuy: That is normal process for negotiating a Directive.

Q749 Dr Harris: I know. They did express concerns at those meetings?
Mr Biosca de Sagastuy: Yes. Those concerns were raised and discussed in Council.

Q750 Dr Harris: I want to move the discussion now to theoretical stuff. From the Commission's point of view, to what extent do you think the precautionary principle was used in the origination and passage of this Directive?
Mr Biosca de Sagastuy: I think it was not used at all.

Q751 Dr Harris: So what you are saying is that people raising concerns—
Mr Biosca de Sagastuy: There is no mention in the Directive about the precautionary principle, nor in the Framework Directive.

Q752 Dr Harris: Is that because people do not think that the precautionary principle is a good principle to use when there is uncertain science but a potential risk?
Mr Biosca de Sagastuy: Again, the Directive is based on sound scientific principles. If you dispute the opinion of the world authority in this field, which is ICNIRP, it is your right to do so, but I cannot follow that.

Q753 Dr Harris: So what you are saying, because I do understand you I think, is even though this is controversial amongst some people it cannot be "blamed on"—or people should not complain about the use of—the precautionary principle because actually the figures are based on good science. I think I understand what you are saying. In the press release of 18 November 2005, Commissioner Špidla stated: "The Directive is designed to protect workers against excessive exposure to MRI and EMF which scientific experts agree is dangerous for health". I would be interested to know on what basis there is agreement of scientific experts that excessive exposure to MRI is dangerous for health.
Mr Biosca de Sagastuy: You will have to put this question to Commissioner Špidla.

Q754 Chairman: Do you agree with him?
Mr Biosca de Sagastuy: No, not on that particular sentence.

Q755 Dr Harris: He also said in this press release: "The risk of MRI is a real one for everybody who is exposed to it regularly, not to parents or their children undergoing treatment." Would you agree with that statement?
Mr Biosca de Sagastuy: Yes.

Q756 Dr Harris: "The risk of MRI is a real one and everybody who is exposed to it regularly . . . ."
Mr Biosca de Sagastuy: I think what Commissioner Špidla meant in that sense was: is MRI equipment safe and is there no risk in using MRI and the answer is no.

Q757 Dr Harris: You are saying that there is risk from using MRI because of the danger of excessive exposure to variable level fields, is that right, acute exposure?
Mr Biosca de Sagastuy: Could you say that again, please?

Q758 Dr Harris: I just want you to expand on your interpretation of Commissioner Špidla's view that the risk of MRI is a real one for everybody who is exposed to it regularly.
Mr Biosca de Sagastuy: I said what I said. MRI equipment is not an intrinsically safe machine so its use has risks due to exposure to electromagnetic fields that these machines emit, therefore the Directive shall be applied to the personnel who are exposed to electromagnetic fields coming from MRI equipment. There is no reason why medical personnel should not be protected as any other worker in the European Community would be protected and have the same levels of protection as anybody else. I think this is the meaning of Commissioner Špidla's press release of 18 November 2005.

Q759 Bob Spink: Do you accept that this Directive could, or at least the medical industry in the UK believes it will, force medical staff to use x-rays more and, therefore, suffer a greater level of risk from radiation?
Mr Biosca de Sagastuy: No, that is not true.

Q760 Bob Spink: Have you heard that view expressed by the medical community?
Mr Biosca de Sagastuy: Yes.

Q761 Bob Spink: You think it is simply wrong?
Mr Biosca de Sagastuy: Yes. It is not only totally wrong but it is also misleading.

Q762 Dr Harris: I am going to talk hypothetically, and I understand you do not accept this at the moment. If it was demonstrated to your satisfaction that, as it happens, perhaps with new techniques, not the existing protocols and new machines, the levels set in this Directive did prevent beneficial use of medical technology in the MRI field in the future, do you think that is a basis to urgently look again at the benefit-risk ratio for those fields to ensure that you are able to use therapeutic medical technology and/or not be forced perversely to use potentially more dangerous technology like x-rays because of the current limits that are being set on exposure?
Mr Biosca de Sagastuy: Not necessarily. I will tell you why. With a patient you can balance risks against benefits but with a worker you cannot. There is an obligation under general health and safety legislation to eliminate the risk or reduce it to the lowest achievable limit. That is the obligation.

Q763 Dr Harris: Regardless of third party benefit?
Mr Biosca de Sagastuy: If for achieving this you have to limit the intensity of the source, or the distance to the same or the time of the exposure of the personnel—the Directive does not explicitly say so,[5] it is for the employer in applying those principles to set that out in the prevention plan to be implemented—by limiting the time the personnel is close to the machine then you have to do it, I am sorry. You cannot cure one person by endangering the health of another one.

Q764 Chairman: Can I just clarify this point because I think what you have just said is really quite important. You are saying that if I as the hospital administrator, the chief executive of the hospital or wherever the equipment is, can look at this Directive and assess on known evidence whether in fact it is safe for you, as the MRI technician, to work for eight hours with that machine then it is okay for them to work for eight hours. It is my decision to interpret the Directive that way, the Commission is not saying there is a time limit for how long you can spend in that room.

[5] *Note by the witness:* Exposure of medical personnel above the limit values set-out in the directive is harmful and shall be avoided.

Mr Biosca de Sagastuy: That is correct.

Q765 Chairman: Do you agree with that, Mr Jansen, because you were shaking your head?
Mr Jansen: Between the Directive and the decision of the hospital administrator that you are talking about there needs to be some national implementation measure because the Directive obliges Member States to take necessary implementation measures and they may limit the possibilities for the hospital administrator further than the Directive because the Directive says it is up to the Member States to achieve even higher levels of protection if they so wish, or implement them taking into account the situation in the Member State concerned.

Q766 Chairman: So the ball is back in the British Government's court then in terms of how they gold-plate this Directive or use it?
Mr Jansen: Yes.
Mr Biosca de Sagastuy: Yes and no. They can impose more restrictive conditions than the Directive but not lower. The specific answer to your question is health and safety legislation imposes an obligation on the employer to evaluate the risks. In this particular case they will have to measure or assess from manufacture's date the levels of exposure of the medical personnel. If the values of exposure are below the action values they do not need to apply the Directive, it is safe and there is nothing to do. If the values are above the action values they will have to take action and the first action is to assess whether the limit values will be exceeded or not and then they will have to train the personnel and mark the zone where there is risk, and so on and so forth, and take prevention measures to limit or avoid exposure. That is what the Directive says. It does not say that medical personnel can stay for only six hours, seven hours or eight hours, that is for the risk assessment and the prevention plan that the employer has to implement.
Chairman: That has been very useful.

Q767 Dr Harris: I am fascinated by this view that you cannot risk the health of health personnel for the benefit of a third party. I understand the point you are making there but would you accept that MRI devices result only in exposure to magnetic fields and there are no known long-term effects of exposure to magnetic fields? I am not arguing that there should be no limits to exposure but there have not yet been shown to be any long-term harms associated with exposure to magnetic fields from MRI scanners. I know you have said that is because the existing exposure levels are low, so we are perhaps in an impasse, and I understand the point you are making, however the point I would like to put to you is that if it could be demonstrated that patients were definitely not getting a benefit because of the inability to use, let us say, new technology, because I do not want to have the argument about whether it does impinge on existing technology, compared to no known worker harm—not risk but harm known—would you not say that saying

"Nevertheless, you cannot do it" is an example of the precautionary principles because you do not want to take the risk? It is not a question of harm versus benefit, it is risk versus benefit.
Mr Biosca de Sagastuy: We do not know how technology will evolve, that is why there are scientific bodies which analyse the health effects.[6] If these scientific bodies state that at the levels already set out in the Directive there are no health or safety effects due to exposure to these levels of electromagnetic fields, we will have to modify the Directive. We will have to report to the Council and Parliament and propose a modification of the Directive. Until there is any such proof the state of the scientific knowledge remains, and it is consistent all over the world: Canada is the same; Japan is the same; Australia is the same; the USA is the same.

Q768 Dr Harris: I just have one more question and it is very brief. Is it your understanding that during the negotiations in Council the British delegation was successful in reducing the burden on industry? Not just removing static fields, but were there other areas where there was success by Britain in relation to other people in reducing the impact on industry through removing different levels below the limit levels?
Mr Biosca de Sagastuy: I do not know.

Q769 Chairman: Was the big achievement dealing with the static, and having got that did they cave in on the rest?
Mr Biosca de Sagastuy: Static fields are currently under revision. At the time of the negotiations for the adoption of Directive there was an announcement that ICNIRP was going to revise its recommendations as regards static magnetic fields. I think that was the main reason why static magnetic fields were not included. I know that the UK was one of the delegations that raised concerns against the setting of an exposure limit value for static magnetic fields because of this revision that was planned by the scientific community in the years to come.

Q770 Dr Turner: Was the question of static fields the main concern that was raised by the magnetic resonance community when you consulted them during the course of the Directive, or were there other concerns?
Mr Biosca de Sagastuy: At that time, yes. Nowadays their concern is not the static fields, but low frequency time-varying gradient fields they have changed position. This was what they expressed at the meeting with the Commissioner. Now it is the range of frequencies between 100 Hz and a KHz.

Q771 Dr Turner: That is their major concern now?
Mr Biosca de Sagastuy: Yes, the exposures due to pulses in that range of frequencies.

Q772 Chairman: Between 100 and 500.
Mr Biosca de Sagastuy: Yes, between 100 and 1 KHz.

Q773 Dr Turner: But it is still true to say that even within that range current equipment is able to be used freely under the Directive. We are still talking about future equipment operating in that frequency range, is that correct?
Mr Biosca de Sagastuy: We are talking about current equipment, all equipment that works in the static magnetic fields, pulse magnetic fields in the range between 100 Hz and 1 KHz, and radiofrequency in the range between 10 MHz and 100 MHz.

Q774 Dr Turner: Yes, but they are raising concerns about those frequencies that are contained in the Directive.
Mr Biosca de Sagastuy: The effects are different. As regards adverse effects on the body, biological effects, if you like, static and low frequency electromagnetic fields induce charges and currents in the body. Your blood, as well as other biological fluids, is a conductor moving in a magnetic field, so you have the effects, due to forces on electric charges, magnetic induction and magneto-mechanical interactions, like electro-stimulation of nerves and muscles (fibrillation) and effects due to discharges when touching grounded conductors. In the medium range the main effect you have is electro-stimulation which can be very important, for instance at induced currents of 1,000 milli-amperes per square metre you would have fibrillation of the heart. At the highest frequencies in the range from 10 MHZ to 300 GHz the main effects are thermal and you risk burns.

Q775 Dr Turner: How did the MR community express their concerns? Are they worried that the Directive inhibits the use of their equipment in those frequency ranges at present? Is that their concern or are they concerned that it is a limitation on future developments?
Mr Biosca de Sagastuy: They mentioned two things. They say at present that the directive will not allow medical personnel to be close to the patient. The second concern is that the Directive will impair the development of newer MRI equipment. Experience demonstrates it is exactly the contrary, the principle contained in the EU health and safety legislation that the risks have to eliminated or reduced by priority at the source has promoted the development of better and safer machines at the same time.

Q776 Dr Turner: Has it been possible to meet those concerns?

[6] *Note by the witness:* The directive explicitly states, in its recital 4 and its Article 3, that it does not address long-term effects, including possible carcinogenic effects for which there is no scientific proof of a cause-effect relationship. As I said the directive only addresses those effects of exposure to emf's which are scientifically established. We do not know how technology will evolve, neither do we know whether the technology evolution will make diagnosis using MRI more or less risky, that is why there are scientific bodies which will analyse the health effects of new technologies and there are political authorities who will decide, based on those assessments, which levels of risk are acceptable for society.

Mr Biosca de Sagastuy: No. As I said, the concern about the limitation of the personnel and whether health personnel would be exposed to fields above the limit values or below the limit values is something that we are going to measure.

Q777 Chairman: Within the piece of research.
Mr Biosca de Sagastuy: By this group that is going to be constituted with the European Radiological Association and the Commission and another body which will perform the measurements and then we will decide who is right, whether it is the scientists or the medical community.

Q778 Dr Turner: But it is a future concern for the moment?
Mr Biosca de Sagastuy: No. This is a concern that they have expressed now.

Q779 Dr Turner: Is that inhibiting current practice?
Mr Biosca de Sagastuy: In our unit we have two medical doctors. One is a radiographer and the other one was a director of hospitals before joining the Commission. We have visited hospitals and seen the medical protocols involved in using MRIs. I can tell you that the normal practice is the medical personnel enters with the patient, positions the patient and walks out. The normal time a person spends inside the room is about five to ten minutes. The medical personnel could not stay longer because they could not stand the noise. I do not know if you have been in the room beside one of those machines but it is quite an experience.

Q780 Chairman: If you have a worker with a child, for instance, you would need to stay with the child throughout that procedure, you could not just leave a young child and then walk out of the room.
Mr Biosca de Sagastuy: It depends on the age of the child. It is the same procedure that is used when you do an x-ray with a child. If it is a very small child the child has a nurse, but it is a very limited time of exposure. Here it is the same. The machines for children are lower powered. You are not going to put a child in a three tesla machine, you can get a very good image with a one tesla machine.

Q781 Dr Harris: We are thinking of interventional procedures on adults using full power machines.
Mr Biosca de Sagastuy: I responded to that earlier. It is a very low powered operation.

Q782 Bob Spink: In January of this year, the UK Minister responsible, Lord Hunt, called a meeting and said that he was " . . . .exercised to ensure that at the end of the day we get the right balance between effectiveness of treatment for patients and staff safety". He called for further work and said: "We can then reach a balanced and proportionate decision in the issue". Clearly he is concerned, and yet you say there is absolutely no concern at all about the ongoing use of MRI equipment in our country, and it is MRI equipment we are focusing on now. The Commission has set up a working group to advise on implementation. Why did it do so if it shares your view that there is no concern at all?
Mr Biosca de Sagastuy: The Commission has done what?

Q783 Bob Spink: The Commission has established a working group to advise on implementation.
Mr Biosca de Sagastuy: No. The Commission agreed with the European Radiological Association to set up a joint working group, a commission, in order to measure exactly what exposures to medical personnel are to decide once and for all who is right, the scientific community or the medical personnel.

Q784 Bob Spink: When will this commission report?
Mr Biosca de Sagastuy: We will have the first meeting in June and there will be a time schedule established, so I cannot tell you.

Q785 Bob Spink: So this is going to take some time. If this working group to advise on implementation came up with some required amendments to the Directive, could those amendments be achieved before implementation in 2008?
Mr Biosca de Sagastuy: It is not for this working group. The mandate of this working group is not to propose amendments to the regulation but to verify whether the claim that the directive will impair the use of MRI equipment is founded. The working group can make recommendations.

Q786 Bob Spink: We understand that. If the result of the working group is that amendments are required, could those amendments be achieved before implementation in 2008?
Mr Biosca de Sagastuy: Again, this group is going to check whether the claims of the medical community—

Q787 Bob Spink: Can I rephrase my question?
Mr Biosca de Sagastuy: If you will not allow me to answer—

Q788 Bob Spink: You do not appear to be answering. If you can answer me directly. If the group comes up with a requirement for necessary change, will the Commission be able to amend the Directive before it is implemented in 2008?
Mr Biosca de Sagastuy: This group will not be mandated to do that, I am telling you. The mandate of the group will be to verify whether the claims of the medical community compared with what the scientific community says about the levels of exposure of medical personnel are right or wrong.

Q789 Bob Spink: If it does not?
Mr Biosca de Sagastuy: Then the Commission will take the measures that we consider necessary.

Q790 Bob Spink: Can it take those measures in time for implementation in 2008?

Mr Biosca de Sagastuy: No, I do not think so.

Q791 Bob Spink: Okay. What further work or research is needed before the full impact of the Directive can be determined?
Mr Biosca de Sagastuy: There is no further impact assessment. What do you mean, an impact assessment? The Directive is there. It is law.

Q792 Chairman: What you are saying is that the expert group you are setting up will, in fact, look at the diversion of opinion between the medical community and the scientific research community and it will then bring its findings back, the Commission will look at those and in light of that will decide whether there are further amendments to be made to the Directive. That is the process, is it not?
Mr Biosca de Sagastuy: Yes.

Q793 Chairman: If they are significant.
Mr Biosca de Sagastuy: Yes.

Q794 Bob Spink: Do you believe that there is any evidence at all that could persuade you personally that the Directive needs to change?
Mr Biosca de Sagastuy: Not at this moment because the scientific community says no.

Q795 Dr Harris: The question of timing is important. I understand your position at the moment. Let us say that the medical community get together with the scientific experts and they agree that a change would be—
Mr Biosca de Sagastuy: I have not said that.

Q796 Dr Harris: I know that, but let us say hypothetically this work continues, there is agreement between the medics and the scientists that a raising of one or both of the limits would be appropriate and then the Commission and the Council and Parliament also agree. You just said in a brief answer you did not think it would be possible to make any changes if all this happened, which I know you do not think will, before implementation in 2008. You did say you thought that was unlikely to be able to happen even if all those things were met. Would you agree that would be unfortunate if that was the case because it would be a pity, would it not, if all those things were in place and you could not make the timing?
Mr Biosca de Sagastuy: If your hypothesis is right then your conclusion is correct, but I am not sure that your hypothesis is correct.

Q797 Dr Harris: Neither am I, so I accept that. What I am saying is, is it not unfortunate that—
Mr Biosca de Sagastuy: From what we know your hypothesis is wrong. That is what the scientific community says.

Q798 Dr Harris: I am talking about the timing. Is it not unfortunate that the timing of doing all this work is such that even if in the remote possibility that I was right, that the scenario I have pictured is correct, is it not a pity, a tragedy, that it will not meet the timetable under those circumstances for amendment before implementation in 2008?
Mr Biosca de Sagastuy: No, because in their normal practice the medical personnel do not exceed the limit of exposure set out by the Directive, therefore there would not be any need for an amendment to the Directive. If you ask me the same things I will give you the same answers.

Q799 Chairman: Mr Biosca, you have been fantastic and you have kept your cool brilliantly, if I might say, and so have you, Mr Jansen. I know that you have been seething at times. Could I ask you two final questions with fairly brief responses. Would you confirm that the Directive is based to a great extent on the ICNIRP guidance?
Mr Biosca de Sagastuy: Yes.

Q800 Chairman: Would you accept that there is considerable criticism of ICNIRP's research which formulated that guidance? I am not saying whether you agree or disagree with it but you would accept that there is real concern about it?
Mr Biosca de Sagastuy: No, this is not true.

Q801 Chairman: That is not true.
Mr Biosca de Sagastuy: The ICNIRP guidelines are not contested anywhere in the world. They are the world authority in this field.

Q802 Chairman: So WHO and ICNIRP is really the basis on which this Directive has been put forward, that is the evidence base.
Mr Biosca de Sagastuy: Yes. This is in line with the American, Canadian, Australian and Japanese standards because everyone in the world follows ICNIRP.

Q803 Chairman: I am glad you have said that because America does not have any of the proposed restrictions which Europe, the European Commission, is putting in place, so how do you explain that?
Mr Biosca de Sagastuy: Yes, it has by means of standards. There are the IEEE standards.

Q804 Chairman: They are significantly lower than you are presenting.
Mr Biosca de Sagastuy: No. I will tell you why. They follow the same basic restrictions as ICNIRP but expressed in a different way, they set what they call the maximum permissible exposure. They set it at magnitudes which are already measurable. For instance, absorption of energy into the body is expressed in watts per kilo. Using a model of the body you can derive the physical magnitudes that will make the body absorb this type of energy, if you like a field of strength. What the IEEE does is expressing the maximum permissible exposures in terms of fields of strength. Where the two differ is not in the maximum permissible exposure in the whole range of frequencies but they do on some

transitional points. The IEEE uses one model of the body and ICNIRP uses another. What ICNIRP does is to interpolate between two frequencies where the IEEE calculates following the model established. There is very little difference.

Chairman: On that note, we have come to the end of our session. Can I thank you very much indeed, Mr Jansen and Mr Biosca. Thank you for your patience with us. We will, of course, let you have a transcript of today's session. Thank you very much indeed.

Wednesday 17 May 2006

Members present:

Mr Phil Willis, in the Chair

Adam Afriyie	Dr Brian Iddon
Mr Robert Flello	Margaret Moran
Dr Evan Harris	Bob Spink

Witnesses: **Dr Stephen Keevil,** Head of Magnetic Resonance Physics, Guy's and St Thomas' NHS Foundation Trust, **Professor Colin Blakemore,** Professor of Physiology, University of Oxford, and Chief Executive, Medical Research Council, and **Professor Ray Dolan,** Head, Wellcome Department of Imaging Neuroscience, University College, London, gave evidence.

Q805 Chairman: May I welcome to this session of the Science and Technology Select Committee our first distinguished panel, Dr Stephen Keevil, Professor Colin Blakemore, and Professor Ray Dolan. Welcome. This is our third case study which is looking at the whole issue of scientific advice to government. We chose specifically the issue of MRI scanners because of the European Directive. We wanted to effect a policy trail to determine where that Directive originated and how it got to the place it is now, and also to look at some of the controversy surrounding the implementation of the Directive and how it will affect what has been a massive investment by the UK Government in terms of MRI scanners in our hospitals. That is the purpose of this morning's session. We are aiming to finish this first session by 25 past 10. I wonder if it would be possible, Dr Keevil, to ask you to chair your panel, in case there is huge argument that breaks out, in which case you can deal with your unruly colleagues on either side.
Dr Keevil: I would be very happy to do that.

Q806 Chairman: Professor Blakemore is known to be difficult! This is the second evidence session. Last week we were in Europe meeting the Commission and the Commission officials told us that the new Directive would have absolutely no impact on treatment using current practices, and the concerns of the medical community and the manufacturers were dismissed by the Commission as "views". What is your view?
Dr Keevil: I have had the opportunity over the last 24 hours to look at the transcript from that evidence session and to share it with colleagues in the MR community. I think the concerted opinion of all those individuals was one of astonishment at some of the comments that were made in that session. When I visited Brussels in March with colleagues from seven other European countries to express our concerns about this Directive, we sent ahead of us a detailed summary of the areas where the Directive is going to impact on MRI, both in current clinical practice and in emerging applications and in research, which very clearly spelt out our concerns. Really, in that context, it is amazing that those individuals could say that there is no impact. There are a number of misconceptions and factual inaccuracies in the evidence that was given. I have already, through the clerk, asked for the opportunity to submit a further written submission which deals with those points in detail.

Q807 Chairman: Does that surprise you, that the Commissioners who were responsible for drawing up this Directive, who have been responsible for it from start to finish, have made such basic errors?
Dr Keevil: One thing that astonished me was to discover from that evidence that this is a process that has been going on since 1992. I am one of probably half a dozen to ten people in the UK MR community who are most engaged with this issue and I was certainly unaware that it went back that far. I think that speaks to the lack of consultation with the community which has gone on. From that evidence it was clear that really they have listened to one source of information: the ICNIRP Guidelines. There was a statement there to the effect: We spoke to ICNIRP and they said there would be no impact on MR, so that is it—you know, putting ICNIRP up to be the experts on MR practice, machine design and use, which I do not think ICNIRP would pretend to be. In that sense it surprised me. I have wondered throughout this process how it is that the guidelines like those that ICNIRP have and the NRPB have, which are very cautious—if you read the guidelines they say that this is a cautious interpretation of limited scientific data—ever got to be turned into concrete exposure limits. I think now, having read the transcript of last week's session, I can understand that, having a bit more insight into the thought processes of the people who were behind those decisions.

Q808 Chairman: Could I pin you down on the issue of what we would call diagnostic applications and ask you to give me a brief answer—and the same applies to the rest of the panel: Do you feel that this Directive will have real impact in terms of diagnostic applications if in fact it is implemented in its current form?
Dr Keevil: Yes. It is true to say that probably the vast majority of clinical diagnostic MR imaging would not be directly affected. It depends to some extent on how the problem of moving through the static field gets interpreted. That is slightly open to different views and interpretations. But there are certainly important areas of diagnostic imaging, important groups who need to undergo MRI, which it would

be much more difficult to image in a post-Directive regime. There are whole new areas, like interventional MR, which would be effectively blocked by this. I know you were told that interventional MR systems are all very low-field machines that pose no problem, and a figure of 0.4T was mentioned—although, given that there is not a static field limit in the Directive, it is not immediately obvious why the static field value is so important—but actually it is not true. In my hospital we have two 1.5T interventional MR systems, and I know that in Professor Dolan's institution another machine is being put in at the moment, so it simply is not true.

Q809 Bob Spink: My understanding is that at the moment, for instance for neurosurgery, the images that you get from 0.4T or even 0.5T machines are quite poor, and that is holding back the development of this. In order to get a better image so that this procedure can be used much more—as it is, for instance, in Australia—you would need more powerful machines to give better images, and that would give much better outcomes for brain surgery.
Dr Keevil: Yes, I think the gold standard now for neuro-imaging is 3T. There are hospitals in the world that are now starting to use 3T for neuro-intervention as well. This is more Professor Dolan's area.
Professor Dolan: The critical point here is that, the higher the field strength, as a general rule the better the spatial resolution is and the ability to see smaller areas of tissue, down to sub-millimetres. That becomes very important in certain areas, for example when it comes to doing neurosurgery, where one has to be very careful at the level at which one excises a piece of brain: one wants to excise what is diseased but preserve what is carrying out important cognitive functions. In the field of neurosurgery, critical developments are going to occur, in the sense that you will be able to inform the patient: "We will be able to do this type of intervention and this is going to be the likely outcome." In the past, because of a lot of neurosurgery was done blind, there were often disastrous outcomes, in terms of people being left, say, with language impairments, or other critical cognitive impairments. For the future in neurosurgery, the ability to inform a patient about what is the likely outcome, so that they can give appropriate informed consent, will depend also upon the ability of the surgeon to know that they can excise a discreet area of brain and nothing else, and the developments in high-field MRI are going to be critical in this respect.

Q810 Dr Harris: The Commission officials, as you saw, were very specific that what has just been said—that this would interfere with diagnostic testing—is an opinion; it is not evidence. They in fact, in contrast, as we will go on to discuss, talked about how the effects on health, backing-up these guidelines, will have been published in peer review journals. Can you help us by identifying that the opinion you give, that these action limits and maximum limits would impact on diagnostic and therapeutic interventional procedures, are published somewhere in the form of evidence, in peer-reviewed scientific journals, with a conclusion to pass muster which states: "These limits would interfere"?
Dr Keevil: The best way of starting that is by looking at the example of my own institution, where we are doing MR-guided cardiac catheterisation on children who traditionally would have had those procedures under X-ray guidance (which involves a dose of ionising radiation, et cetera). We published the first results of that in the *Lancet* in 2003 showing the clinical efficacy. We were not looking there at the occupational exposure on the staff members, but I have done some measurements looking at where the interventionist stands who is carrying out those procedures, right at the bore of the magnet to insert the catheter, and we are over the relevant action value in the Directive (which is in the hundreds to thousands of hertz range for the switched field gradients that are used as part of the imaging process). We are over that action value by a factor of about 40.

Q811 Dr Harris: But that is not published.
Dr Keevil: It is not published.

Q812 Dr Harris: That is just your personal statement.
Dr Keevil: Indeed. However, I know that colleagues at the Royal Marsden Hospital have done some more extensive measurements around their two or three 1.5T scanners, looking both at static field and at gradient field characteristics, and that has been submitted as a paper for review. So it is going through the process. It is not yet published.

Q813 Chairman: Could I come to you, Professor Blakemore. In terms of the impact on research, do you feel that this Directive, if implemented in its current form, will have a significant impact on the very research which Professor Dolan and Dr Stephen Keevil have just been talking about?
Professor Blakemore: There is no doubt that it will have more immediate impact on research than on clinical practice. I cannot comment fully on the impact on clinical practice, but, you know, research has a way of turning into practice. We have seen trends in the way in which scanning has been used in the last few years for clinical treatment which have involved more interaction with the person being scanned, with clinical staff or other staff in the same room moving around the scanner, necessarily, as part of the intervention. It is that sort of situation where there seems to be most focus of concern. That of course is routine in much research use of MRI, where the research often has to engage with a volunteer or a patient while in the scanner, carrying out some particular test with them. If one considers what the likely impact will be in that area, I should like to point out that, within the next few months, MRC and the British Heart Foundation will be funding the installation of a number (probably six to eight) 3T whole-body scans around the country for clinical research—that is research aimed at moving into clinical practice. These are high-intensity

machines, the choice driven by the relationship between resolution and field strength which has already been described by Professor Dolan. There is no doubt that the Directive, if implemented in its present form, would have an impact on such research in this country and indeed around Europe.

Q814 Chairman What steps did the MRC take to establish the potential impact on research of the Directive? Were you involved? Whom did you consult? What representations did you make to the Commission? Because, clearly, you must have seen this coming.
Professor Blakemore: Frankly, I personally—and I think this applies to other MRC staff—had no warning of this at all until about six months ago or thereabouts when I was approached by the HSE and invited to attend a workshop. In fact, Professors Derek Hill and Jo Hajnal went as representatives of the MRC to that workshop. We were not involved in the discussions with the Commission that led to the draft Directive. Perhaps it is not surprising that the Commission was not fully aware of the impact of the Directive on MRI.

Q815 Chairman: But the MRI community from an early point were aware. Was there no discussion with MRC about that?
Professor Blakemore: Not that I was aware of until about six months ago.

Q816 Dr Iddon: Could we look at the health effects. You have mentioned a gold standard, Dr Keevil, of 3T. Are there any adverse health effects at levels like that? If we are likely to exceed 3T in the future because of the improved imaging, do you anticipate that there might be significant health effects later?
Dr Keevil: For one thing, this is not an issue that is just about static fields. There is the static field, there is the switch gradient, there is the RF as well. In terms of the impact of the Directive, our concerns at the moment are mostly about the gradient field issue rather than the static field, because at the moment there is not a static field limit in the Directive. Because this is a Directive that covers such a broad frequency range, it is important to consider those frequency ranges separately because their impacts are different. The physics is different; the biology is different. I think there was a degree of confusion in the evidence you took last week between different frequency ranges. Statements were made that are true in one range but were applied incorrectly to another, so it is important to separate those out. Speaking specifically of the static fields, to respond to your particular question, the effect that people most frequently report in terms of static field, on moving through a higher static field, is a feeling of dizziness. That is quite well attested. People talk about that at 2T upwards, and certainly if you are working at the highest current field strength, whole body system, 7T/8T, then that is a concern and people need to have working practices in place to minimise the impact of that on their work and on their safety, and of course they do. We are a well informed community, we are a very safety-conscious community, and so people do have those procedures in place. There was some comment again last week about the possible mechanism of that, about it being due to the movement of calcium ions in neurons. There is no evidence for that at all—we think it is due to an interaction with the inner ear, in fact—so that is another falsehood in that evidence. Nobody is suggesting, whether we are talking about static field or any of the other frequency ranges, that there are no effects and that we can sit there complacently and have no limits at all. We know there are effects. For example, in the gradient frequency range, if you go to high enough amplitudes, you get peripheral nerve stimulation, where people's muscles start to twitch because they are being stimulated by the currents that are induced. There are real effects and we need to be aware of those and indeed have guidelines and if necessary regulations in place to prevent those from occurring either to staff or to patients.

Q817 Dr Iddon: I think you are saying that most of the health effects are reversible when the patient or the operator is taken out of the room.
Dr Keevil: Yes. I am not aware of any irreversible effects.

Q818 Dr Iddon: The EU Commission has based its Directive on the 1998 ICNIRP guidelines. You have been critical of that procedure. I think you have been quoted as saying that the guidelines were based on "a cautious interpretation of sparse scientific evidence".
Dr Keevil: Indeed.

Q819 Dr Iddon: When the Committee were in Brussels last week, obviously Members put that point, and officials in Brussels vigorously defended their position. Perhaps you would like to make your position clear this morning.
Dr Keevil: Yes. Without wishing to put words into their mouths, the officials were saying that this is the guidance that has come from ICNIRP and they are the experts and so we accept that guidance. To some extent, I can understand that position, but you have to look at what the ICNIRP guidance is saying. Because we are in a grey area, where really there are not proven adverse health effects at these levels of these frequencies, the statement in the Directive that it is about preventing known adverse health effects that occur acutely is not true. There is not the evidence for that.

Q820 Chairman: We specifically asked that question and the response from the Commissioners was: No, there are none.
Dr Keevil: Yes, and yet their Directive is based on the premise that there are.

Q821 Chairman: Absolutely.
Dr Keevil: If you read the Directive, it says this is to prevent known adverse effects.

Q822 Bob Spink: In fact the only evidence they gave was that of flying chairs and scissors—which we all know about.

Dr Keevil: Quite.

Q823 Bob Spink: They can be controlled.
Dr Keevil: These are rather different issues.

Q824 Chairman: I am sorry, perhaps you would finish that reply and then we will move on. I should not have interrupted you.
Dr Keevil: I think that is an important point. If they have made that statement which contradicts themselves in their own statement, that is interesting. Coming back to the issue of the ICNIRP guidelines, we would say that, if you look at that 1998 document, first of all, it is 1998 and ICNIRP themselves have subsequently said in 2004, in a paper that dealt specifically with MR, that that 1998 guidance was "written many years ago" and is now under review—so they themselves have cast some degree of doubt on it or at least acknowledged that it needs updating—and it also acknowledges that there is a wide degree of uncertainty in the scientific evidence that is available. It says that the aim of the guidance there set out is to provide an adequate level of protection, given a number of differing expert opinions. So there is not a settled consensus, even in the expert community, informing the ICNIRP guidelines and they do not pretend there is.

Q825 Dr Iddon: I was not there, but I am looking at the evidence that was collected, and the officials said that there was consensus in the scientific community.
Dr Keevil: The ICNIRP document 1998 does not give that impression. It says there is a number of differing expert opinions and I think that remains the case. There is uncertainty. It is the nature of science. There are wide uncertainties. The NRPB review more recently underlined that and acknowledges the breadth of the uncertainties that there are. The ICNIRP document expressly is setting out to provide an adequate level of protection. I think the way of interpreting that is that it is saying what levels of limits should we adopt if we want it to avoid any possibility of an effect, not that these are limits that are evidenced by positive evidence but that they are there to avoid any possibility of effects.

Q826 Mr Flello: I want to pick up on something you said a few moments ago in terms of the dizziness effects that have been noted. You said there was some suggestion that it was to do with calcium ions but then I think you said, "We think it has more to do with the inner ear." Do you have any evidence on which this conclusion is based?
Dr Keevil: I am not a physiologist. I would look to others for that. My understanding is that the state of the literature at the moment is that it is likely to be an interaction. As you move through the static field, currents are induced in the fluid in the inner ear which causes dizziness. This may be more Professor Blakemore's area.
Professor Blakemore: I do not know the evidence in detail in this field but that seems a much more plausible explanation of acute dizziness.

Q827 Mr Flello: You feel it is plausible but you do not have the evidence on which to base that.
Professor Blakemore: I do not have knowledge of the literature in that area; it just seems more plausible from a physiological point of view.

Q828 Dr Harris: Mr Biosca said, "The ICNIRP guidelines are not contested anywhere in the world. They are the world authority in this field." When the Chairman probed on that, at question 802 of that transcript, "This is in line with the American, Canadian, Australian and Japanese standards because everyone in the world follows ICNIRP." I do not understand how you can say it is sparse when he is so didactic and specific about how it is the authority.
Dr Keevil: It depends how you regard it. It is true that they are the international commission that set guidance in this area, but, if you look at the evidence base underpinning what they have said, it is all about effects that occur at a few tens of hertz, which they have then extrapolated over much higher frequencies. And it is guidelines. You have to look at it intelligently and apply it to your situation and not turn it into a one-size-fits-all set of regulations. It does not make sense to do that. Also, it emerged later in that evidence session that these numbers are not used in the US at all but they have limits that are set out by the IEEE, which it was claimed in that evidence are the same as the ICNIRP.

Q829 Chairman: We asked that.
Dr Keevil: Over the gradient frequency range, which is of most interest to us, they are not the same at all. There is a quite a wide margin. I cannot remember the exact factor but there is quite a wide factor of difference between the exposure limits in those two sets of guidelines. Both of them are based on the same evidence base, it is just that they are given a slightly different interpretation by those different bodies.

Q830 Dr Harris: We asked about how firm this evidence was, because it had been said that this was sparse and the official had a sheaf of papers which were studies. We asked if they were published and he said yes. He talked about experts from the NRPB, the German Institute of the Protection Against Non-Ionising Radiation, the Italian Institute—the results were published in *Physica Medica*—the Finnish Institute, the Health Council of the Netherlands: a study commended by the Government of the Netherlands, and that was in relation to earlier work, but, nevertheless, there was a volume of stuff that he claimed was peer reviewed and published, setting out the basis of the evidence base for these figures.
Dr Keevil: ICNIRP have looked at all that evidence and reviewed it, and yet their conclusion in the 1998 guidelines was that there are a number of differing expert opinions. So it is not the case that all that literature supports a single viewpoint leading to concrete limits. They have said there is uncertainty; there are a number of different views; let us adopt numbers that give an adequate level of protection.

There is no inconsistency between saying all that evidence is peer reviewed and published but it leaves a range of uncertainty, and somebody has come up with some numbers to provide what they describe as an adequate level of protection in that situation.

Mr Flello: At the risk of the Chairman pulling me up on this, what is your view on how ICNIRP can be held up as a good authority when it comes to mobile phone emission limits that—

Chairman: I am going to pull you up on that because that is a whole new inquiry.

Q831 Dr Iddon: My question is related to that. Colin, I am referring to the Weak Electric Fields Group which you work on. Can you tell us what the purpose of that group was? Was it to deal with the controversy about power lines or mobile telephones? Indeed, did you know that your work was going to influence the Directive that has been produced? In the light of that, are you happy at the way in which the group that led to that Directive used your work on the Weak Electric Fields Group?

Professor Blakemore: The Weak Electric Fields Group was set up by the NRPB in 2001. I had been a member of the NRPB's Advisory Group on Non-Ionising Radiation since 1992. That group's remit is to review the evidence for interactions between electromagnetic fields and the body and possible hazards associated with them across the whole range of non-ionising radiation. During the previous years, we had dealt with much of the rest of the spectrum, with ultraviolet light, with lasers, with certain parts of the low frequency spectrum, with fields associated with video displays and, of course, with radio frequencies and mobile phones. One could argue that it was just part of the natural progression of review of the evidence that the NRPB should want to move on to the low frequency part of the spectrum. It has to be said, though, that was not unconnected with some concerns that had been expressed about risks from power lines and part of our remit was to think about that.

Q832 Dr Iddon: Could I pursue that a little further. Are you surprised at the way in which the Commission have adapted their work there? Are you happy with the way they have used it?

Professor Blakemore: I am not sure of the extent to which the review of the Weak Electric Fields Group fed into the discussions of the Commission. It certainly influenced some of the recent discussion of the HSE. I should point out that the Weak Electrical Fields Group considered of a small group of experts who met only once and wrote a brief report. One of their recommendations was that there should then be a workshop. That workshop was conducted—it was chaired by my colleague Professor Noble from Oxford—and there is a full report of that workshop, published in 2003.[7] I suspect that the Commission drew on the extensive published record of that workshop in their considerations.

[7] *Note by the witness:* The citation is: Radiation Protection Dosimetry, volume 166 (2003)

Q833 Dr Iddon: But you had no idea your work was going to lead into the MRI Directive?

Professor Blakemore: No, I did not. It was a surprise to discover that the report of the sub-committee had been quoted during the discussion at HSE a few months ago and cited as evidence in favour of the limits and therefore of the Directive. You will note that I and my colleagues, all the external expert members of that sub-committee, in fact wrote a letter to HSE expressing ourconcern about the interpretation of our report.

Bob Spink: Perhaps we can go to very short questions and answers now because much of what I am going to ask on engagement you have already mentioned to some extent. We have already heard that the MR community came to this feast late. When did you first formally know about this? When did you get notification of it and when did you formally respond first?

Q834 Chairman: Professor Dolan, could you start on this one, please?

Professor Dolan: Yes. Just to put things in perspective, I am director of the Wellcome Trust Funded laboratory whose principle investigative technique is using MRI at 1.5T and 3T. I heard rumblings of this last summer. I was formally notified at a meeting of the Wellcome Trust in October that this legislation was on its way and that it would have a bearing on us, so I have known for six to nine months.

Q835 Bob Spink: This is well after the event has taken place.

Professor Dolan: During the consultation neither I nor any of the experts in my laboratory who would be seen as international experts were ever consulted.

Q836 Bob Spink: Have you drawn the conclusion that this was rushed through without getting a decent evidence base for it because of your opinion in the light of the political considerations?

Professor Dolan: Certainly that is the impression that I and my colleagues—and I think not just in my laboratory but nationally—have formed. The range of application of this Directive was clearly not taken into account, particularly its profound likely effects upon the direction of very important research that is likely to have ramifications for all the major neurological diseases, from dementia right through to schizophrenia.

Q837 Bob Spink: Stephen mentioned this earlier, so I will not ask him again, but the original Directive was flawed: there was no evidence base for the inclusion of static magnetic fields. That was removed, showing the flaw. Did anyone have the opportunity to talk about time varying fields during that period or were time varying fields just not considered at that stage?

Dr Keevil: I have been involved for slightly longer than Professor Dolan in this issue and we first became aware in the UK of this as an issue sometime in the middle of 2003. I have not been able to trace the exact date but it is around that time. In April of that year, industry in Europe, primarily Siemen and

Philips, wrote to the European Commission expressing concerns, not only, as has been suggested, about the static field but in fact about the gradient and time varying field issues as well. It is on the record that that was submitted as early as April 2003. Contact with the HSE in the UK started a few months later. We wrote to the HSE around July 2003, we wrote to NRPB (as it was then), and since then have been involved with them in a dialogue of sorts. I think it is fair to say that our concerns were not taken particularly seriously initially but more recently there has been much better engagement and we are looking together for a solution.

Q838 Bob Spink: From that, do I take it that you were not satisfied with the help you received and the response you got on your behalf from the HSE and the Government during 2003, at least on time varying fields?
Dr Keevil: Certainly not from the HSE. There was no involvement directly with the Government at that stage. That came rather later in the process. With the HSE, no we were not happy with that because, to some extent understandably, their initial response was that this was an issue that should be taken up with NRPB (as it was then—now HPA) because they set the guidelines and the HSE were obliged to implement them—in much the same way as we are hearing from the Commission in relation to ICNIRP: that you do not look at it intelligently; you just apply the numbers as they come out. That was very much driven by the view that was prevalent in Europe and still is, so that is understandable. It became a different story when we started to engage at Government level. I have to say that. That really is where we are now. There is much more an attitude of working together to try to find a solution to this problem.

Q839 Bob Spink: Do you think the industry was at fault in not providing enough evidence or making the HSE aware enough about the issues and consequences of the Directive for the industry?
Dr Keevil: Not to the best of my knowledge. I would not say that. I am not here representing industry and I am not aware of all the lobbying that they carried out. Certainly at the European level, as early as April 2003 they were lobbying about not just the static field but time varying fields. Industrial colleagues were also involved in the lobbying that took place in the UK. So, no, I would say industry were fully engaged.

Q840 Bob Spink: Professor Blakemore, were you forceful enough and proactive enough once you became aware to raise the concerns of the MR community about this Directive.
Professor Blakemore: To some extent, I delegated the responsibility of presenting the MRC's view to individuals who are more expert than I am in this area—which I think was entirely appropriate. But when I became aware that the report of the committee that I had chaired was being cited as evidence I certainly went to some effort to consult my colleagues who had been involved in that committee as to their views on that process. The outcome of that was quite a strong letter summarising our opinions and expressing concern about the way in which our report had been interpreted. The brief of the committee I chaired was to speculate—to speculate—about the possible levels of field strength at which there were detectable interactions with the human body, particularly the nervous system, but without a clear instruction to think about or comment on potential hazards associated with such effects. We did identify a couple of areas where we thought there was reasonably robust evidence for defining the threshold for interaction, but, as we have said in our letter to HSE, on reflection afterwards we could see no clear evidence that those limits, those determinable limits, indicate a hazard. There are two areas of uncertainty—and the word "uncertainty" has been used a lot in the discussion. One is the uncertainty about the extent to which measurements of detectable effects at one part in the spectrum can legitimately be extrapolated to others. I will cite, for instance, the clear evidence that very low frequency fields can induce phosphenes (that is, apparent flashes of light caused by direct activation of the retina). We know that those effects occur over a very narrow frequency band and they fall off very quickly above about 20 Hz. If cells in the retina can be affected by low field strengths like that, then it is conceivable that neurons in the brain could be affected by similar field strengths, and there is less certain evidence—some evidence but less certain—that that occurs. There was an assumption (because of the electrical characteristics of groups of nerve cells) that such effects, if they occurred, would extend over a large frequency range. That turns out not to be true on the basis of current evidence from John Jeffreys, who is an expert in this field who provided some of the strongest evidence of such effects. They too are limited to a narrow frequency band. That is one area of uncertainty about extrapolation of data to determine the thresholds of interaction. The second area of uncertainty concerns speculation about the possible effects on the body above those thresholds. Robert tried to raise the dreaded question of mobile phones. It is worth comparing this present situation with that considered by Stewart.[8] If there had been clear enough evidence—as there is now for effects at the low frequency part of the spectrum—of interaction with the body at very low-strength radio frequency fields, then it would have been very difficult, following the same arguments, for ICNIRP and NRBP not to adopt those extremely low levels, which probably would have stopped radio frequency telecommunication technology. It was only because of the uncertainty of being able to establish a clearly agreed threshold that there were not similar, inappropriate, extremely cautious limits for radio frequencies.

Q841 Chairman: If that seems so obvious to all, how have we got to this point in time, where we are within a short period of adopting this particular Directive

[8] *Note by the witness:* The Independent Expert Group on Mobile Phones, chaired by Sir William Stewart.

that is going to have significant impact, without a body of evidence to support it? How have you all allowed it to happen? We rely on you.
Professor Dolan: One of the answers to that is the failure of adequate consultation.

Q842 Chairman: By the HSE or by whom?
Professor Dolan: At the point where the European legislation was being drafted, I guess national agencies have to take responsibility for appropriate consultation as to the likely impact of the Directive.

Q843 Bob Spink: For the record, could I ask Professor Blakemore to say when MRC was originally contacted by HSE. Are you satisfied that HSE are taking full account of your concerns?
Professor Blakemore: I believe we were first contacted in September of last year. I think HSE is now taking very seriously the growing swell of concern. I have some sympathy with HSE's position because they are not responsible, of course, for writing the Directive, only for implementing it. They are struggling, I think genuinely, to see how a very difficult situation could be retrieved in the face of a Directive which is very difficult to change.
Chairman: We are looking forward to their response.
Bob Spink: Were any of the panel amazed to read the evidence we received from the Director General last week—or is that not in the formal evidence—that if the Directive has gone wrong they will ignore it?
Chairman: That is not in the formal evidence.
Bob Spink: And they will not take infractory proceedings—
Chairman: That is not in the formal evidence.
Bob Spink:—because they might well consider that it is wrong.
Chairman: That is not in the formal evidence.
Bob Spink: I am sorry. Did I get that on the record, though?
Chairman: I do not think we can ask you for comment on what is a private view of the Commissioner.

Q844 Bob Spink: I apologise, Chairman.
Professor Blakemore: It is a very encouraging private view.
Dr Harris: It is not private any more though.
Chairman: At that point we will move on. I have lost control of this Committee!

Q845 Dr Harris: Professor Blakemore, would you agree with the following assertion that it is not possible at present to say that exposure to radio frequency regulation, even at levels below national guidelines, is totally without potential adverse health guidance, and that gaps in knowledge are sufficient to justify a precautionary approach?
Professor Blakemore: I think you might be quoting from a sentence that I played a part in writing.

Q846 Dr Harris: Would you agree with that?
Professor Blakemore: I certainly would agree with it.

Q847 Dr Harris: Would you then agree with the statement that: as a precautionary approach, the ICNIRP guidelines for public exposure be adopted for use in the UK?
Professor Blakemore: Yes. I did agree with that. You are quoting, of course, from the Stewart Report, the report of the Independent Expert Group on Mobile Phones.

Q848 Dr Harris: Of which you were a member.
Professor Blakemore: Of which I was a member. That recommendation of course was made in the knowledge that to adopt ICNIRP guidelines for radio frequency radiation would not impede mobile frequency telecommunications technology. What it would do would be to send a signal that we should be aware of the concerns, employing the precautionary principle, and not race ahead with technology which would push exposure levels up further.
Dr Harris: I would question that—and I want go too far down this path—because if you try to get a signal in North Oxford you will find it difficult because mobile phone masts have been resisted by people in North Oxford on the basis of the Stewart Report. I will show you my postbags and—
Chairman: Dr Harris, I do not want to get on to mobile phones. I want to keep specifically to MRI.

Q849 Dr Harris: I would question your analysis, therefore, that the Stewart Report and your coverage of it, particularly in its reference to the precautionary principle, has not impeded the ability to use that technology.
Professor Blakemore: The implementation of ICNIRP guidelines has certainly not impeded the technology. The public unfortunately go beyond the logic of the explicit limits of exposure stated by ICNIRP in their concern about mobile phone masts. We all know that.

Q850 Dr Harris: To what extent would you say the Directive with which you disagree has been based on the precautionary principle? Is that part of the problem, would you say, whether you agree it is the right version of the precautionary principle or not?
Professor Blakemore: I think we are seeing now that the intransigence—and I use that word advisedly—of the Commission, in considering the concerns that have been expressed, goes far beyond the precautionary principle. In the Commission's document on precautionary principle, which I think was published in 2000, its interpretation of the precautionary principle is as follows: "Where action is deemed necessary, measures based on the precautionary principles should be *inter alia* proportional to the level of protection, based on an examination of the potential benefits and costs of action or lack of action and subject to review in the light of new scientific data." I think we have seen those principles infringed in the discussions around the issue of the Physical Agents Directive.

Dr Keevil: I absolutely agree. One of the issues we have is the way in which the status of pieces of evidence has somehow sort of grown out of all proportion through the process. If you look at the ICNIRP guidance, it is a review of all the literature and it says, "There are uncertainties. Let's come up with some numbers to exclude possible effects" and that sounds to me like a precautionary approach. If you go back to the definition that you had right at the start of this inquiry from Sir David King, the precautionary principle being the idea that a lack of consensus should not prevent action, it is almost a case study of that: "There's a lack of consensus but let's have some numbers and let's have some action" but somehow that has then been taken as concrete limits. The Directive does not say that it is precautionary, it says, "These are thresholds for known adverse health effects," so somehow the status of the evidence has grown and it does not reflect what ICNIRP perhaps is saying about it.

Q851 Dr Harris: I understand that, because this started with "no known adverse health effects", but Professor Blakemore quoted from the 2000 document, and, if you look at what the European court said in respect of the beef ban, "Where there is uncertainty as to the existence or extent of risks to human health, the Commission may take protective measures without having to wait until the reality or seriousness of those risks becomes apparent" so everyone who wants to take a stronger precautionary approach can pick a judicial definition almost of the precautionary principle. I want to ask Professor Blakemore, in particular, as someone who has influenced policy in this area, whether he thinks there is a problem with the precautionary principle and interpretation of it and a lack of a definition in it in this area.
Professor Blakemore: I think it is generally agreed there are serious problems with the precautionary principle because of the variety of interpretations of it. When there is variety but the underlying principle is to be cautious, then usually the most conservative of the interpretations wins out—and the example you have quoted there is obviously at the conservative end. The key, though, to all of this is surely that we should take into account, in our consideration of appropriately cautious and protective measures, the risks that might be associated with implementing those measures, but also the loss of the benefits associated with preventing the use of technology. In the case of MRI, it is very, very clear: the hazards associated with other approaches (for instance X-rays or positron emission tomography, which are in some ways alternatives to MRI) far exceed, on the basis of known and certain evidence, the risks that might be associated with MRI.

Q852 Dr Harris: I want to give you a chance to influence what the Government does. We have institutions like the HSE and the NRPB and we have people negotiating at the Commission, we have Ministers in Council, and the word "precautionary" approach or principle is flying around, but do you think it would be of value for the UK Government to do more work on how it is going to apply the precautionary approach—including the issue you mentioned of risk versus benefit and identifying the opportunity cost of being too cautious—in its policy and negotiations?
Professor Blakemore: I think a serious piece of work on the interpretation of the precautionary principle would be very helpful.

Q853 Margaret Moran: I think you have made very clear, Dr Keevil, your view on the response given by the Commissioners and you are submitting some further information on it, so I will not go into that. Since my colleague blew the gaffe on some private discussion which seemed to indicate that the Directive might be amended, let me make it clear that there is some difference of view. Let us assume, as we have to, that the Directive will be implemented within its current timetable. Given that assumption, what new evidence has been provided to the Commissioner to persuade him to establish a joint working group? In other words, what has happened between the point at which the Directive has been signed and sealed over there and the different thoughts emerging?
Dr Keevil: That process relates back to a meeting that I mentioned earlier when I went with a group representing the radiology and medical physics communities in Europe to meet with Commissioner Spidla. Ahead of that, we sent a summary of what we thought the main impacts would be on clinical practice and research in MRI, and we had what I felt at the time was a very positive meeting where he responded to that by saying he would set up this working party, the remit of which would be to look at the evidence for the claims we were making to see whether, essentially, they were true. That is a very valuable step. It is limited in some ways, because, if you are purely looking at current practice in MR, there is a risk that you would close off things which might develop in the future. As Professor Blakemore was saying earlier: research begins to turn into clinical practice. So it is not necessarily the panacea, but it was certainly a very positive move and I think that was because of the initiative that the European MR community took in setting up a meeting with the Commissioner and presenting that evidence. What was said in Brussels when this Committee went there seemed, to some extent, to fly in the face of that, because they were expressing a great deal of scepticism about that working party and what it might turn out and obviously had a very entrenched view of what the outcome was going to be.

Q854 Margaret Moran: Were you given any assurances about the composition and remit of the working party?
Dr Keevil: Assurances might be putting it too strongly. The Commissioner said that they would establish a working party to examine the extent to which practice was affected by the Directive. That was fleshed out as: Would the Directive restrict the use of MRI and so reduce patient benefit and would it limit the evolution of the discipline? It was agreed

that would be set up by the Employment Directorate General but would have input from the MR radiology and scientific MR community in Europe. Since we came back from that meeting in Brussels, I have heard no more about that working party, and so it was news to me that we are going to have a meeting next month. As far as I am aware, the exact composition has not been determined but there was an agreement that it would have input from our community. I came away with the impression—and it is in my notes—that the community would participate not only in determining the composition but in determining the mandate of that working group; whereas there was a very firm view in the evidence that you received last week that the mandate is set and is quite narrow and it will just have some sort of advisory role and not be able to really recommend changes to the Directive in itself. But that may simply be my misinterpretation.

Q855 Margaret Moran: If it has that mandate, do you think it will be of any benefit?
Dr Keevil: It then depends on what notice the Commission takes of the outcome. If, as I would imagine, it does demonstrate that there is a real impact on MR—and I think, to a large extent, we have already demonstrated that impact so it should not be a difficult task—and we present that evidence to the Commission, it is then a question of what they do with it. The Commissioner said to us in March that if the working group did establish that there was an impact on practice, defined in the way I have described, then he would be open to changes in the Directive—although he said it would not be an easy process and may not be successful, because of course it now has to go back through all the European institutions. So that was very encouraging.

Q856 Adam Afriyie: To all intents and purposes, as we know publicly at the moment, the Directive will be reviewed in 2009. What evidence or research needs to be undertaken before then on EMF and static fields and who should fund it?
Dr Keevil: That is a very difficult question. The research field of EMF interactions with biological systems is quite a broad one and it is not one in which I am involved. There are large uncertainties, as I was saying. In some of those there is work in place already to try to close them down. There is work at UCL, for example, looking at possible effects of time varying fields on evoked potential to the brain. That is work of which I am aware.

Q857 Adam Afriyie: But you are not at the stage where you have a list of work that would need to be completed in order to—
Dr Keevil: There are lists of what the research questions are. Again, this is not really my field, but some are very broad questions, which are not things, I would imagine, that are going to be solved in that timeframe. They are ongoing research questions. There is always going to be a degree of uncertainty. I think the solution may be more in recognising that uncertainty. Mainly, to some extent, it is about ICNIRP recognising the uncertainty and reinforcing the fact that there is uncertainty in the evidence that has informed their limits. They are reviewing their guidelines at the moment.

Q858 Adam Afriyie: Professor Blakemore, if research is identified that will be required for the review, is MRC prepared to fund it?
Professor Blakemore: We have already indicated to HSE that we will be prepared to consider funding—preferably in partnership—in this area, depending, obviously, on the quality of the proposals that are received. Could I say, just to extend Stephen's comment, that the biggest and most impressive experiment has already been done, and that is the fact that some 400 million people have been exposed to MRI scanners with, as far as I know, no recorded health problems as a consequence.

Q859 Chairman: Or to the workers.
Professor Blakemore: Nor to the workers. That is a pretty good starting point. The MRC and others have identified areas where work could be done and where capacity exists in this country to do it well. I think this work could be done quite quickly.
Bob Spink: Could I put on the record that this has been going on for 34 years now, to my knowledge, since the first scanners were developed in Radlett by EMI in 1972.
Chairman: That is a comment on the record. Thank you for the final comment from my colleague Bob Spink. Could I thank you very much indeed, Professor Dolan, Dr Keevil and Professor Blakemore.

Witnesses: **Lord Hunt of Kings Heath,** a Member of the House of Lords, Parliamentary Under-Secretary of State for Work and Pensions, **Mr Geoffrey Podger,** Chief Executive of the Health and Safety Executive; **Dr John Stather,** Deputy Director, Centre for Radiation, Chemical and Environmental Hazards, Health Protection Agency, and **Dr Alastair McKinlay,** Head of the Physical Dosimetry Department, Centre for Radiation, Chemical and Environmental Hazards, Health Protection Agency, gave evidence.

Q860 Chairman: Welcome to our second panel of the morning. I hope you have enjoyed listening to the evidence of our first panel. I noted from the number of heads that were shaking and nodding that you have obviously got some views on that! Minister, clearly there are some real issues that have to be addressed in terms of MRI scanners and this particular directive. Can you clarify who has taken the lead for the Government on the directive, and from where the advice has been obtained?

Lord Hunt of Kings Heath: It is clearly my responsibility, as Minister for Health and Safety in the Department for Work and Pensions. I take advice from the Health and Safety Commission; and

they, in turn, are advised by the Health and Safety Executive. In the question of the scientific issues that are under discussion, formal advice is received from the Health Protection Agency. That is the formal line of advice and reporting.

Q861 Chairman: Are you totally dependent, Minister, on that advice from the HPA? Do you ever go outside?
Lord Hunt of Kings Heath: No, I do not believe I am totally dependent. The formal position, as I understand it, is that the HPA statutorily advises the Executive and the Commission; again, the Commission gives formal advice to me, but as a minister it is then in my own hands to decide what to do with that advice. If I thought that I needed other advice, whether it be scientific, policy or in any other field, I believe it would be open to me to seek that advice.

Q862 Chairman: There does appear to be a scenario that this was a set of broader directives that were agreed at European Commission level, and for this one in particular ICNIRP gave a set of advice; NRPB, the predecessor to the HPA, gave a set of advice, which was then passed to the Health and Safety Executive, which was then passed to you, and was then agreed as the position to go in front of the Commission. There seems to have been a blind acceptance throughout that chain that that advice was sound and could be interpreted in the way it was. Is that fair?
Lord Hunt of Kings Heath: I am not sure that is entirely fair. Clearly, I have only been in this job for a year, so I was not present in the Government during many of the critical decisions around the original negotiating stance on the directive; but the actions I have taken since I became aware of the issues show that the Government is able to take a view and seek further independent advice. The moment I became aware of the issue, I sought advice, of course, from the Health and Safety Executive, but I met with the clinicians concerned. As has already been inferred, a series of actions took place in order to resolve the problems. Clearly, if this issue had come to ministers before then, a similar kind of process could have been undertaken. On the other hand, it is true to say that the ICNIRP guidelines, endorsed as I understand it by HPA, are a pretty powerful body of evidence in terms of any government coming to a decision in this kind of area, and might be considered perhaps to be the best available evidence at the time.

Q863 Chairman: Dr McKinlay, you were actually the Chair of ICNIRP between 1996 and 2004.
Dr McKinlay: Sorry to correct you, Chairman—from 2000–04.

Q864 Chairman: My apologies—I am elevating you already! You were the Vice-Chairman. You were obviously an influential player.
Dr McKinlay: I was the Chairman from 2000 to 2004 and Vice Chair from 1996 to 2000.

Q865 Chairman: So throughout the whole of that period you were right at the heart of this. What is your view? Why was there no questioning the effect that this would have on the MR community?
Dr McKinlay: I think we have to appreciate first of all that the exposures referred to and that we are discussing currently about medical resonance imaging are only one very small part of the entire electromagnetic frequency range, and that ICNIRP, in developing its guidelines, covered not only all of the electromagnetic field frequency range—and mobile phones have already been mentioned in this respect, which is a very important aspect—but also optical radiation and ultrasound and infrasound radiation. ICNIRP covers that entire spectrum, but it does not concern itself in that sense with particular practices and frequencies; it concerns itself with rigorously examining the evidence for health effects in people from the scientifically-reviewed evidence; and then it issues guidelines and gives advice to cover that entire frequency range, of which of course those frequencies are an important part.

Q866 Chairman: But you stand by the advice that ICNIRP gave to NRPB, as it was, and then to HSA?
Dr McKinlay: Yes, I do. I appreciate very much the analysis that Dr Keevil gave earlier. ICNIRP does exercise caution in coming to its advice on guidelines; that is intrinsic in the way ICNIRP operates. It is dealing with the health of people and it does exercise caution, both in interpreting the science and in arriving at the guidelines that we give. I would emphasise that they are guidelines. We do not recommend legislation and we do not recommend—such as in the EC directive—regulations.

Q867 Chairman: We will return to that because, clearly, the Commission has interpreted this and has now put it into—
Dr McKinlay: That is a matter for them.
Chairman: Of course, yes.

Q868 Margaret Moran: What was the initial view of the directive taken by the Health and Safety Executive, given that your own regulatory impact assessment could not identify any health and safety effects or benefits?
Mr Podger: Again, like Lord Hunt, I have had to reconstruct history, since, as you know, I arrived in HSE in November of last year. It is clear from the beginning that HSE did not favour this directive, which it regarded as not having benefits and not conferring additional protection on workers over the previous regime; and that has consistently been HSE's view. It is important to put on record, when we discuss what clearly is a problem we now have with one aspect of it, that HSE never advised ministers that there was benefit in this directive; we only began negotiating on it when it was clear that other EU countries would prevail and that the directive would be pursued. As you know, in 2003 the UK, reflecting our advice, tried to take MRI scanners altogether out of the directive. The difficulty that arose is that when the static fields issue

was resolved satisfactorily from the point of view of UK interests, we believed at that point—and this is where, from our perspective, it went wrong, for which I express some regret—that both MRI clinicians and also the industry were content with that outcome as it applied to MRI. I say very openly to the Committee that that judgment has proved to be mistaken, and it is a matter of considerable regret to us because our interest throughout was to keep in touch with the whole range of stakeholders affected by this rather wide-ranging directive, and to seek to meet their legitimate interests.

Q869 Dr Harris: Did you say that Britain tried to take MRI scanners out of the directive in 2003—
Mr Podger: Yes there was, not only by the UK; several countries sought to remove them from the scope of the directive.

Q870 Dr Harris: Not just static fields?
Mr Podger: No.

Q871 Chairman: We heard evidence to that effect from the MEP, Liz Lynne.
Mr Podger: Yes, and we would support that, and supported it at the time.

Q872 Margaret Moran: Were you suggesting in your response just now that you did not consult widely enough during this process, because we are quite far down the line and surely it is for you to be raising the alarm and to be consulting with the industry? Who did you consult with? Why did you not effectively make representations that were needed when they were needed?
Mr Podger: The question, very clearly, is why we did not connect with the previous witnesses. That is essentially the point. That is clearly our concern. The reason is what I said earlier, which is that we had consulted with manufacturers and technicians, and we had had some clinical engagement, although certainly with the benefit of hindsight insufficient—and I would be the first to say that. What was not realised at all was that there were these minority of clinical interventions and interventions, as we have been told this morning, from the research point of view, that there would be a problem with the directive, and that we had not appreciated it by September 2003. If we had appreciated it, it is fair to say, given HSE's general record of consulting with stakeholders, that we would then have been able to seek out those who were the experts and discuss it with them.

Q873 Chairman: But you were being told that before. The MR community were telling you that and were reporting that. The only time there appears to have been any response is when the MR community went public.
Mr Podger: The answer to that question is that, as I understand it—

Q874 Chairman: Is that a fair assumption?
Mr Podger: No. Our understanding—I can only tell you, Chairman, what our understanding is—and this is what I have discovered both from looking at the papers and discussing with people who were there at the time—is that it is clear from the beginning that entirely justifiably the MR community had a large number of concerns about this directive, not simply this issue about the small proportion of interventions—the issues of static fields and the more general issue as to whether this directive was needed at all. Our understanding, by the time the static fields issue was resolved, was that the concerns of the community had been met. It is quite clear that this is not the case, and I do not seek to dispute that. I merely state to you that that was where colleagues were at that time in 2003.

Q875 Chairman: I will return to this a little later. I am going to move on now. Minister, in practice what do you expect to be the impact on research and treatment if this directive continues without being amended or changed in any way? Do you think it is going to have a serious effect?
Lord Hunt of Kings Heath: You have heard the clinicians this morning, who clearly think it is going to have a serious effect. Equally, you have met with the Commission officials—

Q876 Chairman: Who said that there would be no effect.
Lord Hunt of Kings Heath: Yes. I believe that I need to be guided by what is the best evidence available. As a result of the meetings that I instituted last autumn and the work programme that has now been agreed between HSE and the clinicians, we have set in train a series of work actions, which I hope will allow us to come to a considered conclusion on those matters. That is the intent, both in terms of the action taken in this country, but also the work that the Commissioner has agreed and which, happily, from the evidence you received last week, should start in June.

Q877 Chairman: Are you optimistic that we might see some change to this?
Lord Hunt of Kings Heath: I am hopeful, if the evidence suggests that there should be some change made; but I think it is a little too early to say that. Anyone who has had any undertakings with Europe knows that one has to be cautious about that. As far as the relationship that has been established between HSE and the clinicians is concerned, I am satisfied that that is on a firm footing and that the work can proceed as swiftly as possible. I am obviously hopeful that that will produce some hard evidence on which we can then go forward.

Q878 Dr Iddon: The MRI community here are obviously alarmed by this directive. Is that replicated in the other European communities?
Lord Hunt of Kings Heath: There has not been ministerial engagement on that particular issue, so I cannot tell you that I have picked up concern at a Member State level. When I met clinicians, one of

the things I encouraged them to do was to work with clinicians in other countries, and the combination of that was the meeting they held with the Commissioner. Clearly, my understanding is that according to the clinicians we have met this morning, other clinicians do have concerns, and obviously I would hope that those concerns do come to the attention of Member States. From my point of view I have not picked up other Member State concerns at the moment.

Q879 Chairman: You are familiar with the 2003 regulatory impact assessment; it does not discuss the potential impacts on the use of MRI; it just mentions that 1,250 workers would come under the directive. Were you happy with that as a regulatory impact assessment?
Mr Podger: The truth is that that regulatory impact assessment was done very quickly because, as you know, the proposal only suddenly appeared out of the blue in September 2002. The honest truth, I think, is that it was the best that could be done at the time. Equally, as you know, the regulatory impact assessment was essentially very critical of the directive, and, as I am sure the Committee also knows, the HSE had pressed on more than one occasion for the Commission themselves to do a proper regulatory impact assessment of their proposals, and was very dissatisfied with the fact that it was not done. I think the fact that later in the year we backed trying to get MRIs out of the directive altogether shows that we were very alert to the general issue.

Q880 Chairman: Dr McKinlay, I understand that the HPA commissioned some work on the evidence base of EMF exposure, and a 600-page document edited by Professor Roger Ordidge, who told me that, having presented you with this information, not even a response was given to it, let alone any use of it. Are you aware of that?
Dr McKinlay: I am not personally aware of it. I could refer you to my deputy director, here.
Dr Stather: A lot of information has come in. Maybe I could look at the process we went through over the four years between 2000, when the Stewart report came out.

Q881 Chairman: Can you just answer this specific question? A 600-page dossier—
Dr Stather: I do not recall having seen a 600-page dossier.

Q882 Chairman: Even though you commissioned it and paid for it? You are not even aware that it exists.
Dr Stather: I know we have lots of papers presented.

Q883 Chairman: Professor Roger Ordidge assured us that he did do a massive trawl of all the available literature, and presented it to HPA. It was commissioned by HPA. He presented it to HPA and he did not even get an acknowledgment that he had handed it in, because you were more concerned with mobile phone masts.
Dr Stather: I think that is not true; we are concerned with issues across the whole spectrum. We did get evidence from a large number of people and could have got information from Sir Roger Ordidge as well, but we did not commission anything from him. I am clear on that.
Chairman: We take your word for that.

Q884 Dr Iddon: Minister, it looks to me, as a scientist, as if quite weak scientific evidence has quite properly, as Dr McKinlay has pointed out, led to guidelines which have now been turned into the Physical Agents directive—inflexible absolute limits that now have to be enforced. Would you say that that is probably a true statement?
Lord Hunt of Kings Heath: Clearly, the directive is based on the guidelines and they do have some absolute limits in them, which would be due to be translated into law in this country; so I would agree with that supposition. As you know, the Government itself did not want to see this directive brought into place, acting on the advice that you have already heard from the Health and Safety Executive that the health and safety benefits were very difficult to see; and that in any case current health and safety legislation and the guidelines that had already been produced by the HPA's predecessor were sufficient. That is the basis on which we took our discussions into Europe. The problem from our point of view is that although, when the original wider Physical Agents directive was first discussed in Europe in the early nineties, clearly there was a lack of consensus then. By the time the new directive was proposed around 2002, life had moved on, and this country was isolated in that position of not wanting to see the directive brought in. As ever in that situation, we were faced with a position of going into outright opposition, when in so doing you probably lose influence over what was in the directive; and clearly the decision was taken that given this was going to be a *fait accompli*, our best efforts would be in trying to ensure that the directive was as satisfactory to this country as possible. You will know that as a result of those negotiations we were to a certain extent successful. The static field limits were withdrawn. Where we were not particularly successful was in asking for a new impact assessment, as I gather you have discussed already with the Commission officials.

Q885 Dr Iddon: I think that makes the British Government's position absolutely clear. Dr McKinlay, what consultations were there between ICNIRP and the Commission during the development of this directive? Can you lead us through that process?
Dr McKinlay: Sure. Can I ask you for your patience if I refer to my notes here? There is a chronology of interaction. I was very pleased to be invited to this Committee about ten days ago, so I have done all my own research work, going back 16 years. I hope it is complete. I have tried very hard to make it accurate and complete, so I will take you through it, if you wish.

Q886 Chairman: Can you do it very briefly, because we are desperately short of time?
Dr McKinlay: It will be brief, yes; it is a brief chronology. I guess it goes back to 1990/91, just before ICNIRP was formed in 1992. There was a report, which has already been referred to, published in *Physica Medica*, which set out a paper concerning occupations of workers and physical agents. That was asked for by DG5, the health directorate of the Commission. This was not an ICNIRP project but it was a common project of NRPB and an Italian institute and a German institute, which were European members of ICNIRP's predecessor. That is the first involvement. Then in the period 1992 to 1996, advice on exposure of the public to NIR was provided again to DG5 from European ICNIRP members. A report was compiled by an *ad hoc* working group comprising scientists from those three institutions, and this was published. I have a copy that I can leave with you; it is entitled *Non-Ionising Radiation: Sources, Exposure and Health Effects.* It did cover EMF within that. In 1996 and 1997 there was an ICNIRP panel of exerts, who were invited, again by DG5, to investigate the occurrence of electromagnetic hypersensitivity. This is an issue that has returned quite recently, particularly in respect of mobile-phone masts. So ICNIRP was looking at that, way back in the mid-nineties. Then in 1997/98 there was exposure of the public to EM fields. You remember the European Council recommendation limiting exposure of the public, which encompassed the ICNIRP guidelines. We provided clarification of the guidelines, the cautionary nature of the guidelines, the meaning of reference levels and basic restrictions and how they should be used. That work is referenced in the annexes of the Council recommendations. That, again, is DG5. In 1999 to 2001 there was concerted action given to ICNIRP from the European Commission. Concerted action was a task where they pay not for the work that is done but for an allowance for meetings, and travel expenses and such like; so that concerted action was on possible health risks to the general public from the use of security and similar devices. You can see these devices in shops, if you walk through the magnetic loops. Indeed, here, in the House of Commons, you walk through these devices. That was for DG13, and that was published in 2002. Now we come to the nitty-gritty, I guess—2003. We had a meeting of three of us, that is myself, Professor Bernhard, who was the vice chairman of ICNIRP during that period, and the scientific secretary Rudiger Matthes from Germany. We had a meeting in Luxembourg with the head of Employment and Social Affairs, DG—and there was also another gentleman, Antonius Angelides. There were no formal minutes taken of this meeting, to my knowledge. However, I can inform you as to what took place, if you want me to develop that a little, because that is quite an important meeting.

Q887 Chairman: I want to bring you specifically back to MRI. In 2003–04 ICNIRP provided significant guidelines on MRI, and as such ICNIRP would have known that—or what would have been the impact of that guidance on MRI?
Dr McKinlay: I was going to return to that as my final point, because I think that came up in the earlier evidence. I know of no evidence like that, or advice that ICNIRP gave to the EC specifically on MRI. As I said at the beginning, we do not concern ourselves with exposure to the particular device with a particular frequency; we deal with the scientific evidence for health effects, and we issue the guidelines. We gave lots of advice in terms of the guidelines and understanding the guidelines, but that was interpreted in that way—

Q888 Chairman: But, with respect, in 2002 you said that the ICNIRP 1998 guidelines were out of date. I cannot fathom what influence or what was the way in which you then influenced the Commission, in terms of saying, that those guidelines were out of date.
Dr McKinlay: I think what you are referring to is the static magnetic field guidelines in particular. In fact, as I was going to go on to say, at that particular meeting in 2003 probably the most important advice that ICNIRP gave to the Commission was that because the static magnetic field guidelines were being currently reviewed, because of all the activity that was going on in terms of assessment and review, and because we knew that ICNIRP were going to revise the guidelines, they should not include those in the directive; they should not include static magnetic fields in the directive. That was the clear advice we gave. We also gave that advice in writing in a reply to a letter sent by the Italian permanent representative, because it was the Italian presidency at that time that took the guidelines through to fruition. She wrote to ICNIRP and asked whether the static magnetic fields were under revision, and whether they were likely to be revised. We replied in the affirmative and said to her that it would be inadvisable to include static magnetic fields in the directive. I have the letters that cover that.

Q889 Dr Iddon: It is accurate to say that ICNIRP are not content—not content that their guidelines, as they existed at that time, were correctly used to draw up the Physical Agents directive?
Dr McKinlay: Again, as I said at the beginning, we issued guidelines. It is up to governments and super-national governments to decide about regulations. We do not lobby on this. We do not have a view about it, but we do provide scientific advice.

Q890 Dr Iddon: With respect, you have already admitted in front of this Committee this morning that you felt that your guidelines were out of date and that you were about to review them.
Dr McKinlay: For static, yes.

Q891 Dr Iddon: Did you make that point to the Commission?
Dr McKinlay: Yes, we did.

Q892 Dr Iddon: Quite strongly?
Dr McKinlay: Yes, we did. We have the letters—for static we did.

Q893 Chairman: But not for variable fields.
Dr McKinlay: No, because the revision of variable fields—well, it seemed rather a long way away because ICNIRP has to wait for the completion of the health risk assessment from the World Health Organisation before it will revise its guidelines. That is part of the ICNIRP process. We look to those very high-level activities within the World Health Organisation, and those have not been published yet.

Q894 Dr Iddon: If I could ask either of you from the HPA; how influential was the work of the group that Colin Blakemore sat on, the Weak Electric Fields Group, in informing the work of, as it was then, the NRPB?
Dr Stather: After the Stewart report that you have heard about which recommended the adoption of ICNIRP guidelines for the public for mobile phone frequencies, we were asked by HSE what was meant by mobile phone frequencies. Out of that discussion we set up a group under Alastair to look at electromagnetic fields, across the whole spectrum. As part of that initiative, we established the group under Colin Blakemore to look specifically at weak electric fields. We produced a consultation document in 2002 that went out to government departments and others and we had an open meeting;[9] so there has been a process of consultation in terms of how we finalised the guidelines that were published in 2004, essentially adopting ICNIRP guidelines for the UK. The key points of the advice we got from government in terms of shaping those recommendations was to clarify where there were uncertainties, which we did, across the whole spectrum, and look at those uncertainties in relation to where further work was needed. We laid that out in the context of the guidelines we produced.

Q895 Dr Iddon: But were you as surprised as perhaps Colin Blakemore was that the work of that group had influenced the formation of the Physical Agents directive?
Dr Stather: Well, we were not aware that it was going to do.

Q896 Dr Iddon: There was no discussion—is that what you are saying?
Dr Stather: In relation to the directive, no. We just set up the group to advise us, educate if you like, NRPB as it was then, in relation to how we shaped the guidelines for the UK.

Q897 Dr Iddon: Does it seem rather odd that an important EU directive is being formulated, based on evidence that a group here has provided; but there is no direct link between the Commission and the group?
Dr Stather: Well, HPA and NRPB as it was is an advisors body. We advise government departments and others on radiation protection matters, and that is as much as we do, and acknowledge the uncertainties, as Colin Blakemore also said, around the guidelines.

Q898 Chairman: You appreciate, John, that what we are trying to do is to find—the purpose of this inquiry is to look at scientific advice to the government and how it gets there and to try to do that audit trail. It is a classic case, is it not, of something that is going to have a significant effect, so that is the purpose.
Dr Stather: Yes.

Q899 Dr Harris: Mr Podger, you said that you thought that the UK had sought to remove MRI from the directive in 2003 in Council.
Mr Podger: I am not sure at which meeting it was but it was certainly tried either in council or a sub-committee of the council.

Q900 Dr Harris: Because we have not had that from the UK representative even though they had every opportunity to tell us, "we are on your side; we are on the side of the people who wanted to remove it"; and indeed we heard from an MEP with a particular interest in this that in the presence of—that the UK had refused to support a proposal to take out MRI from the directive.
Mr Podger: That is not my understanding.

Q901 Dr Harris: Can you provide us in writing with some evidence of the point at which the UK did seek to remove MRI completely from the directive during that negotiation, if it was then, because that is not clear? Minister, the other thing you said which was a little surprising was that the UK effectively opposed the directive as best it could. I understand that some of these things are inevitable with qualified majority voting, but we did hear from Mr Biosca—and it is in the transcript of evidence that I hope you have had a chance to see—that "your comment" on the HSE saying they could find no benefits from the implementation of this directive—"your comment is very surprising when the UK authorities supported the directive in council". That must have jumped out at you, and you must have already instigated a process of correction or written to say, "no, that is wrong". He was there.
Lord Hunt of Kings Heath: Can I ask Mr Podger to answer the specific detail.
Mr Podger: It certainly jumped out at me when I read that transcript, and I thought it was a very disingenuous comment by the Commission, if I may say so. The point, as the Commission are well aware, is that it is normal practice for any Member State to object to something in principle and find that they are outnumbered, to essentially indicate a willingness to go along with the principle of the measure, while seeking to amend it in a way that makes it more acceptable to them. I am quite clear that the Commission understood throughout that period that that was the UK's position. Hence, while it is entirely true as a matter of fact that the UK did not say "we will vote against this" the Commission understood perfectly well what the preference of the

[9] *Note by the witness*: as well as publishing a consultation draft on the web in May 2003.

UK would have been and the reason why it was following this particular course. As I say, it is perfectly normal in Brussels negotiations, as you all know.

Q902 Dr Harris: I accept that. My final point is that he then said: "How about the report of the NRPB in the UK on proposals for limiting exposure to electromagnetic fields?"—which he then described as "proposals for setting limits to exposure"—and it covered the public and workers as well. Do you recognise what he is referring to?
Lord Hunt of Kings Heath: We may have to check that back and write to the Committee but my assumption is that he was referring to the original NRPB guidelines, which were in existence in this country, which I think departs not a lot, if anything, from the UKREP guidelines. Our position is very simple. We felt that there was no need for the directive because we already have these guidelines. We already have the legislation, the parent Health and Safety at Work legislation. We thought that that was sufficient for this country, and that is why we could see no health and safety benefits by adopting the directive.
Dr Harris: That is very clear.

Q903 Chairman: Mr Podger, I am now a little confused about something you said earlier, and I have just gone back through my notes. You said that in terms of the static fields, that was the main thrust of your argument through the Commission to have that area removed, and you were not so bothered about the variable fields.
Mr Podger: No, I think, with respect, what I was seeking to say was that HSE's impression from the other stakeholders with which it was dealing was that once the static fields had been removed, once that had been agreed, that there was not a significant outstanding problem in relation to MRI. That was what was understood by us at the time. As events have subsequently shown, this was erroneous. To try to answer Margaret Moran's earlier question, that was the reason why we did not engage in further consultations on the specific issue.

Q904 Chairman: What surprises me about this—and perhaps the information we got from Dr Keevil needs to be amended—is that from July 2004 the HSE, despite the fact that static fields were removed from the directive, had been stating that they should not have been removed, and that the HSE would seek to enforce it in the UK, because it is in the NRPB guidance. Even as late as 6 June 2005, the HSE will seek to include a 2-tesla static field limit in UK legislation. In other words, HSE, despite having got this out with the Commission, in terms of static fields, is now seeking to put it in as far as Britain is concerned. In other words, we are going to gold-plate this directive when it is not even needed—so can you clarify that?
Mr Podger: Certainly—and I had anticipated this question having been provided with the written evidence!

Q905 Chairman: That is why I provided you with it!
Mr Podger: We are not intending in any way to gold-plate this directive, which the Committee will have well understood by now is not a favourite of the HSE. In particular we are not proposing to in any way re-introduce the static field issue. I have to say to you, Chairman, to be entirely honest with you—and I understand this comment was made by somebody from HSE and is accurately reported in the evidence we have received—that it is not our policy.
Chairman: It is important to put that on the record, and we are very grateful to you.

Q906 Mr Flello: Lord Hunt, in terms of variable fields, has any attempt been made to amend the exposure time for time variable fields, given that this was raised, I gather, by the medical community back in mid 2003?
Lord Hunt of Kings Heath: I think I will refer you back to the answer that Mr Podger has given. It seems from what I have read of what happened that we, the Government, were of the view that the issue was in relation to static fields, and it was thought that with the removal of those levels the problem had been dealt with. As it has transpired, in the view of the Commission we have seen that this is not the case. The intention in the negotiations—one of the fears in the negotiations is that the Commission would adopt even harder levels than was in the ICNIRP guidelines, so that the position that this country took was to try and ensure that the Commission did not go for levels other than the ones in the guidelines. That is the position in terms of the negotiations we were involved in.

Q907 Mr Flello: Would it be perhaps fair to say that even though three years ago the clinicians were saying that there was an issue around the time variable fields, it was almost all or nothing; the thrust was put in trying to get rid of the whole issue around MRI scanners at all, and it was only late in the day when they realised it would not happen, and people started looking at the other issues?
Lord Hunt of Kings Heath: I am not sure I have enough knowledge of the to-ings and fro-ings of the negotiations at that period, but the sense that I have is that although a number of countries wished to remove MRI altogether from the directive, the general feeling around the table was that it having been agreed that the static field levels would be removed, the problem had been dealt with. As far as I am concerned it was only last autumn that I became aware that clinicians had a major problem with what had been agreed. From that, we have taken various actions to see what we can do to sort this problem out.

Q908 Mr Flello: Do you feel that the whole consultation around this issue was badly handled?
Lord Hunt of Kings Heath: Can I say that my general experience of the way the HSE handles consultations is very extensive. I know from work that I have been involved in around the Noise at Work Regulations and the Working at Height Regulations, where they

have got heavily engaged with stakeholders who have had concerns about various aspects of regulations, where they have very extensively worked with them to look at the practicalities of the regulations, to make sure that the advice that runs alongside those regulations is practical. So I believe that the general way of working of the HSE is commendable in terms of the way they deal with stakeholders. However, when it comes to the issue of the people they consulted a few years ago, I would say that the glaring omission from that were the medical royal colleges. You will know that my background is the Health Service, so that is the thing that strikes me. With the benefit of hindsight, it would have been better if HSE had had a more extensive consultation with the medical royal colleges. If they had done, I would hope that these issues would have been raised then rather than last autumn—but again this is with the benefit of hindsight. In general, the Health and Safety Executive is, I believe, good at consultation.

Q909 Mr Flello: Is it fair to summarise that as being 99 per cent of the time they get it right but this one has gone badly wrong?
Lord Hunt of Kings Heath: Clearly, something has happened over the last few years, which has meant that the issue– you have heard from clinicians—has not been fully considered by the Government, and clearly something went wrong with the process. It may well be—and you asked the clinicians that question—that the colleges might have been more active. My experience of the medical royal colleges is that they are not slow in coming forward, and gain ready access to Government departments. It may be that they could have done more as well, but I am not seeking to hide behind that. I do think that the HSE should have consulted more widely with the medical field, yes.

Q910 Mr Flello: Mr Podger, you seem to be nodding in firm agreement.
Mr Podger: I want to put on the record that I entirely agree with what Lord Hunt has said. That is clearly the case.

Q911 Dr Iddon: With nuclear magnetic resonance we have a static magnetic field, and we have concentrated on that this morning throughout this meeting; but we have to sweep the patient with an alternating radio frequency. You do not seem to have commented on the health aspects of that. Is anything known about the alternating radio frequency affecting the health of a patient in a static magnetic field?
Dr Stather: There is not that much information on epidemiology of patients exposed to MRI. As an organisation we have asked for work to be done on a number of occasions over the last ten years. There is not that much concrete evidence. Of course, our advice is about exposure of people not just particular patients, but people as a whole—including people whose work brings them into contact with electromagnetic fields.

Q912 Dr Iddon: The research seems to be being done on the strength of the magnetic field and not the effect of the sweeping radio frequency, which is also necessary to flip the spins of the nuclei, the atoms.
Dr Stather: The advice we produce obviously reviews static and time varying fields to the extent that information is available from epidemiology, but not particularly patients exposed to MRI.

Q913 Dr Harris: Dr Stather, the British Institute of Radiology say they wrote to you in August 2003—indeed, they were advised to write to you expressing their concern about the new guidance; and in our evidence they said they never got a reply. Have you had a chance to look at that assertion in their evidence? Why did they not get a reply?
Dr Stather: That was in relation to the document we put on our website for consultation (in May 2003) about what we were saying about the guidelines. We did not write to individuals; we got many comments that came in but we did not respond to individuals. We put a response document on our website which included the points made by the medical community on MRI. I have a copy I can leave with you, if you wish.

Q914 Dr Harris: That would be helpful. I am grateful for your acceptance that HSE did not consult widely enough. On 25 October 2005 you were asked about this specifically by Lord Oakshott, and your response was: "I assure the noble Lord that the HSE has consulted medical people on a number of occasions during the progress of the directive." Were you unaware of the paucity of the consultation—
Lord Hunt of Kings Heath: That answer was true because HSE can supply you with a list of medical organisations. Clearly, in preparing for the Select Committee I looked very closely into the medical organisations that were invited, and my conclusion, as I said to you, is that I think we should have invited the medical royal colleges. I believe my answer to that question was accurate in the House of Lords.

Q915 Dr Harris: I am not suggesting it was not accurate. Can I turn to the precautionary principle. You will have heard the discussion we had in the previous session. I guess the easiest thing to ask you is whether you have any comment to make particularly in respect to Government policy on the precautionary principle. Do you think the precautionary principle played a part in the evolution of this directive and that an extreme or too-firm version of that has led to some of these concerns? Second, regardless of that, do you think there is work to be done on the precautionary principle even in terms of the way it guides UK policy and negotiations, or at least at EU level?
Lord Hunt of Kings Heath: On the first question, as we learnt, the directive is based on the ICNIRP guidelines so I guess the question that one has to pose is: are the ICNIRP guidelines based on the precautionary principle and—

Q916 Dr Harris: Whatever that is!
Lord Hunt of Kings Heath: Whatever that is. I read the evidence that David King gave to you a couple of weeks ago, which I thought was very helpful in making clear his view that it was an approach rather than a principle. He said that it is an approach in which risks are analysed as best we can; and he said we cannot freeze ourselves into total inaction on the basis of unknowns which prevent us from doing anything new with science and technology. That seemed to me to be a reasonable description of the approach that had been taken. Whether there needs to be more work in this area as far as the UK Government is concerned—clearly, the advice of the Committee will be extremely helpful in that regard. One of the problems of course is that the more precise you make it, you may be boxing yourself in. It seems that there is a trade-off here between a degree of flexibility and a very precise description of what the precautionary principle should be. As far as Europe is concerned, what I particularly would wish Europe to consider is the broader impact of what it is they may be introducing. For instance, what is the trade-off between introducing the directive in this regard if the impact is as the Commission say and you are no longer able to use the procedures in the way you wish to do it—if the alternatives produce more risk for patients and staff, how do you take that into account? The question is, as to whether Europe is in a position to take that into account. I am not sure at the moment if it is sufficient.

Q917 Dr Harris: The Commissioner said when we raised this that you cannot talk about third parties when you are dealing with the protection of workers. That is their view, but you have to deal with the risk benefit in isolation for the workers and it is unfair to subject a worker to risk simply because there may be some benefit to a third party, even though it is a human.
Lord Hunt of Kings Heath: I do not think I necessarily share that view. I think it is much better that we make decisions in the round where you balance off the risks to the various partners in any transaction.
Chairman: To be fair, Mr Spidla is coming back from that hard-line view as well, so hopefully there will be some movement.

Q918 Dr Harris: Dr McKinlay, did you have something to say about ICNIRP's approach on the precautionary principle?
Dr McKinlay: Yes. ICNIRP did not invoke the precautionary principle or precautionary approach in respect of its guidelines. I stated before that it adopted a cautious approach in the interpretation of the science. This is quite different. In fact, we attempted to spell out the HPA's policy and NRPB's policy in this review in 2004. It was referred to earlier—we separated the known adverse health effects. The known adverse health effects in the context of the ICNIRP guidelines were referring to those health effects where we understood what the mechanisms were. The unknown health effects, if you like—to put the converse—is really the issue of carcinogenesis, the issue of cancer. We spelt out very clearly on this—because that is a major concern still in the community as to whether electromagnetic fields can cause cancer; it is one of the major issues with mobile telephony, for example, and rightly so; it has been rigorously examined. This approach in terms of advising the Government that they should consider the need for the precautionary aspects of policy really came about because of the epidemiological evidence on childhood leukaemia from power lines, and it is a very sensible separation of the precautionary approach, the interpretation of the scientific data and the cautionary aspects which I think are policy, and quite rightly the aspect that government should be dealing with. That is ICNIRP's view certainly, and I think the HPA's view.

Q919 Margaret Moran: What specific outcomes of the meeting held on 5 January with MR stakeholders have emerged, and what further work or research is needed as a result of that; and is the Government prepared to support that?
Lord Hunt of Kings Heath: Yes, the sequence of events is that I met with the Royal College in October. That then followed on with a stakeholder meeting at the beginning of January, between HSE and various clinicians with an interest. I subsequently met the college again, and am due to meet them very shortly. They have agreed a series of work programmes, really looking to see what research is available in the areas of concern, and looking at some of the practicalities—the question of whether in fact, if the directive was implemented, to what extent it will be impossible for clinicians to use the techniques they want. It is looking to see what evidence is available, what research needs to be commissioned, and what the practicalities are. At the same time, we encourage the clinicians to talk with their colleagues within Europe. I hope that the result of this work, which is being done together, will produce the evidence base that will then enable us to come to a firm conclusion. As you will have seen from your own considerations and the witnesses you have received, at the moment we are still faced with a disagreement between that expressed by the Commission officials and the clinicians. Everything we do in this area has to be evidence-based.

Q920 Chairman: Is there a time frame, Minister, for that?
Lord Hunt of Kings Heath: I do not know. I can certainly write to you about the various time frames involved. Clearly, though, we want to get on with this as quickly as possible, in terms of the UK; but also we want to encourage the European working group that has been agreed, which happily is now going to meet in June to get on with this work as quickly as possible. I do not know whether Mr Podger can help with the time lines on this.
Mr Podger: No, I am afraid I cannot. Various meetings are going on currently. I may say the outcome of the 5 January 2006 meeting is available on the website, and we are more than happy to give it to you as a published document.

Q921 Margaret Moran: You have admitted the omissions, particularly in relation to the royal colleges, but what involvement has there been in discussions directly with the Government Chief Scientific Adviser, the Chief Scientist at HSE and the Chief Scientist at the Department for Health? Why did the Department for Health not relay any concerns at an early stage?

Mr Podger: As I understand it—and I think this would be normal—in these kinds of specialist issues you would not normally expect to ask the Chief Scientist or the Chief Scientific Adviser. We are talking about the specific issue, I assume, of people who need to work closely with magnetic resonance imaging to assist the patient or in some way intervene. As I indicated before, that issue was not picked up at the time, which was the difficulty and it was from that that the failure to consult came. In general terms, specialist issues on directives would be considered by HSE with the relevant public bodies, which was done by colleagues in the HPA, and it would also be considered with the relevant stakeholders.

Q922 Margaret Moran: So you would not normally consult with the Chief Scientific Adviser or—

Mr Podger: No, in terms of seeking to understand the implications of the directive and the extent to which they were acceptable, we would normally consult with both other public bodies that had a specialist role, and we would also seek to consult with stakeholders who had an interest.

Lord Hunt of Kings Heath: A letter was sent by a number of clinicians to Patricia Hewitt, the Secretary of State for Health, last autumn. I received a copy of that, so I was aware of that communication. Secondly, of course if one takes the work stream we have now put into practice, which will come to a conclusion at some time in the future, it is of course very much open to me, as the minister concerned, to seek wider advice, and I am always prepared to do that. My hope is that we will reach a conclusion that everyone can sign up to, which will then inform what we do in relation to Europe. Clearly, if there continues to be disagreement, it is very much open to me to decide to seek further advice.

Q923 Margaret Moran: Given the time, perhaps you would like to write to us on this, but clearly you have admitted that this process has not been without severe flaw. In fact, the whole thing seems to be rather bizarre in terms of the audit trail between the research emanating from one point and ending up as a directive at another. In that context there must be lessons to be learned in respect of how scientific advice is used by the Government to inform negotiations on EU directives. Can we ask you to respond in writing to that on specific lessons that will be taken into account by the Government in the future?

Lord Hunt of Kings Heath: I am very clearly of the view that we need to learn lessons here, but I must say that the position of the Government is that it did not want this directive. It took the view that it would negotiate to get as acceptable a position as possible, but we thought we had done so with the various changes that were made, including the removal of the static levels. It transpired later that this particular issue around MRI that the clinicians had brought forward had not been dealt with effectively. The most striking issue that comes forward is that if we had been aware that this was likely to be a major problem, I am sure we would have taken earlier action; but of course we do want to learn from this, and we will listen very considerably to the recommendations of the Committee.

Chairman: On that note, Minister, can I thank you for being so frank with us this morning. It has been a useful session. At the end of the day the job of this Committee should be to improve the process, not simply to find fault, and hopefully we will do that. Thank you very much indeed, Mr Podger, again for your frank views. Thank you, Dr McKinlay—it is nice to meet you at last. Dr Stather, thank you again for your input.

Written evidence

APPENDIX 1

Memorandum from the Health and Safety Executive

THE USE OF MRI EQUIPMENT: THE EU PHYSICAL AGENTS (ELECTROMAGNETIC FIELDS) DIRECTIVE

Executive Summary

HSE has implemented Government policy on restriction of exposures to Electromagnetic fields (EMFs) in a consistent and proportionate manner for many years. Government policy has been developed after careful consideration of the conclusions of national and international reviews of the scientific evidence of harm. HSE and the Department of Health have led the move to share information and ensure a joined up approach across all Government Departments and associated organisations providing a strong basis for restriction of exposures to EMFs.

Introduction

1. The Health and Safety Executive (HSE) is a non-departmental public body with specific statutory functions in relation to health and safety, which reports to the Health and Safety Commission (HSC). HSE receives scientific advice on matters of radiation protection from the Radiation Protection Division of the Health Protection Agency (HPA-RPD), which has a statutory duty to advise the Government, and from other sources. HSE employs a number of Specialist Radiation Inspectors who review the advice and work with policy colleagues to decide the best use that can be made of it.

The EU Physical Agents (Electromagnetic Fields) Directive and Magnetic Resonance Imaging

2. The Electromagnetic Fields Directive, to be transposed into law by April 2008, is based on international guidelines for restrictions on exposure to EMFs. These guidelines, designed to prevent the onset of adverse acute effects on health, have also been adopted by the HPA who, following their reviews of the scientific literature, consider that they provide the appropriate level of protection for people.

3. The Directive applies to all workers who are exposed to EM fields including those using magnetic resonance imaging (MRI) equipment. During negotiations on the Directive, the Council and the European Commission took account of concerns expressed by representatives of the electro-medical equipment manufacturers and others that, pending further international reviews of the science, the ELVs should not include static magnetic fields.

4. More recently, concern has been expressed by those engaged in MRI related work that the Directive is likely to have an adverse impact on the continued use of MRI equipment with current specifications, this effect being particularly severe in the healthcare sector. The practitioners argue that during either diagnostic scanning or interventional treatment of patients, they are likely to be unable to comply with the applicable ELVs during certain modes of operation. This, they argue, may prevent them from using this technique. Their arguments also extend to questioning the strength of the scientific evidence upon which the ELVs are based, together with a view that adverse effects are not experienced when these are exceeded.

5. HSE has considered these views and held a meeting of stakeholders to discuss the issues on 5 January 2006. It took place in conjunction with the Department of Health (DH) and the Medicines and Healthcare products Regulatory Agency (MHRA) and was chaired by a senior HSE official assisted by an independent facilitator. It was a positive meeting at which all stakeholders had an opportunity to express concerns. HSE officials are now considering what action to take to address the issues raised and progress implementation in partnership with key stakeholders. A report of the meeting will be placed on HSE's website.

Sources and Handling of Advice

What impact are departmental Chief Scientific Advisers having on the policy making process?

6. Evidence based policy is an essential part of HSE's core business and pivotal to the achievement of its PSA targets. The HSC Science Strategy 2005–08 sets out how HSE will apply science to provide a sound evidence base to help deliver the HSC's vision and mission to protect people's health and safety by ensuring that risks in the changing workplace are properly controlled. See: http://www.hse.gov.uk/science/strategy0508.pdf. The Chief Scientist is responsible for HSE's science policy and direction and is committed to ensuring that its policies are based on the best available scientific advice, in line with the recently revised Government Chief Scientific Adviser's (GCSA's) "*Guidelines for the use of Scientific Analysis in*

Policymaking", 2005. HSE has produced a statement for the implementation of these Guidelines at: http://www.hse.gov.uk/science/gl2000res05-04.pdf. The Chief Scientist monitors, annually audits and reviews implementation of the Guidelines, ensuring that they are assimilated into HSE practice and that the principles are widely understood and applied. As a member of the HSE Board, the Chief Scientist is also able, where appropriate, to advise the Board on the significance, validity and use of scientific advice provided to the policy makers.

7. HSC receives integrated scientific and technical policy advice from some Subject Advisory Committees, which comply with the GCSA's *Code of Practice for Scientific Advisory Committees*. See: http://www.hse.gov.uk/aboutus/hsc/iacs/index.htm.

What is the role of the Government Chief Scientific Adviser in the policy making process and what impact has he made to date?

8. The Office of Science and Technology will discuss the role and overall impact of the GCSA. HSE has valued the GCSA's role in independently assessing its performance in obtaining and using scientific evidence in sensitive areas of policy making, eg Asbestos regulations.

Are existing advisory bodies being used in a satisfactory manner?

9. The responsibility for the way that medical equipment is used rests with the individual healthcare providers within the overarching general advice and guidance provided by DH or agencies such as MHRA. HSE has regulatory oversight of compliance by employers with the relevant health and safety legislation and recognises the need to work closely with MHRA on specific safety issues. This is consistent with HSE's policy of using existing and relevant bodies where appropriate rather than creating new ones. In 1993 a forerunner of the MHRA prepared "*Guidelines for Magnetic Resonance Equipment in Clinical Use*". This was revised in 1997, and again in December 2002. The medical professional bodies (Institute of Physics & Engineering in Medicine, Royal College of Radiologists, British Institute of Radiology, College of Radiographers, British Association of MR Radiographers) were all represented and consulted during the drafting process. A manufacturers' trade association was also consulted. The National Radiological Protection Board (now HPA-RPD) and HSE also participated. MHRA have indicated that they intend to review this publication in 2006–07. HSE intends to participate in this review.

Are Government departments establishing the right balance between maintaining an in-house scientific capability and accessing external advice?

10. HSE's in-house science and engineering capability (approximately 25% of staff numbers) is used to support the development of policy, to make regulatory judgements on the acceptability of risk controls in technically complex industrial environments and to investigate incidents arising from the failure of those controls. This in-house capability includes the Health and Safety Laboratory (HSL), and in-house agency of HSE with 250 scientists and engineers who carry out high quality research and forensic investigation work. External expertise is used to meet short-term shortages, provide expertise for which HSE has no long term need, especially in the investigation of major incidents, and provide independent scientific advice on particularly complex issues.

11. HSE regularly reviews the use it makes of science. The most recent of these reviews reported to the HSE Board in 2004. This review looked both at the level of support HSE's businesses required from science and the make-up of that science. It concluded that, whilst the overall proportion of resource dedicated to science was broadly right, HSE needed to increase its Social Science and Human Factors capabilities balanced by some reduction in its engineering capability. Changes in demand for support had already brought a substantial expansion of HSL's social science group and a decline in its Fire, Explosives and Engineering groups.

12. The balance between the use of external and internal specialist expertise is also subject to scrutiny. Whilst in the past it would have been the norm for guidance on industry good practice to be prepared by HSE it is now becoming more usual for the work to be undertaken by an industry working group with input from HSE.

13. Traditionally HSE has made limited use of external science in its frontline activities because of the inability of external experts to make regulatory judgements. However, this position is being reviewed in a study that seeks to draw on the experience of other government departments and private industry organisations.

14. As well as using external expertise directly, HSE's specialists maintain strong networks with industry and academia, exchanging information and research findings, and exploring ways of improving risk control methodologies.

Relationship Between Scientific Advice and Policy Development

What mechanisms are in place to ensure that policies are based on available evidence?

15. HSE is in the unique position of having a first rate scientific staff, comprising almost 800 in-house specialists across a very broad range of disciplines, under the same command as those responsible for policy-making and delivery. HSE has organised its specialists to facilitate the provision of effective support and thereby ensure that policy and delivery plans are based on sound science. For example, the successful development of HSE's Management Standards for work-related stress depended on a robust scientific understanding of the causes of stress at work. To ensure this happened, a team of HSE's Occupational Psychologists were fully integrated into the policy development team for the duration of the Standards' development. A key aspect of the development of the Management Standards was a series of workshops specifically aimed at canvassing the expert views of scientists and practitioners working in the field of occupational stress.

16. HPA-RPD has a statutory function of providing scientific advice to Government on radiation matters and HSE's specialists act as the route by which this advice is incorporated into HSE policy-making. In formulating its advice the HPA adopts a multi-faceted approach consisting of extensive reviews of the scientific literature, workshops with invited experts to address specific issues and consulting with the wider scientific community. The output is made freely available on their web site. The resulting draft advice is then considered within HSE and as appropriate by other Government Departments (OGDs) and attention is drawn to apparent gaps or lack of clarity. This process of consulting fully and widely ensures that the advice from which policies are derived is based on the available scientific evidence.

Are departments engaging effectively in horizon scanning activities and how are these influencing policy?

17. HSE has set up a horizon scanning system to systematically anticipate, identify and prepare for new or changing risks. The system is looking ahead three to 10 years to inform strategic thinking, planning and decision-making. It encompasses the full range of social, behavioural, scientific, technological, political and economic issues related to workplaces and work activities. HSE also participates in appropriate DTI Foresight initiatives; especially the recent programme "*Exploiting the Electromagnetic Spectrum*".

18. HSE commissioned HPA-RPD (formerly NRPB) in 1993 to produce a report on the potential impact of the first proposals for a Physical Agents (EMFs) Directive. This report and subsequent addendum to take account of changes proposed by the European Commission in August 1994 was published as NRPB R-265. The probability of a revived proposal for a Directive on EMFs adopting international guidelines was anticipated by HSE in 2001 and HPA-RPD was again commissioned to review the published evidence to indicate potential impact on UK industry. Their report was published in September 2002 (NRPB W24).

19. HSE part sponsored an International Workshop (hosted at HPA-RPD in April 2004) to look at the fundamental science of interactions of the large static magnetic fields employed in MRI systems with people. The identified gaps in knowledge have been incorporated into a revised Agenda for Research published by the WHO International EMF Project.

Is Government managing scientific advice on cross-departmental issues effectively?

20. In 1994 an Interdepartmental Liaison Group was established to ensure the effective discussion of cross-departmental issues on non-ionising radiation. This forum comprises officials from OGDs, the devolved administrations, HPA and other regulators (eg Ofcom and Ofgem). It is a good example of joined up Government and one that allows the sharing of information and consideration of scientific advice. For MRI, regular discussions have taken place between HSE, DH and the MHRA. This has ensured the consistent and effective application of scientific advice, and HSE's development of policy has taken OGD's views fully into account.

Treatment of Risk

Is risk being analysed in a consistent and appropriate manner across Government?

21. HSE played a leading role in the Government's Risk Handling Improvement Programme and is maintaining strong contacts with OGDs to develop consistent risk analysis and management tools and methodologies.

22. The current sensible risk management debate and revision of publications such as "5 Steps to Risk Assessment" are opening up issues to the public and risk analysis professionals. This should ensure that the issues are thoroughly discussed, and result in the development of high-level sensible risk management principles endorsed by the wider health and safety and risk management communities.

23. HSE's guidance for inspectors and other staff to assess whether risks have been reduced as low as reasonably practicable (ALARP) has been publicised internally, and made publicly available through its website.

Has the precautionary principle been adequately defined and is it being applied consistently and appropriately across Government?

24. Through its central role in the UK Interdepartmental Liaison Group on Risk Assessment (ILGRA), HSE led on producing a document[1] that defined and analysed the use of the precautionary principle. This work was passed to HM Treasury when ILGRA was disbanded in favour of the structures set up under the Risk Handling Improvement Programme.

25. HSE's policy and practice on using the precautionary approach in addressing hazards subject to high scientific uncertainty is published in its decision making framework document "*Reducing Risks, Protecting People*".

How does the media treatment of risk issues impact on the Government approach?

26. Specialist journalists, including those in the national media, tend to provide balanced and accurate coverage, but when stories become headline news the effect of sub-editors and other non-specialists can be unpredictable. The media imperative to gain readers/viewers can lead to coverage becoming unbalanced. This is not always the case, for example, current coverage of the Buncefield fire is, in many instances balanced, but it creates problems when coverage is slanted to create a "good" story.

27. Where this happens criticism may be levelled at the regulator/government and it becomes necessary for government to present a balanced view to ensure that proportionate action can be taken. Media coverage may sometimes either exaggerate or be dismissive of incidents or issues, which may lead to public over-reaction, or when issues are played down, make appropriate action difficult because the public do not take it seriously. In circumstances where public/stakeholder cooperation is necessary balanced media coverage is important.

28. Unbalanced media coverage of health and safety issues and incidents, linked with popular accounts of the "success" of a compensation culture can lead to employers or others being excessively risk averse and bureaucratic in their approach. Engaging directly with journalists to ensure they clearly understand risk issues or appreciate the parameters in which risk is properly considered, demands considerable Government resource. HSE has specifically committed resource to communicate effectively the case for sensible health and safety controls, and promoting the management of risk, not its elimination.

Transparency, Communication and Public Engagement

Is there sufficient transparency in the process by which scientific advice is incorporated into policy development?

29. HSE's aim, when formulating its approach to address a new problem or policy issue, is to make all stakeholders aware of its plans. Diverse mechanisms are used, including both formal and informal meetings with key sectors, trade organisations, small and medium enterprises, employees and pressure groups and all those likely to have an interest in the issue. As well as setting out its ideas, HSE invites views and takes these into account. Where appropriate, HSC will also publish consultation documents. These describe how HSE intends to use scientific advice and provide consultees with the opportunity to comment. This process also embodies an internal challenge on account of HSC representing a wide range of informed stakeholders. The nature of received comments is also made freely available to enable consultees to see the extent and the way in which these have been incorporated into the policy making process. The HSC holds its meetings in public and HSC papers and the minutes of its meetings are posted on the HSE web site wherever possible. In summary, HSE adopts a policy of complete openness.

Is publicly-funded research informing policy development being published?

30. HSE's policy for the implementation of the CGSA Guidelines on the Use of Scientific Analysis in Policy Making is that all research findings involved in the process of decision-making are published and publicly available on HSE's website free of charge. HSE's science web pages, which were redesigned in Autumn 2003 and are continually updated, are at: http://www.hse.gov.uk/science/index.htm. They provide access to technical reports produced from HSE research as well as a projects directory for work commissioned since 2001. Feedback on projects commissioned is welcomed and the directory enables users to comment on the work being undertaken. Research reports available on HSE's website include CRR 226 (1999) "*Assessment and management of the exposure of workers to electromagnetic fields in the workplace*" and RR 338 (2005) "*Measurement and analysis of magnetic fields from welding processes*".

[1] This document "*The Precautionary Principal: Policy and Application*" was published on the ILGRA website at Ministerial agreement. http://www.hse.gov.uk/aboutus/meetings/ilgra/pppa.htm#2

Is scientific advice being communicated effectively to the public?

31. A new e-newsletter, HSE Science and Research Outlook (http://www.hsesro.com/), provides information on all aspects of HSE's science programme together with an opportunity for public comment. Alongside the newsletter, foresight reviews will be published and comments invited from stakeholders.

32. HSE's Infoline provides the public with a readily accessible source of technical advice on general health and safety issues. Statements may be prepared, with input from appropriate HSE specialists, in anticipation of events that may raise public awareness of an issue. When issues arise through the media, information sheets will be prepared for use by both Press Office and Infoline. Detailed technical support is provided to answer complex or obscure questions. Informal feedback from users of Infoline supports its effectiveness.

Evaluation and Follow-up

Are peer review and other quality assurance mechanisms working well?

33. HSE works with other partners and stakeholders as part of its process to quality assure research outputs. Processes, which are proportionate to the particular projects, range from internal review through to external peer review, presentations, workshops and publications in peer-reviewed literature. Formal peer review of outputs from individual projects or groups of projects is undertaken where relevant. However, although valuable, much of this external input is received at the end of research projects and HSE aims to establish better mechanisms for involving academic and professional institutions at the beginning of the process, eg constructive partnerships to assist in the development of more coherent programmes of research. HSE's Competition of Ideas exercises provide a mechanism to present broad issues (or specific policy questions) to the research community who are invited to put forward proposals.

34. The Chief Scientist manages HSE's science budget in accordance with business needs and priorities, exercising an appropriate challenge function with regard use of public funds, competition, etc. Owing to the nature and breadth of HSE's work, it is not appropriate to establish standing external review arrangements for proposal appraisal. The requirement for peer review is notified at the proposal development stage and detailed on the Project Record Form. Details of newly commissioned research work are posted on HSE's research project directory, that allows for comments to be attached. In respect of the current case study, a project entitled "International expert workshop to review the interactions of static magnetic fields relevant to possible adverse health effects in people" was hosted by HPA-RPD) and was reported in a focussed issue of *Progress in Biophysics & Molecular Biology*, Vol 87, Nrs 2-3, Feb/April 2005. Links are provided to outputs from completed projects at:
http://www.hseresearchprojects.com/ProjectSearch.aspx.

35. HSL undertakes periodic audits involving international teams of renowned scientists to assure the quality of its science. The reports of these science audits are published on the HSL website.

What steps are taken to re-evaluate the evidence base after the implementation of policy?

36. HSE adopts various approaches, eg, by participation in scientific fora both at European and global level it can identify early warnings on possible changes to the fundamental evidence base or if new risks appear. HSE also liases with officials who attend meetings such as Cooperation in Science & Technology organised by the European Commission.

37. HSE and DH have been key sponsors of the WHO International EMF Project from its inception in 1996. A programme of international technical seminars reviewed the published research database and identified critical gaps in knowledge. A WHO agenda for research was published that has acted as a priority list for funders. Many current research projects worldwide are now assessing the health risks from exposures to the different regions of the electromagnetic spectrum. Any changes in scientific understanding will lead to a review of decisions to ascertain whether existing policy needs amendment.

January 2006

APPENDIX 2

Memorandum from the Health Protection Agency

MRI Equipment: The EU Physical Agents (Electromagnetic Fields) Directive

I understand the Scientific and Technology Committee is to review scientific advice and policy related to the use of MRI equipment and the EU Physical Agents (Electromagnetic Fields) Directive. I am writing to you as I have Directorate responsibility within HPA for work on non-ionising radiation. This includes exposures to electromagnetic fields (EMFs).

We are aware of the concern that has been raised by the medical community about the Physical Agents Directive and its implications for the use of MRI equipment. The issues raised related to the high level static fields and also time-varying electromagnetic fields that medical staff could be exposed to when using the equipment. The concerns relate to the guidelines in the Directive, which largely derive from those recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP). The lead departments for UK input to the Directive were the Department of Health (DH) and the Health and Safety Executive (HSE).

In May last year, NRPB (now the Radiation Protection Division of the HPA) recommended the application of the ICNIRP guidelines across the UK for EMFs in the range 0-300 GHz. This followed an extensive review of the scientific information underpinning the guidelines and a consultation exercise on our web site. The advice and a review of the main issues raised during the collaboration are available on the HPA web site:

Advice—http://www.hpa.org.uk/radiation/publications/documents_of_nrpb/abstracts/absd15-2.htm

Scientific Review—http://www.hpa.org.uk/radiation/publications/documents_of_nrpb/abstracts/absd15-3.htm

Consultation Response—http://www.hpa.org.uk/radiation/publications/w_series_reports/2004/nrpb_w59.htm

As a result of the concerns raised by the medical community about the use of MRI and questions raised by Ministers, HPA posted on its web site an Information Sheet on MRI-EC Physical Agents Directive. This summarised the issues that had been raised and the requirements of the EC Directive. It also detailed exposure limit values, covered MRI exposures and recent work on exposure guidelines by ICNIRP and HPA as well as the roles of the HSE and the Medicines and Health Care Products Regulatory Agency. We received comments that the Information Sheet had been helpful to officials in Government Departments in briefing Ministers.

Responsibility for controls on occupational exposure to EMFs lies with the HSE and we received information on 23 October 2005 that the organisation was to set up a Forum to discuss the issues raised by the medical community on the use of MRI and the implications of the Directive. The meeting will be on 6 January 2006. We will be represented by Dr Alastair McKinlay, Head of the Physical Dosimetry Department, who led the development of NRPB/RPD advice on EMF exposure guidelines as well as being Chair of ICNIRP up to May 2004. He will be accompanied by Mr Steve Ebdon-Jackson who is responsible for the Intentional Medical and Environmental Exposure Department (IMEEx) and Dr Rick Saunders, the Group Leader in Radiation Effects Department, who has been responsible for much of the work we have done reviewing health effects of exposure to non-ionising radiation. Mr Arwel Barrett has the lead for HSE.

I give below the link to the Information Sheet on our web site and also attach a Word file.

http://www.hpa.org.uk/radiation/understand/information_sheets/mri_ec_directive_2004_40_ec.htm

If you need any further information or copies of the reports referred to in the Information Sheet, I will be able to provide them for you.

November 2005

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APPENDIX 3

Memorandum from Dr Alan M Calverd

Introduction

I write in my personal capacity, but with the particular experience knowledge and interest acquired in my capacity as the EU Authorised Representative for the FONAR Corporation, Melville, Long Island, USA, and as Technical Manager of one of its customer Companies operating clinical MRI systems in the UK.

In view of the short time available to me for comment, these notes have been prepared in good faith but have not been cleared by FONAR or any other Company or group with which I am associated. They represent my personal opinion only.

The Future of Interventional Radiology

I have been privileged to work in the past with Prof Louis Kreel and a number of other innovators in the field of realtime x-ray-guided surgery and angioplasty. The benefits of these minimally intrusive, low-risk and low-cost procedures compared with open surgery are manifest, and they have taken their place in the routine armamentarium of most hospitals.

The next logical stage in the development of such procedures is clearly to explore the benefits of MRI, which permits better visualisation of soft tissues without the use of toxic contrast agents, and can be used to characterise the chemical status of a region infused with a cytotoxin, or the physical state of a polymerising resin. In principle this allows us to, say, precisely ablate a tumour with negligible damage to surrounding tissues, or to effect exquisitely controlled repairs of fractured or collapsed bone.

Britain at the Leading Edge—for Now

The key to image-guided interventions is the ability of the surgical team to access the patient close to the surgical site, and to carry out anaesthesia and intraoperative monitoring safely and efficiently. To this end, FONAR have developed the OR360 "operating theatre in a magnet", currently the only MRI system that allows unrestricted access to the patient, and among the most powerful (thus fastest and most precise—ie safest) open MRI systems on the market.

The first commercial OR360 in the world is now nearing completion at the Oxford Nuffield Orthopaedic Centre, where it will be used, with considerable support from the manufacturers, to explore its potential for high-throughput routine imaging and in truly "hands on" interventional procedures. ONOC was particularly favoured for this work on account of its established reputation in orthopaedic radiology and the unique enthusiasm and expertise of its clinical research and development teams.

Development of intraoperative imaging in this, the likely precursor of a new family of MRI equipment, clearly encourages operators to work close to and even inside the primary magnetic field and gradient fields, which are confined between the pole pieces above and below the patient. The optimum positioning of, say, a surgeon's hand, is determined by the patient's anatomy: there is no substitute for tactile sensation in medicine, and the OR360 uniquely permits the combination of direct contact through a surgical tool, with the ability to visualise anatomy and chemistry deep inside the patient.

The proposed EU restriction on operator exposure to time-varying gradient fields will severely restrict the scope of work that can be legally done in such machines, and will place severe limits on the development of both the equipment and its applications. I fear that clinical research in interventional MRI will be effectively curtailed in the UK, and British patients will be denied the benefits of those techniques that have been developed. If the future of close-contact interventional MRI in the UK is is doubt, there seems little point in putting the machine into use at all, and several million pounds of NHS capital expenditure may as well be written off before it is switched on.

Critique of the EU Directive

The "precautionary principle" is, *reductio ad absurdam*, the antithesis of any form of progress or innovation. It is an anomalous basis for legislation in a rational society that generally prefers evidence to superstition or ignorance, and it sits ill with the British courts' insistence on proof of actual harm in determining real cases. Until the 20th century, no human had been subjected to an acceleration in excess of 1g, or travelled faster than a horse. Adoption of the precautionary principle in, say, 1900, would have prevented the development of the aeroplane or the motor car.

The supposed basis of the Directive's exposure limits to time-varying magnetic fields is an arbitrary multiplier applied to a reported threshold for some subtle, transient physiological effects. If the same arithmetic were applied to such transient effects as hearing or vision it would be illegal to speak or switch on a light.

A familiar transient physiological effect, such as vision, hearing or the sensation of touch or temperature, is not a health hazard. A novel transient physiological effect cannot be considered to be a health hazard unless it has been shown to be detrimental to health, or some plausible mechanism of potential harm can be adduced from our present knowledge of physiology. Simply because *homo sapiens* has not been exposed to time-varying magnetic fields in the historical past is no reason to suppose that they are a danger to health now, and there is no evidence from the last 30 years of magnetic resonance imaging that gradient fields have harmed any operator to date.

It is not clear what authority a free trade organisation like the European Econmomic Community has to prevent the development and application of interventional MRI in the UK.

January 2006

APPENDIX 4

Memorandum from the British Chapter of the International Society of Magnetic Resonance in Medicine

I am writing on behalf of the British Chapter of the International Society of Magnetic Resonance in Medicine to endorse the Joint Submission forwarded to you by Dr Stephen Keevil, on behalf of a number of Scientific and Professional bodies. This details many aspects of the development of policy regarding occupational exposure to Magnetic Resonance devices.

I would like to note that much of the basic research and early development underlying this major medical diagnostic resource occurred in Britain. In the early stages of introducing this new instrumentation into clinical use, the NRPB developed, in close consultation with the magnetic resonance (MR) community, some very useful guidance that stood the field in good stead for many years. This particularly concerned exposure of patients and volunteers, but also helped define issues that might be of concern to staff. Quite rightly at that time it was conservative, and limits were set at precautionary levels. In that and subsequent revisions it included guidance that balanced benefit against risk, and dealt with substantial health effects that might be damaging to a patient's health, rather than with the emphasis of the current European Physical Agents Directive on effects that give rise to perceived sensations, with no evidence that these lead to health effects.

Unfortunately, as you will see from the Joint Submission, there has been very little active consultation with the MR community in the UK in the preparation of these new occupational standards and legislation. This has resulted in a Directive with limits based on considerations of phosphene induction providing a model for adverse effects on the nervous system. Such a perceived effect does not, however, equate with any short or long term harm to the individuals. At higher exposure levels a better characterised effect, peripheral nerve stimulation (PNS), has been observed in many patients and volunteers. Even though the threshold for PNS occurs at current densities some 100 times greater than the limits in the Directive, the sensations can be acceptable to both volunteers and patients, and, again, are not known to result in any long term effects. Staff performing interventional procedures have been able to perform delicate motor tasks in the presence of the switched fields, for the benefit of patients, and prohibiting such tasks will have a range of detrimental effects for both patients and staff.

With this Directive being enforced, interventional procedures now being employed increasingly under MRI control would need to be substituted by the older techniques using X-ray monitoring, which deliver a radiation dose to both patients and staff. For staff, who perform repeated procedures, these doses are cumulative. While in the regulations governing the use of radiation, there is an appreciation of benefit to society that can be balanced against potential harm to the worker, similar considerations do not appear to apply to non-ionising radiations, where the potential hazards are much lower, albeit less well documented. Thus in order to reduce a non-documented potential risk from non-ionising radiation, both staff and patients will suffer an increased radiation dose, contrary to the general obligation to reduce individual and population radiation doses wherever possible. It is a matter of concern that none of the bodies involved in preparing either safety recommendations or legislation appear to have any obligation to consider the balance of personal risk against benefit to society.

The Directive will prohibit staff supporting patients (often anxious individuals or children), and anaesthetists supervising patients (often children) who need to be sedated during scanning from performing these operations close to the scanner, which could compromise the scanning procedure, or observation and monitoring of the sedated patient.

The Directive implements a concept of health for the worker that is absolute (based on World Health Organisation definitions), and deals only with short term perceived effects without consideration of the worker's ability to balance these effects against the value of the task undertaken. It also takes no account of the social benefit of the task, and a balance of the individual's exposure and society's benefit. In health employment it is common to accept certain hazards, whilst controlling these very carefully, for the benefit of the individuals treated.

Interventional use of MR is a growing area that has potential benefit in a range of diseases, where the detailed local anatomy, the potential to obtain information on the functional status of tissues, and the lack of ionising radiation exposure offer obvious benefits. While much emphasis is currently on vascular techniques, the rapid development of new scanner technology aiding access is likely to lead to a wider range of operative procedures, biopsies, and minimally invasive therapies, all under the interactive control of a skilled operator. It is unlikely that automated approaches to these interventions will replace direct manipulation close to the magnet for some considerable period. Prohibiting these developments will adversely affect health research and practice in the UK.

It is important to record that the magnetic resonance community has a major commitment to the safety of all involved in the use of magnetic resonance. This is effected through scientific meetings and publications, identifying good practice, and participating in the development of guidance, standards and regulations. Based upon our experience of staff and patient exposure, we feel that the Directive will limit the benefits of this technology, with no evident staff benefit.

January 2006

APPENDIX 5

Memorandum from the British Institute of Radiology

I am writing on behalf of the British Institute of Radiology, which is an interdisciplinary society bringing together the professions involved in the application of radiation and other methods of diagnostic imaging in medicine, to improve the detection and treatment of disease.

In 2003 the Institute became aware of a proposal for a new European Directive that would restrict occupational exposure to electromagnetic fields, in the process creating significant difficulties for a number of aspects of Magnetic Resonance Imaging (MRI) in clinical practice and research. The proposed limits were based on hypothetical rather than established adverse effects on health, yet the effect would be an increase to both staff and patient exposure to the well-established hazards of ionising radiation from alternative, X-ray based imaging techniques.

The chair of our MRI committee wrote to the Health and Safety Executive in July 2003 pointing out the shortcomings of this proposal. It was quite a detailed letter, setting out the scientific case and potential impact quite clearly, and was co-signed by five of the UK's most eminent MR scientists and clinicians.

In reply the HSE said that our concerns were "misdirected" and suggested that we should contact NRPB, the body responsible for UK guidelines on EMF exposure. They also said that our views would be kept in mind when the Directive was considered at the European Social Questions Working Group.

The same group of scientists and clinicians wrote to the NRPB on behalf of the Institute in August 2003. This was at a time when NRPB was consulting on revision of its existing guidelines on EMF exposure, and so appeared to be quite timely. We have never received a reply to this letter, and the new guidelines published by NRPB in 2004 did not reflect our concerns.

Subsequently the magnetic resonance community repeatedly tried to influence negotiation and implementation of the Directive, but the HSE told us that it is constrained by the NRPB guidelines. These guidelines are based on precautionary interpretation of very sparse data, and explicitly do not address the issues involved in specific exposure situations (such as medical imaging). This calls for application-specific risk-benefit assessment, which the Directive does not allow as it contains absolute exposure limits that apply regardless of context. No agency appears to be responsible for interpreting the NRPB guidelines in the light of other factors and advice.

The Institute has contributed to the joint submission to the inquiry from the MR community, which sets out the scientific issues and the issues around consultation and handling of scientific advice. We hope that these comments will be of help to the Committee, and would be happy to provide further advice and assistance if required.

January 2006

APPENDIX 6

Memorandum from the Royal College of Radiologists, the British Institute of Radiology, the Institute of Physics, the Institute of Physics and Engineering in Medicine, and the British Chapter of the International Society for Magnetic Resonance in Medicine

1. Executive Summary

1.1 The Physical Agents (Electromagnetic Fields) Directive contains occupational exposure limits that would restrict the use of MRI equipment, with damaging consequences for medical treatment and research. In particular, it could prohibit interventional MRI, a new technique that may replace X-ray guided procedures, improving treatment and eliminating ionising radiation hazards to patients and staff.

1.2 The exposure limits, presented as thresholds for "known short-term adverse effects", are based on extremely cautious, in effect precautionary, interpretation of limited scientific data. The same limit values were recommended for use in the UK by the Health Protection Agency (HPA) in 2004, but more accurately described by the Agency as "a cautious approach . . . to indicate thresholds for adverse health effects that are scientifically plausible".

1.3 Against this, around 400 million patients have been imaged using MRI, with no evidence of adverse effects at the EMF exposure levels indicated in the Directive.

1.4 Negotiation of the Directive on behalf of the UK was the responsibility of the Health and Safety Executive. The HSE relied excessively on a single source of advice—the HPA guidelines—ignoring the nuances in that advice and resisting input from the MRI community. The community repeatedly indicated shortcomings in the scientific evidence and the likely impact of the Directive, but it was necessary to go to the press and to ministers before our concerns were taken seriously. The HSE and government are now seeking a solution, but options are limited as the Directive has been adopted and the UK is obliged to implement it.

1.5 In this memorandum the MR community addresses the questions posed by the Committee by highlighting how failings in the treatment of advice, handling of evidence and understanding of risk have led to this situation. The memorandum also makes reference to the failings of the proposals themselves, to show that the case advanced by the community was well substantiated and strongly argued, which is relevant to consideration of whether external advice was sought or acknowledged.

2. Introduction

2.1 *The Submitting Organisations*

2.1.1 *The Royal College of Radiologists (RCR)* is the professional body for clinical radiologists and oncologists in the UK. It is established by Royal Charter as "an authoritative body for the purpose of consultation in matters of public and professional interest concerning clinical radiology and clinical oncology".

2.1.2 *The British Institute of Radiology (BIR)* is a multidisciplinary learned society, bringing together the professions involved in radiology to share knowledge and improve the detection and treatment of disease.

2.1.3 *The Institute of Physics (IOP)* is a membership organisation devoted to increasing the understanding and application of physics. It has a worldwide membership of over 35,000, and is a leading communicator of physics with all audiences from specialists through government to the general public.

2.1.4 *The Institute of Physics and Engineering in Medicine (IPEM)* is a professional body dedicated to promoting the advancement of physics and engineering applied to medicine and biology and representing the interests of engineering and physical sciences in the provision and advancement of health care.

2.1.5 The British Chapter of the International Society for Magnetic Resonance in Medicine (ISMRM) is the UK branch of a multidisciplinary association devoted to the development and application of magnetic resonance in medicine. Its aims include provision of information and advice on aspects of public policy concerned with MRI.

2.1.6 Collectively, these organisations represent the united voice of the magnetic resonance community in the UK. Their members work in both clinical and research settings and include radiologists and other medical specialists, radiographers, medical physicists, industrial scientists and academics.

3. Background

3.1 *Magnetic Resonance Imaging*

3.1.1 Magnetic Resonance Imaging (MRI) is a medical imaging modality that uses magnetic fields and radio waves to produce detailed images of the body. Unlike X-ray and nuclear medicine, it does not use ionising radiation, and is thus safer for both patients and staff. It has widespread and growing applications.

3.1.2 There are almost 500 MRI scanners in UK hospitals, performing over one million examinations each year. The government has recently invested around £100 million in over 100 new scanners, which will play a crucial role in waiting time reduction for cancer patients. The UK is leading in MRI research, with considerable investment from the funding councils, research councils and medical charities. MRI is increasingly important in preclinical research, attracting significant funding from the pharmaceutical industry. The UK is also a major centre for manufacture of MRI magnets, with two of the world's largest manufacturers based here.

3.1.3 MRI is beginning to be used in interventional procedures that have traditionally been performed under X-ray guidance: improving image quality, providing additional information, and eliminating ionising radiation dose to patients and staff. There are interventional MRI facilities at several UK hospitals, responsible for a number of breakthroughs in the field, and further installations are planned as the technique matures.

3.2 *The Physical Agents (Electromagnetic Fields) Directive*

3.2.1 Directive 2004/40/EC[2] was adopted on 29 April 2004, and member states have four years to transpose it into national law. The Directive limits occupational exposure to electromagnetic fields (EMF) in the frequency range 0–300 GHz, claiming to protect workers from "known short-term adverse effects in the human body". It sets "exposure limit values" that may not be exceeded, and subsidiary "action values", expressed in more easily measurable terms, to ensure compliance with these limits. Limits are stated explicitly in the Directive, with no room for leeway in implementation or exceptions for specific occupational sectors.

3.3 *Impact of the Directive on MRI*

3.3.1 MRI uses EMF in three frequency ranges, all within the scope of the Directive.

3.3.2 *A static magnetic field (0 Hz)*. Early drafts of the Directive contained a static magnetic field exposure limit of 2T (tesla). This was later removed, although an action value of 200mT remains. A review in 2009 may re-introduce a limit.

3.3.3 *A time-varying magnetic field, known as a "switched gradient" (100s–1000s Hz)*. Over this frequency range limits are set in terms of the electrical current induced in the body by the changing magnetic field, and are such that staff will not be permitted to stand close to the scanner while it is operating. This is the main source of concern to the MR community.

3.3.4 *A radiofrequency field (10s–100s MHz)*. Here limits are set in terms of specific absorption rate (SAR) to limit heating. The limits are very low, and it is possible that some MR activities may be affected.

3.3.5 The impact of the Directive on MRI may be summarised as follows.

— 3.3.5.1 It will be difficult to monitor patients requiring close supervision during imaging—eg anaesthetised or sedated children, very sick patients and uncooperative psychiatric patients—since staff will not be able to stand close to the scanner.

— 3.3.5.2 Movement of staff near the scanner may be restricted even when it is not operating. The static magnetic field is present at all times, and movement through it will expose staff to a time-varying field that may breach the relevant limit. This will also affect testing of magnets during manufacture and maintenance of installed systems.

— 3.3.5.3 Most interventional MR procedures will become illegal, as clinicians will not be permitted to stand close enough to the scanner to perform them.

— 3.3.5.4 Some functional MRI studies will become impossible—eg studies on deaf-blind subjects, where staff "sign" into the palm of the patient during imaging.

— 3.3.5.5 Additional problems will arise if a static field limit is introduced in 2009, the severity of which would depend on the limit adopted. A 2T limit would make use, cleaning and maintenance of the latest generation of 3T scanners effectively impossible.

3.3.6 The extent of these problems will vary between scanners and with the type of imaging being performed. However, there are clearly substantial difficulties that cannot be eliminated by changing working practices or re-designing scanners. There is likely to be increased recourse to X-ray and CT imaging in place of MRI, resulting in unnecessary ionising radiation dose burden to patients and staff. X-ray guided interventional procedures can result in a significant risk of cancer for the patient, while a recent study found that almost 40% of interventional radiologists have signs of radiation damage to the eyes.[3]

3.4 *The Evidence Base*

3.4.1 Exposure limits and action values in the Directive were adopted from guidelines issued by the International Commission on Non-ionising Radiation Protection (ICNIRP) in 1998.[4] These guidelines are 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. In the switched gradient frequency range, limits are inferred from biological effects (not adverse health effects) observed at 20–60 Hz, but assumed on an essentially precautionary basis to be relevant up to 100,000 Hz. Much of the original work dates from the 1980s, and some has never been replicated.

[2] Official Journal of the European Union L 159 of 30 April 2004 (and corrigenda L 184 of 24 May 2004).
[3] Junk A *et al* (2004) *Society of Interventional Radiology Annual Meeting*. Phoenix AZ.
[4] International Commission on Non-Ionizing Radiation Protection (1998) *Health Physics* 74 494–522.

3.4.2 In 2004 the National Radiological Protection Board (NRPB—now part of the Health Protection Agency, HPA) recommended adoption of the ICNIRP guidance in the UK.[5] In the switched gradient frequency range, justification focuses on essentially precautionary assumptions about the electrical properties of the central nervous system, based on mainly theoretical arguments advanced by the *Ad Hoc* Weak Electric Fields Group.[6] It is described as "a cautious approach . . . to indicate thresholds for adverse health effects that are scientifically plausible".[7] These are much weaker statements than those in the Directive. The HPA's decision to adopt the ICNIRP limits in the face of considerable scientific uncertainty was based as much on a desire for international harmonisation as on science.

3.4.3 Neither ICNIRP nor HPA considered the fact that approximately 400 million patients have been imaged using MRI, involving exposure to switched gradient fields well above the occupational exposure limit, with no indication of adverse effects. Limitations on patient exposure are based on peripheral nerve stimulation, which occurs at a threshold about 100 times the occupational exposure limit contained in the Directive.[8]

4. Consultation with the MR Community in the UK

4.1 Appendix A summarises action taken by the MR community to draw the attention of government agencies to the weak evidence base underlying the Directive and to its potential impact on MRI. A list of the scientists and clinicians involved in these activities appears in Appendix B. In addition, the stakeholder meeting in January 2006 was attended by 54 people from all sections of the MR community and relevant agencies.

4.2 During passage of the Directive, the MR community repeatedly raised concerns with the Health and Safety Executive (HSE), which conducted negotiations on behalf of the UK. Although the scientists involved were internationally acknowledged experts in MRI, they were unable to influence the HSE's position. A stakeholder meeting involving all affected sectors was held in July 2004, but this was concerned with implementation of a Directive that had by then been adopted, and was unable to address fundamental issues about the exposure limits themselves.

4.3 In September 2005 a group of scientists, including Nobel laureate Sir Peter Mansfield, issued a press release about the issue. The HPA responded[9] by acknowledging that there is no evidence of deleterious effects, but recommended caution in case there are unknown long-term effects—an issue excluded from the ICNIRP guidelines because of lack of evidence and explicitly excluded from the Directive.

4.4 Events took a more encouraging turn once Lord Hunt of King's Heath and senior HSE policy staff became involved. All sections of the MR community were invited to a stakeholder meeting, concerned largely with how the problem that we now have is to be solved and the detrimental impact of the Directive on MRI alleviated. However, the situation is now very difficult because the Directive has been adopted and the UK is obliged to implement it.

5. Relevance to Issues being Considered by the Committee

5.1 *Sources and Handling of Advice, and Relationship Between Scientific Advice and Policy Development*

5.1.1 HSE has limited resources and expertise in medical applications of EMF: during meetings in August 2003, it emerged that HSE was unaware of the existence of interventional MRI or of high-field MR imaging.

5.1.2 The position taken by HSE in European negotiations therefore relied heavily on external advice. HSE turned primarily to the HPA guidelines, which they interpreted as providing support for the limits in the Directive. But the HPA's assessment of the scientific evidence (see paragraph 3.4.2) falls well short of asserting the existence of "known short-term adverse effects in the human body" as is claimed in the Directive.

5.1.3 The HSE has stated that the Directive will have little impact on MRI, since it replicates existing HPA advice that we should already be following. This fails to recognise the distinction between cautious guidance, which can be considered alongside other factors as part of a wider risk assessment, and statutory exposure limits. It assumes that the limits should be applied rigidly in all situations, whereas HPA has stated that its recommendations "do not address detailed aspects of applying the guidelines to specific exposure situations".[10]

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[5] NRPB (2004) *Documents of the NRPB* Vol 15 (2).
[6] Weak Electric Fields Group position statement. Appendix A to *Documents of the NRPB* Vol 15 (3).
[7] NRPB (2004) *Documents of the NRPB* Vol 15 (3) p 137.
[8] International Electrotechnical Commission (2001) IEC standard 60601-2-33.
[9] http://news.bbc.co.uk/1/hi/health/4264228.stm
[10] NRPB (2004) *Documents of the NRPB* Vol 15 (3) pp 5, 10, 135.

5.1.4 The HSE should have drawn on more diverse sources of advice, to both supplement and aid in interpretation of the HPA guidelines. The UK has extensive expertise in MRI, including safety aspects. Unfortunately the HSE declined to give due weight to this expertise until the matter was raised in the press and the responsible minister became involved personally.

5.2 *Treatment of Risk*

5.2.1 In our opinion the derivation of exposure limits from sparse evidence in the ICNIRP guidelines is manifestly precautionary, in that "potentially dangerous effects . . . have been identified, and . . . scientific evaluation does not allow the risk to be determined with sufficient certainty".[11] Therefore, application of these guidelines in the EU should be guided, inter alia, by proportionality and cost-benefit analysis. Both economic and non-economic aspects of cost-benefit assessment are necessarily specific to a given setting: the considerations appropriate to medical MRI are likely to differ from those relevant to, for example, the telecommunications industry. However, the limits are not presented in the Directive as precautionary values, but as established thresholds for onset of adverse effects.

5.2.2 The HPA advice uses the term "caution" when assessing uncertain scientific data that inform the numerical limits, and "precaution" only in respect of possible further measures related to long-term effects of exposure.[12] However, we maintain that the HPA's adoption of numerical limits is precautionary according to the EU definition. It is based on a key assumption about central nervous system function described in the literature as being appropriate if one wished to adopt "a precautionary principle."[13]

5.2.3 These inconsistencies in terminology, and failure to understand the status of scientific evidence and of guidelines derived from it, led HSE to believe that exposure limits were necessary to protect the health of workers, whereas there is no positive evidence to this effect.

5.2.4 Given this belief, regulators were unwilling or unable to consider the fact that prohibiting some MRI practices would lead to increased radiation risk to staff.

5.2.5 Exclusion of patient risk from ionising radiation from consideration in the context of occupational exposure is of particular concern: medical staff routinely bear risk in order to provide healthcare. If this were not accepted, then X-ray imaging and certainly X-ray guided intervention would have to be prohibited.

5.3 *Transparency, Communication and Public Engagement*

5.3.1 Communication between the MR community and the HSE during passage of the Directive was poor, and there was no input to negotiations at European level. We were told that the HSE was bound by HPA and ICNIRP advice, and that scanner design and clinical practice would simply have to change to accommodate the Directive.

5.3.2 This is in marked contrast to the experience of the medical imaging community during negotiation of Directives relating to ionising radiation, where meaningful dialogue resulted in sensible legislation.

5.3.3 The MR community is now working with the HSE to try to solve the problems that have arisen. We are grateful to Lord Hunt and to senior HSE policy staff for their constructive and open approach. We believe that better consultation earlier in the process could have influenced the UK's position and hence the content of the Directive. It should not have been necessary for the community to go to the press and escalate matters to ministerial level in order to be taken seriously by the HSE.

5.4 *Evaluation and Follow-up*

5.4.1 Most of the scientific data that informed the ICNIRP guidelines had been peer reviewed. The HPA literature review in 2004 is widely regarded as a definitive summary of the state of the science. However, it is not clear that the process of sifting evidence and theoretical speculation in order to develop exposure limits has been subject to equally rigorous evaluation. The leap from cautious, guarded statements in the ICNIRP guidelines to "known . . . adverse health effects" in the Directive would certainly not have survived objective scientific review.

6. Recommendations for the Committee to Consider

— 6.1 The government should consider whether it is appropriate for the same agency, and indeed the same small group of individuals within it, to have responsibility for consultation, negotiation, implementation and enforcement of legislation. In this situation it is easy for views to become entrenched and for other interests to be excluded from meaningful participation.

— 6.2 Government agencies should draw more widely on the expertise of professional bodies and funding bodies (public, charitable and commercial) to develop a clearer understanding of the implications of legislative proposals. Meaningful consultation with these bodies should be a statutory requirement when UK representatives are formulating positions for negotiation at European level.

[11] Commission of the European Communities (2000) Communication from the Commission on the Precautionary Principle. http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf

[12] NRPB (2004) *Documents of the NRPB* Vol 15 (3) p 210.

[13] Attwell D (2003) Radiat Prot Dosim 106 341–348.

— 6.3 Development of science-based health and safety guidelines and legislation should be subject to a robust peer review process. It might be appropriate for the Royal Society to lead on this, drawing on the expertise of other learned and professional societies, as well as the HSE.

— 6.4 Greater consistency is needed in the use of terminology—particularly the definition of "precautionary"—to ensure that the status of pieces of evidence is preserved throughout the process of policy development.

— 6.5 The government should seek amendment of the Directive, at least to exclude MRI from its scope, on the basis that it is disproportionate and that any benefits are hypothetical and heavily outweighed by the costs.

— 6.6 An essentially precautionary approach has been adopted because of the lack of relevant scientific evidence. Rather than curbing valuable activity on this basis, appropriate research should be commissioned to inform development of more credible guidelines. A steering group should be established to define research needs, drawing on recommendations from the recent HSE stakeholder meeting and other sources.

January 2006

APPENDIX A

ACTIVITY BY THE MR COMMUNITY CONCERNING THE DIRECTIVE

Date	*Action*	*Outcome*
July 2003	BIR writes to HSE expressing concerns.	HSE response — Issues about limits should be directed to NRPB.
August 2003	BIR writes to NRPB expressing concerns as part of consultation on new guidance.	No response—concerns not addressed in guidance.
August 2003	HSE inspector visits MRI research centres to discuss concerns.	Comments by inspector — HSE's hands tied by NRPB and ICNIRP limits. — Manufacturers and users must redesign scanners and practices to comply.
19 September 2003	Meeting of MR scientists with HSE.	— Static magnetic field limit dropped from Directive as ICNIRP have withdrawn that part of guidance. — HSE will still seek to enforce this limit in the UK because it is in the NRPB guidance.
26–27 April 2004	ICNIRP/NRPB meeting on static magnetic fields.	More research and data collection needed.
June 2004	IPEM writes to MHRA expressing concerns about consequences for ionising radiation protection.	Issues will be discussed at forthcoming HSE stakeholder meeting.
27 July 2004	HSE stakeholder meeting covering all affected employment sectors.	HSE position — Manufacturers and users must redesign scanners and practices to comply. — Static field limit should not have been removed—HSE will seek to enforce it in UK because it is in NRPB guidance. — Increased patient exposure to ionising radiation is not relevant, as Directive is about occupational exposure. — Concerns of the MR community are "esoteric and of no interest to anyone else in this room". Implementation group established with input from MR community.
October 2004	IPEM raises concerns about consequences for ionising radiation protection with HSE contacts.	HSE ionising radiation inspectors believe risk-benefit analysis is needed.

Date	*Action*	*Outcome*
October 2004	Letter to MHRA raising concerns about conflict with IR(ME)R in intervention.	Reply from Department of Health — No conflict will exist, as MR technique will be illegal. — Subsequent apology from DH and offer to involve community in stakeholder group. — Stakeholder group subsequently abandoned—DH believes MHRA input sufficient; HSE says patient radiation protection not an issue as Directive is about occupational exposure.
October 2004	IPEM meeting on EMF attended by HSE.	HSE position — Manufacturers and users must redesign scanners and practices to comply.
6 June 2005	Debate with HSE at UKRC conference.	HSE position — Manufacturers and users must redesign scanners and practices to comply. — No case for medical staff to be treated differently from other groups. — HSE will seek to include 2T static field limit in UK legislation. 96% of audience support motion that Directive will be detrimental to clinical services and research.
20 September 2005	Group of eminent scientists write to Health Secretary raising concerns.	DH response (believed to have been prepared by HSE) — Directive not onerous, as limits follow existing guidance. — Health of workers "of paramount importance". — Data on acute effects "well established". — Stakeholder meeting will be held.
20 September 2005	MR scientists and clinicians hold press conference highlighting concerns.	European Commission response[14] — Experts agree excessive exposure to MRI dangerous to health. — Risk is to those exposed regularly, not patients. HPA response[15] — ". . . there is a lack of evidence for deleterious effects". — But need to be cautious in case there are long-terms effects.
September–December 2005	Letters to HSE from scientists, funding bodies and charities expressing concerns.	(Preparatory to stakeholder meeting in January).
20 October 2005	Meeting of RCR with Lord Hunt of King's Heath and HSE.	Main points of agreement — Further research needed on exposure limits. — HSE will explore options for renegotiation or amendment of Directive. — Need to establish exact extent of the problem for MRI. — Directive will be a low priority for enforcement. On 25 October Lord Hunt confirmed in parliament that the static field limit has been removed.[16]

[14] http://www.esmrmb.org/index.php?pid=409&SID=cf56847d32bff904b5a31433eff64982, with response from European Society for Magnetic Resonance in Medicine and Biology (ESMRMB).

[15] http://news.bbc.co.uk/1/hi/health/4264228.stm

[16] http://www.publications.parliament.uk/pa/ld199900/ldhansrd/pdvn/lds05/text/51025-02.htm#51025-02_spopq0

Date	*Action*	*Outcome*
25 November 2005	RCR writes to Lord Warner expressing concerns.	Lord Warner concerned about impact on clinical MRI.
5 January 2006	Stakeholder meeting at HSE.	Agreement that work is needed on — Quantifying extent of problem, — Defining research needed, — Updating ICNIRP guidance, — Decoupling MRI from rest of Directive.
24 January 2006	Meeting of RCR with Lord Hunt and HSE.	Forthcoming.

APPENDIX B

INDIVIDUALS KNOWN TO HAVE MADE REPRESENTATIONS ABOUT THE DIRECTIVE

Name	*Position*	*Actions*
Professor Gareth Barker	Institute of Psychiatry, King's College London	(16)
Professor Colin Blakemore	Chief Executive, MRC	(16)
Professor Peter Dawson	Registrar, RCR	(15)
Dr Stuart Derbyshire	School of Psychology, University of Birmingham	(16)
Mr Günter Dombrowe	President, BIR	(13)
Professor Wladyslaw Gedroyc	Consultant Radiologist, St Mary's Hospital	(11)
Professor Penny Gowland	MR Centre, University of Nottingham	(3) (5)
Professor John Griffiths	Head of Basic Medical Sciences, St George's Hospital Medical School; past Chair, ISMRM British Chapter	(1) (2)
Professor Donald Hadley	Clinical Neurosciences, University of Glasgow	(1) (2)
Professor Jeff Hand	Radiological Sciences Unit, Hammersmith Hospitals NHS Trust; past Chair, IOP Medical Physics Group	(7)
Professor Janet Husband	President, RCR	(13) (17)
Dr Peter Jackson	President, IPEM	(13) (16)
Professor Peter Jezzard	Centre for Functional MRI of the Brain, University of Oxford	(13)
Dr Stephen Keevil	Consultant Physicist, Guy's and St Thomas'; Chair, IPEM SET Committee	(3) (7) (12) (14) (15)
Dr Robert Kirby-Harris	Chief Executive, IOP	(13)
Professor Sir Peter Lachmann	President Emeritus, Federation of the European Academies of Medicine	(16)
Professor Martin Leach	Co-director of MR group, Royal Marsden Hospital; Chair, ISMRM British Chapter	(1) (2) (7) (16)
Dr Robin Lovell-Badge	Head of Developmental Genetics, NIMR	(16)
Dr Catherine Ludman	Consultant Radiologist; Chair, BIR MR Committee	(1) (2)
Professor John Mallard	Professor Emeritus, University of Aberdeen	(13)
Professor Sir Peter Mansfield	Nobel Laureate; Emeritus Professor, University of Nottingham	(13) (14)
Dr Donald McRobbie	Consultant Physicist, Charing Cross Hospital; past Chair, IPEM MR SIG	(6) (10)
Dr Virginia Ng	Consultant Neuroradiologist, Maudsley Hospital	(16)
Professor Roger Ordidge	Deputy Head of Medical Physics and Bioengineering, University College London	(1) (3) (4)
Professor Dudley Pennell	Director of Cardiovascular MRI, Royal Brompton; President, British Society of Cardiovascular MR	(13)
Professor Sir George Radda	Former Chief Executive, MRC; Emeritus Professor, University of Oxford	(16)
Professor Reza Razavi	Deputy Head of Imaging Sciences, King's College London	(9)
Professor Peter Styles	Former Director, MRC Biochemical and Clinical Magnetic Resonance Unit, University of Oxford	(13)
Dr Andrew Taylor	Consultant Radiologist, Great Ormond Street Hospital	(14) (15)

Name	*Position*	*Actions*
Mr James Thurston	Consultant Physicist, King's College Hospital; past Chair, IPEM Radiation Protection SIG	(7) (8)
Dr Janet de Wilde	Manager of MR National Evaluation Team	(4) (7)
Professor Steve Williams	Head of Imaging Sciences, King's College London	(16)
Sir Martin Wood	Honorary President, Oxford Instruments plc	(13)
Professor Ian Young	Emeritus Professor, Imperial College London	(1) (2) (13) (14)

(1) Letter of July 2003 to HSE
(2) Letter of August 2003 to NRPB
(3) Meetings with HSE inspector, August 2003
(4) Meeting with HSE inspector, September 2003
(5) ICNIRP meeting in Oxford, April 2004
(6) Letter of June 2004 to MHRA
(7) HSE stakeholder meeting, July 2004
(8) E-mails to HSE radiation inspectorate, October 2004
(9) Letter to MHRA, October 2004
(10) IPEM EMF meeting, October 2004
(11) HSE implementation group since December 2004
(12) UKRC debate, June 2005
(13) Letter to Health Secretary, September 2005
(14) Press conference, September 2005
(15) Meeting with Lord Hunt, October 2005
(16) Letters and e-mails to HSE September–December 2005 (those known to authors, excluding institutional responses)
(17) Letter to Lord Warner, November 2005

APPENDIX 7

Memorandum from the Institute of Physics

The Institute of Physics is a scientific membership organisation devoted to increasing the understanding and application of physics. It has an extensive worldwide membership (currently over 35,000) and is a leading communicator of physics with all audiences from specialists through government to the general public.

The Institute is a signatory to the evidence submitted by ourselves and the Royal College of Radiologists, the British Institute of Radiology, the Institute of Physics and Engineering in Medicine and the British Chapter of the International Society for Magnetic Resonance in Medicine. The evidence used the case study of the use of MRI equipment and the EU Physical Agents Directive to highlight significant concerns amongst physicists and the MRI technology user community about the Directive, which seeks to define safe levels for equipment operators' exposure to electromagnetic fields, and the failure of government agencies to take proper account of the community's concerns.

MRI is a revolutionary, physics-based, non-invasive, imaging technique that has changed the nature and enhanced the quality of diagnosis for a great many patients worldwide. There are currently more than 20,000 MRI machines around the world performing more than 60 million clinical examinations on patients every year. MRI is now a standard diagnostic tool in a large number of hospitals, improving treatment, cutting waiting times and saving lives.

MRI is in many ways the ideal medical imaging technique, as it can identify all kinds of tissue, poses no health risks and there is no limit to the number of images that can be safely taken. In addition, patients do not require any preparation and there is no need for recovery time. As a research tool, it has allowed doctors to see the inner structures of the brain, imaging the effects of thought processes, to see how they respond to stimuli and manage emotion. Currently, scientists are working towards combined MRI scanners to produce real-time images of internal organs.

In view of the considerable advantages in utilising MRI (over other more dangerous techniques) and the significant constraints on this utilisation posed by the Directive, the introduction of this Directive is bewildering. This bewilderment is exacerbated by the HSE and HPA ignoring the deeply held views of the scientific and medical community opposing the introduction of this Directive, and ignoring the overwhelming scientific advice that has been offered to them.

The Institute hopes that the Committee will use the evidence to address failings of the policy process in dealing with this Directive, in light of the comprehensive concerns expressed and the recent publication of the Chief Scientific Adviser's revised Guidelines on Scientific Analysis in Policy Making.

January 2006

APPENDIX 8

Memorandum from the Engineering and Physical Sciences Research Council (EPSRC)

1. This memorandum provides evidence from the Engineering and Physical Sciences Research Council (EPSRC) in response to the above inquiry, in relation to the case study "The use of MRI equipment: the EU Physical Agents (Electromagnetic Fields) Directive".

Introduction

2. EPSRC is the main UK government agency for funding research and training in engineering and the physical sciences, investing around £500 million a year in a broad range of subjects—from mathematics to materials science, and from information technology to structural engineering.

3. The Council operates to meet the needs of industry and society by working in partnership with universities to invest in people and scientific discovery and innovation. The knowledge and expertise gained maintains a technological leading edge, builds a strong economy and improves people's quality of life.

4. The work of EPSRC is complementary to other research investors including other Research Councils, government agencies, industry and the European Union. The Council actively engages in and encourages partnerships and collaborations across disciplines, boundaries and internationally.

5. EPSRC also actively promote public engagement in science, engineering and technology.

EU Electromagnetic Fields Directive

6. EPSRC welcomes any appropriate legislation that ensures the continued safety of the researchers it supports.

7. MRI is a technique used by parts of our research community. On 18 January 2006, EPSRC's research portfolio included 95 grants related to MRI with a value of £28.2 million. The directive may affect some areas of this portfolio, in particular where experimental procedure requires the researcher to locate within one to two million of the edge of the bore whilst imaging. It is also possible that the directive may preclude certain promising interventional MRI techniques thus limiting further and future developments.

8. Our community has expressed concerns that the impact of the legislation may be disproportionate to the actual risk associated with exposure to the electromagnetic fields in question. The community in question is very safety conscious, in particular the medical imaging community (probably through experience with X-Rays). We believe that with the appropriate evidence base, the community will actively seek to implement the directive quickly and effectively.

9. There is however a concern amongst our community that at present the evidence base for the proposed exposure limits defined in the directive is poor. In particular, there is a belief that the limits in the 100Hz–100KHz range are based on limited experimental data for the frequencies most important to MRI, and they are extrapolated from effects that have not been shown to occur at MRI frequencies. Some people argued that these limits should be set based on peripheral nerve stimulation, not central nervous system effects.

10. EPSRC has been in consultation with a number of other bodies over this directive (in particular the MRC, Wellcome Trust, HSE and AMRC). In particular we have been looking to identify possible research challenges associated with the directive and three immediate ones seem to present themselves:

- Computer modelling to establish actual exposure of MRI workers. This is key to help understand how much of a problem the directive may pose.
- Research to further verify the actual exposure limits proposed (eg has the correct biological model been used).
- Research into approaches to reduce magnetic field exposure (eg through changes to work practices, innovation in equipment design etc).

11. These scientific challenges are of varying fit to EPSRC's remit, but we will continue to consult with other bodies to ensure a collaborative approach.

12. With respect to "SCIENTIFIC ADVICE, RISK AND EVIDENCE: HOW GOVERNMENT HANDLES THEM", it seems clear that sections of EPSRC's community do not feel that the evidence used to support the EU directive was adequate. A series of research challenges are beginning to be developed that

will investigate these supposed deficiencies and provide further evidence for any future revision or confirmation of the directive. In the mean time we understand that the directive will be implemented as it stands. The implementation notwithstanding, perhaps a consultation process and involvement of all stakeholders at the earliest stage would have led to a smoother implementation of new policies and regulations.

January 2006

APPENDIX 9

Memorandum from the Wellcome Trust

1. The Wellcome Trust welcomes the opportunity to respond to the questions raised by the House of Commons Select Committee on Science and Technology in its inquiry on the handling of scientific advice, risk and evidence. This response will focus mainly on the case study identified by the Committee: "The use of MRI equipment: the EU Physical Agents (Electromagnetic Fields) Directive", but will also make some general comments about the use of scientific advice from the Trust's perspective.

2. The Wellcome Trust is an independent research-funding charity, established under the will of Sir Henry Wellcome in 1936. It is funded from a private endowment, which is managed with long-term stability and growth in mind. The Trust's mission is "to foster and promote research with the aim of improving human and animal health". One way the Trust works to meet its mission is by stimulating an informed dialogue to raise awareness and understanding of biomedical science, its achievements, applications and implications. The Trust also seeks to provide the best available evidence and information in order to ensure that there is a good balance between the needs of research and those of society.

3. We argue that the UK Government must ensure that the process for seeking scientific advice is as comprehensive for the development of European legislation as it is for UK policy. Specific points made in this response include:

- the need to develop effective methods to alert all relevant stakeholders to EU consultations;
- the need to improve mechanisms of communication about EU policy decisions, for example the Government should create a web portal to provide information about the progress of EU decisions;
- the importance of the best available evidence informing policy-making; and
- the need to use a proportionate and consistent approach for the analysis of risks.

Background to the EU Physical Agents (EMF) Directive

4. The Physical Agents (Electromagnetic Fields) Directive 2004/40/EC was published by the EU in 2004, and must be implemented into national law by Member States by 30 April 2008. There are concerns that the Directive could have serious consequences for the use of magnetic resonance imaging (MRI), both in the clinic and for research purposes.

5. The Directive defines maximum exposure levels for electromagnetic fields (EMF) to protect workers from risks to their health and safety. This will apply to all operating staff and those maintaining equipment, but not to patients. The exposure limits included in the Directive for gradient fields (100–1000 Hz) will prevent workers from standing close to the bore during imaging. This could prohibit interventional MRI (including neurosurgery, cardiac catheterisation and tumour ablation); limit the provision of patient care during investigations, for patients under general anaesthetic, children or psychiatric patients; and restrict practical maintenance and routine cleaning. The use of new, more powerful high-field scanners in clinical research will be particularly limited, and the development of new MRI methodologies and improvements in technology—a particular strength of research in the UK—may be threatened.

6. In draft stages, the Directive included a limit for exposure to static fields (0 Hz), which would have had a significant impact on all uses of MRI equipment. This limit was subsequently removed from the Directive during negotiations, mainly as a result of lobbying by industry and manufacturers, co-ordinated through COCIR (the European Coordination Committee of the Radiological, Electromedical and Medical Information Technology Industries). There is concern that static limits may be reinstated during implementation in the UK or in future reviews of the Directive.

7. It is not yet known how the Directive will be implemented in the UK, although the UK Government has now realised the implications and the "unintended consequences" for the MR community. The impact of the Directive was raised in a debate in the House of Lords on 25 October when Lord Hunt of King's Heath expressed concerns. The Health and Safety Executive (HSE), responsible for transposing the Directive, held a roundtable discussion meeting in January 2006 with key stakeholders to consider the implications for MRI users, and will also consult on the proposed regulations in Summer 2006.

8. The Wellcome Trust has made a substantial investment in MRI, supporting high-quality basic research in imaging and funding scanners and related research infrastructure. The Trust is keen to ensure that the concerns of the MR community are recognised and reflected in the implementation of the Directive. We were not invited to be involved in previous discussions about the Directive but are now pleased to be included in the dialogue.

Sources and Handling of Advice

9. The UK Government must ensure that the process for seeking scientific advice from stakeholders is as comprehensive for the development of European legislation as it is for UK policy. The EU has already published the Physical Agents Directive, leaving the HSE with little room for manoeuvre. Similarly, the EU Directive 2001/20/EC on Good Clinical Practice in Clinical Trials was finalised before all stakeholders in the UK were aware of the implications. The Government must develop better means of alerting all relevant stakeholders to EU consultations at an early stage in the negotiations. It is too late if scientific advice is obtained in the UK after European legislation has been published, when it must be implemented regardless of the implications.

10. With the development of both European and UK policy, it is crucial for Government departments to be aware of the range of stakeholders and breadth of views that exist for any given topic. This will require appropriate expertise in-house, to ensure that all relevant groups are consulted and to access appropriate advice externally. Although departments do make an effort to consult, the exercise will only be effective if the right experts are identified for each topic. Care needs to be taken to ensure that there is not too heavy reliance on a limited number of specialists.

11. As well as identifying representative experts, it is also important to engage in a constructive dialogue and to ask the right questions at an early stage of consultation. Again, this will depend on appropriate knowledge of the area in-house. Involvement of the scientific community, and the process of handling advice, does not always appear to be consistent or systematic across different departments.

12. These concerns apply to the Physical Agents Directive, where input from the MR community was not sought until late in the process. They apply equally to other cases, for example during the development of legislation relating to human tissue, initial discussions were confined to a particular group of stakeholders. The concerns of the wider research community were only addressed after the introduction of the Bill.

13. Improving communication and collaboration between different Government departments should help to identify the wider implications of forthcoming legislation. The updated "*Guidelines on scientific analysis in policy making*", issued by the Office of Science and Technology, provide little detail about the handling of cross-departmental issues. There could be a role for the departmental chief scientific advisers to work together to ensure the early identification of issues and the inclusion of all relevant stakeholders in discussions.

Are existing advisory bodies being used in a satisfactory manner?

14. Within the UK, we have found that Government departments do generally appear to respond to the recommendations of advisory bodies in an appropriate manner. However the implications when specific advice is implemented too literally in a wider context are not always considered. For example, the Human Genetics Commission (HGC)'s recommendation that testing DNA without consent should be made a criminal offence was initially introduced into the Human Tissue Bill in a way that went significantly beyond the scope envisioned by the HGC and would have been unworkable. Some advice may need further assessment and interpretation to ensure it is appropriate when integrated in a more broad-reaching policy.

Relationship Between Scientific Advice and Policy Development

What mechanisms are in place to ensure that policies are based on available evidence?

15. The Physical Agents Directive does appear to have been based on advice by the appropriate advisory bodies, taking account of the evidence available at the time. The Directive adopts the exposure guidelines of the International Commission on Non-Ionizing Radiation Protection (ICNIRP), published in 1998, which were based on a review of the science by external advisory committees.

16. In the UK, the National Radiological Protection Board (NRPB) (now the Radiation Protection Division of the Health Protection Agency (HPA)) recommended in 2004, following a scientific review, that the UK should adopt the ICNIRP guidelines. This recommendation also recognised the benefits of international harmonisation on exposure guidelines. In 2004, the NRPB published *Advice on Limiting Exposure to EMF (0–300 GHz)*, providing guidance for workers and members of the public. These guidelines were based on a *Review of the scientific evidence for limiting exposure to EMF (0–300 GHz)*, also published in 2004 and open for consultation.

17. However, there are serious concerns about the scientific basis for the exposure limits in relation to MRI, and in particular the lack of available evidence in the frequency range most relevant for MRI systems. A recent paper by Hill et al[17] reviews the evidence, concluding that "the scientific basis for the exposure levels is incomplete and inconclusive". The main concerns are that:

— most research has been carried out on the frequency range 50–60 Hz, which is not necessarily applicable to gradient fields in MRI (500 Hz);

— evidence from volunteer studies, using a higher field strength, were not peer-reviewed and have not been replicated;

— there have been very few relevant animal and cellular studies. In a National Academy of Science review, *Possible health effects of exposure to residential electric and magnetic fields*, 10 experiments included frequencies relevant for MRI. Of these, seven showed no effect, one showed a change in calcium concentrations, one showed chromosomal aberrations but had a high number of null experiments, and one detected development changes but these were not statistically significant; and

— some of the guidance is based on potential adverse health effects due to chronic exposure, but the Directive states that it only relates to short-term adverse effects and does not address long-term effects.

18. It has therefore been argued that further research is urgently needed to collate relevant evidence about the impact of EMF exposure at the frequencies used by MRI. A number of priority areas have been identified, but it is not clear which body should be responsible for funding such research.

19. One of the difficulties seems to be that neither ICNIRP nor NRPB specifically considered MRI applications when assessing exposure to electromagnetic forces. The lack of evidence in the appropriate frequencies was therefore not identified. In 2002, the HSE commissioned the NRPB to identify the industrial sectors likely to be affected by any legislation resulting from the implementation of EMF Directive. The report considered electricity generation, resistance welding, induction and dielectric heating, plasma discharge applications, security and access control, telecommunications and broadcasting, but there was no mention of medical applications. Similarly, the HSE's Regulatory Impact Assessment relating to the Directive, published in November 2003, focused mainly on the electricity generating and broadcasting industries. Medical applications were listed briefly but there was no analysis of the potential impact on MRI uses. This raises a number of issues about defining the remit of advisory bodies and the identification and inclusion of all relevant stakeholders, as discussed above.

20. With regard to policy formulation in the UK, we welcome the recent changes introduced by the Government's Chief Scientific Adviser, and the new role of scientific advisers within each department, which reinforce the commitment to incorporate scientific advice into policy development. We particularly support the continued emphasis on the development of evidence-based policy. The introduction of public health interventions, for example, must be informed by the latest scientific evidence.

Treatment of Risk

21. The Physical Agents Directive generally adopts "a cautious approach" to the interpretation of scientific data. The exposure limits are based on "precautionary values", and are set at levels significantly below that at which known physiological effects may occur. The limits are also absolute—there is no scope for time averaging, or for less restrictive limits for brief exposures. However, the Directive addresses only short-term "negative health effects" and does not consider long-term chronic effects.

22. This approach to risk management differs from that for ionising radiation where an assessment of the different risks and benefits is central. Although there is a requirement for risk assessment in the Directive, there is no similar risk-benefit analysis. If one were included, it should consider not only the benefits to the patient of diagnosis, treatment and research using MRI, but also the risk that if the use of MRI is reduced, the use of X-rays is likely to increase. This would put patients and staff at greater risk and expose them to ionising radiation which has recognised adverse effects.

23. The lack of clear definition, and range of conflicting interpretations, for the precautionary principle raises concerns that the principle may be inappropriately invoked as an argument to limit scientific progress. The work of the UK Interdepartmental Liaison Group on Risk Assessment (ILGRA) has helped to clarify how the precautionary principle should be applied across Government departments in the UK.[18] We particularly support their conclusion that the precautionary principle "should not be an obstacle to innovation" and call for this approach to be consistently adopted by all departments.

24. The analysis of risks must be proportionate, consistent, and transparent across Government. An example is the complex issue of the use of patient data. Data from the NHS is invaluable for future health research. Information gathered from individuals and populations can inform studies examining interactions between health, the environment and genes. Responsible sharing of personal datasets between Government

[17] Hill DLG, Mcleish K, Keevil SF, Impact of electromagnetic field exposure limits in Europe: is the future of interventional MRI safe? *Acad Radiol* (2005)12:1135–1142.

[18] *The precautionary principle: policy and application*. ILGRA (2002).

departments could also help to inform the development of public health policy. However, issues of patient confidentiality, and access to patient data for research purposes, are confused. When making decisions about data sharing, an analysis of the risks and benefits should be one of the issues included in the assessment, and decisions should not be disproportionately cautious. There is a real need for a regulatory framework that balances the risks and inspires public confidence, but the approach must be both coherent and proportionate.[19]

Transparency, Communication and Public Engagement

25. With regard to European legislation, we would suggest that the UK Government is not doing enough to engage stakeholders about EU policy decisions. It is currently extremely difficult to follow the progress of Directives through the EU. For example, we have recently experienced difficulties tracking the review of the Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. Difficulties are exacerbated because more than one EC department is involved in the negotiations and there is no single source of information. We suggest that the UK Government should develop improved mechanisms for communicating information with stakeholders. One possibility would be to create a web portal for EU legislation, which would provide information about the status of each EU Directive and details about the timetable for negotiations and implementation.

26. Within the UK, it is usually much easier to follow the development of legislation. Most of the relevant research is now being published, although the process by which specific research informs policy is not always transparent. We believe however that the mechanism of pre-legislative scrutiny could be used more often. For example, the development of the Human Tissue Bill would have benefited considerably from such a process; we note that the Government originally undertook that this would happen. Many improvements were made to the Mental Capacity Bill following pre-legislative scrutiny.

27. Although there is good evidence that the public is supportive of science, there is concern that there is little public awareness of scientific regulation. In a recent study by MORI for the Office of Science and Technology, 84% of people said they knew "not very much" or "nothing at all" about the way science is regulated. The research also found that more than half of the UK public does not know that scientists are regulated by government bodies or agencies.[20] It is therefore crucial to engage the public in dialogue about policy issues, and to discuss the benefits and risks associated with new developments in science. Such communication must be open and transparent to build public confidence.

28. The Wellcome Trust seeks to engage society with the science we fund, and public engagement is a priority to foster an informed climate within which biomedical research can flourish. As part of this work, the Trust tracks attitudes and knowledge about specific biomedical research issues to help to influence public funding and policy-making. In 1998, the Trust funded a report on "*Public perspectives on human cloning*" and more recently, research on "*Public attitudes to the use of human tissue in biomedical research*".[21] Both studies revealed a very low awareness of existing regulations and advisory bodies, and there was little confidence that any system of regulation could effectively control research. These results emphasise the importance of engaging the public in an informed discussion about scientific advice. The Trust has also recently commissioned a qualitative research study on "*Public attitudes to governance of biomedical research*". A report of the findings is expected to be published in September 2006.

29. The Trust's Biomedical ethics programme also supports a range of research into social, ethical, legal and public policy aspects of biomedical science. Publications have considered a number of issues, including applications of pharmacogenetics, collections of human biological samples, forensic genetics and assessment of capacity to consent to medical treatment. Researchers are particularly encouraged to think about how the findings of their work might be relevant to other audiences.[22]

Evaluation and Follow-up

30. The Physical Agents Directive does include steps to re-evaluate the evidence base following implementation, with a review every five years built into the Directive. This will consider any changes "that may be warranted in the light of new scientific knowledge", and will be informed by ICNIRP. It is hoped that further evidence relating to frequency ranges relevant for MRI will be available in time for the next review in 2009. We would also encourage the Government to discuss concerns about the evidence base with ICNIRP as it updates its guidelines, and to address issues relating to the funding of further research raised above.

[19] These issues are discussed further in *Better use of personal information: opportunities and risks*. Council for Science and Technology (2005).

[20] *Science in Society: Findings from qualitative and quantitative research*. Conducted by MORI for the Office of Science and Technology, Department of Trade and Industry (2005).

[21] *Public Perspectives on Human Cloning: A social research study*. The Wellcome Trust (1998), available at http://www.wellcome.ac.uk/node5250.html. Public attitudes towards the use of human tissue in biomedical research. Prepared by Opinion Leader Research for the Wellcome Trust (2004).

[22] More information about the programme can be found at http://www.wellcome.ac.uk/doc_WTD003247.html

31. The best available evidence must inform policy-making to ensure that there is a sustainable environment for biomedical research. We would be happy to discuss any of the issues raised in this response in more detail if this would be helpful.

January 2006

APPENDIX 10

Memorandum from Royal College of Radiologists

I am writing to you on behalf of the Royal College of Radiologists to welcome your Inquiry and to thank you for the opportunity to give written evidence.

The EU Directive in question, when enacted as law in the UK, will have a very seriously detrimental impact on the practice and development of clinical magnetic resonance imaging (MRI). It will be difficult to perform MRI scans on sedated, anaesthetised, or simply very ill, patients needing monitoring; scanning of children will become difficult or impossible; and the development of the important new field of interventional MRI (performing minimally invasive surgery on patients guided by MRI) will be arrested.

Ironically, many of the patients not able to have MRI may have computed tomography (CT), a technique associated with a significant burden of ionising radiation.

The course suggested by the HSE, namely to try to live with the legislation by developing technologies and procedures to circumvent it, such as remote monitoring and robotics, seems to us to put the cart unnecessarily before the horse.

My College would support any good scientific research into the possible effects of electromagnetic fields and, since patient and staff safety are for us paramount, we would take any convincing findings of significant danger very seriously. However, it is simply the case that at present there is virtual unanimity amongst competent authorities in the field that there is no credible scientific basis for this damaging Directive.
Its origins and evolution would, we believe, make a very good case study for your committee.

January 2006

APPENDIX 11

Memorandum from the Institute of Physics and Engineering in Medicine

The Institute welcomes the inquiry of the House of Commons Select Committee on Science and Technology into the "Scientific Advice, Risk and Evidence: How Government Handles Them". The Institute is pleased that the Select Committee has chosen the circumstances surrounding the use of MRI equipment and the EU Physical Agents (Electromagnetic Fields) Directive as one of the case studies. The Institute supports the submission compiled by Dr Stephen Keevil on behalf of this Institute, and the British Institute of Radiology, Institute of Physics, Royal College of Radiologists and the British Chapter of the International Society for Magnetic Resonance in Medicine. The submission places in context the various communications made to government agencies and departments about the concerns of the scientific and medical community in relation to the adverse impact on healthcare programmes.

On behalf of the Institute I should like to make more general comment.

The EU Physical Agents (Electromagnetic Fields) Directive encompasses many industries. The commissioning of the Directive is unlikely to have been promoted as a major benefit for the "healthcare industry". Hence it is possibly not surprising that the passage of the Directive has seemingly bypassed the healthcare industry, and in particular the problems that will occur with the use of magnetic resonance imaging for medical procedures that require intervention from a health professional. There may indeed be other concerns that have not yet surfaced with other techniques used in hospitals.

It is perhaps surprising that government agencies have apparently not consulted adequately with scientific professional bodies given that the membership is most likely to consist of the expertise able to give good advice on such matters. The reasons for this could be the lack of awareness of the professional expertise available to government through professional organisations or a fundamental lack of knowledge of the potential implications. Such circumstances have not occurred previously when the EC Council Directive 96/29/Euratom and EC Council Directive 96/43/Euratom were being developed. Indeed, with the formation of these Directives, subsequent UK legislation and guidance, the Institute's members seemed to be actively engaged. It might be interesting to understand better why the above EC council Directives enjoyed greater involvement and acceptance by the scientific healthcare community.

One of the probable reasons is that the biological effects, hazards and risks of ionising radiations are better understood than those associated with electromagnetic fields. It was probable also that government bodies and agencies were aware of the expertise available through scientific and professional bodies on such matters

involving ionising radiations. There was also probably an incentive for wide and rigorous consultation relating to these directives given public perceptions associated with "radiation". However, professional organisations and the scientific community must take responsibility for not promoting sooner the need for definitive research into the biological effects and potential risks of electromagnetic fields. Some will argue that the case was made at an appropriate stage, but this then prompts the question as to whether the communication channels to government on such matters are well understood. It appears with the restrictions associated with this legislation (ie the Directive), that the MRI scientific community has awakened to the needfor such research. However, it is of considerable concern that legislation will be enacted without reasonable evidence of the need for such restrictions. To the medical community such legislation will seem to follow an "over precautionary" principle. Indeed how should government respond without available scientific evidence?

In summary, it should be very helpful if the Inquiry might examine also the role and mechanisms of scientific professional bodies in providing advice and evidence to Government. The scientific community must take responsibility for not bringing matters to government attention in a timely way, and perhaps government needs to examine whether routes of communication are well understood and effective. Where the scientific community believes government agencies and departments are not addressing concerns, there maybe hestitation also in bringing matters to the attention of ministers. The Institute should welcome contributing to the Inquiry as required.

January 2006

APPENDIX 12

Memorandum from Professor I R Young, Imperial College, London

Abstract

This submission suggests that a major problem with the use made of scientific advice by Government is the lack of any quality monitoring of much of what is proposed to it. The recent (2004) European Directive on Physical Agents (Directive 2004/40/EC)[1] concerned with the exposure of workers to electromagnetic (EM) radiation in the range of 0 Hz to 300 GHz is taken as an example of where the attitudes of a small—and, seemingly, unrepresentative—group of scientists has led to legally enforceable requirements which have no justification on the basis of available evidence. The relevance of this example is more immediate than might otherwise seem since the inspiration for, and much of the scientific basis of, the Directive, seems to have originated in this country at what was then called the National Radiation Protection Board (NRPB) based at Harwell, but which is now part of the Health Protection Agency (HPA), which is a component of the Department of Health. It is advocated that the sort of peer review assessment process employed to evaluate University research performance as part of the allocation of resources to individual establishments, should be extended to all research groups advising the Government—including its own employees—with the results of the evaluations being published in the media.

Introduction

Government because of the nature and background of all but a very few politicians depends absolutely on the integrity of those advising it on complex technical matters. The senior civil service is similarly largely lacking in the scientific knowledge to make judgements about such issues on its own account. As a consequence, comprehension and advice about scientific and engineering issues has to be supplied either by outside advisors or by such scientific expertise as has been retained inside the civil service (bearing in mind that many of the agencies having that expertise have been privatised over the years—Qinetiq being only the latest example). Government is thus totally unprotected against the possibility that the advice it is receiving may be biased or incompetent, or otherwise flawed. It is all too easy for a vociferous minority to seize control of a situation, and exploit for its own ends.

This submission uses the formulation of the European Directive on EM Physical Agents[1] as an illustration of the problem since much of the scientific formulation of the basis of the Directive was actually done in this country by NRPB (as it then was) at Harwell. As a consequence the country, should it decide it is actually going to implement the Directive as enacted, and enforce it (which may well not happen throughout much of the EU as Brussels has cheerfully admitted—but has been promised here), is in the absurd position of regarding X-ray systems (which do have a known benefit—as well as a well established risk) as less hazardous than MRI (which also has a known—and expanding—benefit but no known risks) because it is "scientifically plausible" that it might have some quite unknown and detected risk (to quote NRPB in its 2004 defence of its acceptance of the ICNIRP guidelines[2] which are the scientific basis of the EU Directive)[3]—and that the "precautionary principle" should be applied. Huge numbers of things are scientifically plausible—including that a huge asteroid might hit the Earth on the 1 April next at 12 noon—and destroy it. Since this asteroid would be very apparent it would have been detected—and the future would

have been predictable without dramatic intervention. Using what is no more than a possibility which runs counter to all known experience as the basis of a recommendation is both dangerous and scientifically incompetent—and exceeds the remit of such organisations which enjoins them to consider the implications of their recommendations for those affected in all manner of ways including the costs to the community at large. The use of the "precautionary principle" has already been tested (in 1994)[4] in the English Courts—and it was then declared an incorrect approach.

History—or Some Ideas as to How We Got Here

I do not propose to go into a detailed critique of the recommendations made by NRPB and others, since others will have done that, but rather try and suggest how we reached the position we have, and show how vulnerable Government and others are to misdirection. The story begins with the first attempt to produce Guidelines for the scanning of MRI patients. NRPB formed an advisory group (of which I was a member) in about 1980, which resulted in some initial Guidelines in 1981. These were based largely on what seemed reasonable. There were no known problems with EM fields (apart from heating at higher frequencies which was a well understood phenomenon), so the levels decided on were what seemed reasonable. FDA in the USA had no ideas at this time—but produced some first guidelines of their own a couple of years later, which were remarkable only for their chauvinism in preferring what was clearly already suspect data from a US scientist to the rather better argued UK version.

Subsequently NRPB sought to align their original Guidelines with the FDA ones, but, in so doing, added an additional criterion which has never been introduced in the USA. This was a dose related factor—saying essentially that you ought to be exposed to a magnetic field for only a certain amount of time each day, so that if it is a very high field you ought to stay in it for only a short time and so on. There is absolutely no evidence for this, but it seems to have arisen because there is a dose issue with X-rays. (X-rays have an enormously greater photon energy than those used in MRI (by a factor of 109 or so) and so are likely to be much more destructive of complex biological molecules and structures.) No-one has ever been able to justify this requirement—and nobody ever bothered about observing it. ICNIRP attempted a justification of it in its 1994 Recommendations on Static Magnetic Field Levels[5]—but the defence is so absurd as to be laughable. (It uses the physics of the magnetic flowmeter—which it gets wrong—and a constant blood flow rate—which is absurd—to come up with an induced current—which exceeds its own guidelines—and follows this masterpiece with a paragraph beginning with the word "Thus" which allows field exposures 10 times higher than that on which they have based their argument for short periods of time (duration unquantified). In fact ICNIRP has used a model depending on an acute effect (lasting perhaps a second) to justify a requirement lasting hours. Though ICNIRP now suggests that the 1994 Document might be withdrawn, it is the basis of one part of its 1998 Guidelines, and the idiocy above is echoed by NRPB in its 2004 acceptance of the ICNIRP recommendations. In order to come up with something sensible the Directive has simply enshrined the lowest level suggested by NRPB (as a "reference value" which can be easily applied, though they have ducked the issue of a "limit value" which it is mandated shall not be exceeded, but cannot actually be easily measured in this frequency range). It may be because of their continuing use of this unjustified dose concept—or for other reasons—but NRPB has refused to revise its guidelines for patient scanning as well. FDA in the United States has done so on several occasions and now permits substantially higher field levels in some respects. These are, however, key factors in delivering better diagnostic information, so that NRPB, which has claimed it "sees no reason" for any revision apparently does not consider patient benefit as motivation for doing anything. In practice, many people in this country regard the NRPB guidelines as discredited, and irrelevant—and follow FDA practice.

The influence of NRPB—which has provided ICNIRP with senior personnel and much of its scientific support—is paramount, so it is unnerving to find that many of its recommendations—which appear at first sight to be so well supported have, in fact, very little—if any—justification at all. Much of the advice which they use to support their views is, in reality, their own. Thus NRPB cites the views of the "Weak Electric Fields Group"—an "independent" group—though packed with their staff and with secretarial services supplied by themselves. I understand that at least one of the independent members of that Group have told colleagues that they consider that their advice was over-interpreted. AGNIR—another such Group—is, equally, an NRPB creature in reality. One of my colleagues has analysed the references cited by NRPB and found that the actual basis in the peer reviewed literature is minimal. Most of what they cite in support of their positions is actually reviews of other reviews of a minimal literature.

Consequence

When Ministers are questioned about the issues surrounding the EU Directive they have to consult their Civil Servants. Those in Whitehall have a similarly limited understanding—and so seek the help of their "expert" colleagues—who are those who generated the problem in the first place. One can see this happening with all manner of technical issues—from energy policy, through health to defence. We currently have no means of ensuring that the advice that reaches Ministers and is implemented by Government is not based on prejudice rather than a truly judged assessment of the realities. It is idle to say that that is the role of the Opposition, as they are comprised of people with the same sort of background and training as those in Government, and are vulnerable therefore to the same sort of misdirection.

I think we must seek a method of ensuring that the quality of advice reaching ministers and others is of the highest quality. Such advice is always likely to be controversial—it would barely be needed otherwise—but we can attempt to ensure that there is no special pleading, or deliberate attempts to promote a particular obsession whether it is right or wrong. Academics submit to "peer review" every time they despatch a paper for publication or a grant application for funding. I don't think this is feasible for the quality control of advice to Government. Universities are assessed more broadly for the quality of their research output and grant obtaining achievements every five years, and Government funding through the Higher Education Funding system (via HEFCE of SHEFC for example) is distributed according to the performance which has been demonstrated. This process could, and should, be extended to Government scientific advisors and scientific units which are embedded in Ministerial Departments. The major independent scientific and medical organisations (the Royal Society, the Royal Academy of Engineering, the Academy of Medical Sciences) should be asked to review the performance of these units, by appointing small teams, in each case, to perform a review of their performance analogous to that undergone by University Departments—with a similar range of assessments from one to five*—which should be published. Politicians would thus be given an unbiased view of the quality of the people on whom they were depending, and the likely quality of what they are being told. These reviews should take place at roughly the same intervals as the University Research assessments—say every five years, and should involve the same sort of process in which those being assessed are asked to submit a listing of their output. Variations in the form of the data provided to the assessors will be needed to allow for the differences in function and remit which will be found from one Department to another. However, the assessment could, and should, include a consideration as to whether good value is being provided. Issues of privacy and secrecy may well be cited in order to justify avoidance of proper scrutiny, but it should always be possible to obtain enough information which can be placed in the public domain for an adequate assessment to be made. Certainly all those units which supply scientific and economic advice to Government should be assessed, including quasi-clinical organisations such as those supplying forensic information to the police, or specialist research units such as the Road Research Laboratory.

January 2006

References

1. Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). Official Journal of the European Union L 159 of 30 April 2004 (and corrigenda L 184 of 24 May 2004).
2. International Commission on Non-Ionizing Radiation Protection. Guidelines for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz). Health Physics 1998:74:494–522.
3. National Radiological Protection Board. Review of the scientific evidence for limiting exposure to electromagnetic fields (0–300 GHz). Documents of the NRPB 2004:15(3):1–210.
4. R v Secretary of State for Trade and Industry ex p Duddridge [1995] 1 EJRB 18 (HC); [1995] Env LR 151 (CA). The case concerned an application for judicial review of a decision by the Secretary of State for Trade and Industry not to apply the precautionary principle to limit emissions of electromagnetic fields from high voltage electricity cables.
5. International Commission on Non-Ionizing Radiation Protection Guidelines on Limits of Exposure to Static Magnetic Fields, *Health Physics* Vol 66, No 1, pp 100–106, 1994.

APPENDIX 13

Memorandum from the Medical Research Council

1. The Medical Research Council (MRC) notes that this Inquiry is focussing on three specific case studies:

1. The technologies supporting the Government's proposals for identity cards.
2. The classification of illegal drugs.
3. The use of MRI equipment: the EU Physical Agents (Electromagnetic Fields) Directive.

2. The MRC has no comment to make on the first of these. On the classification of illegal drugs, MRC funds research which has a lot to contribute to policy-making in areas such as psychosis and cannabis. However, the normal practice has been for individual scientists to serve on advisory committees. We are therefore not in a position to offer evidence on previous scientific advice on the current classification of drugs, but we hope to be involved in the recently announced review of the drugs classification system.

3. On the third, the MRC has a significant interest. The MRC is a major research funder and also an employer of specialist staff using high field magnetic resonance techniques. However, it was not consulted until recently by Government about the proposed legislation.

4. Magnetic Resonance Imaging (MRI) and Magnetic Resonance Spectroscopy (MRS) are technologies in which the UK has been a world leader—as recognised for example in the Nobel Prize awarded to Peter Mansfield—and remains at the cutting edge of technology development. The MRC and other funders are supporting development of 7-Tesla imaging and spectroscopy in Nottingham, one of only two Universities in Europe with these facilities.

5. As well as entering routine clinical use in many areas, MRI is also proving a mainstay of fundamental brain research, as well as research in areas such as cancer, cardiovascular research, and metabolism and obesity. New methods and uses are constantly emerging—(functional MRI, event-related fMRI, Diffusion Tensor Imaging, 3He diffusion MRI etc). Increased and innovative use of MRI forms an important part of the national strategy for strengthening clinical research. For instance, the MRC is funding a number of 3T whole-body MRI machines for dedicated research use as part of a coordinated funding plan to create new clinical research facilities and to strengthen experimental medicine. Use of MRI in animal experiments is not only improving the range and quality of information obtained, but also, in some cases, reducing the numbers of animals used. The result of work in animals is driving new applications of MRI, both experimental and clinical, in humans. Also, in some areas, the use of MRI is actively decreasing risk to patients by substituting for the use of ionising radiation, for example by providing alternatives to Positron Emission Tomography.

6. It would seem that the proposed regulations would restrict current uses of MRI—to a degree that exceeds the realistic risk from magnetic fields—and would also stifle innovation in use of the technology, long before any risk/benefit analysis could be attempted.

7. The MRC is particularly concerned that high-field machines (above 1.5 Tesla) will become much more difficult to operate and maintain, and downtime increased significantly, with a corresponding restriction in routine clinical use and reduction in research productivity.

8. I wrote to the relevant section of the Health and Safety Executive last September along the lines outlined above expressing regret that the MRC had not been consulted. I urged the HSE to consider closer dialogue with specialists in uses of MRI/MRS in medicine and medical research, in order to help it explore ways of implementing the Directive without damaging one of the UK's key scientific and technological strengths. I also asked that the regulations should be flexible and capable of adaptation and reinterpretation as new technical opportunities emerge, so that they do not become a barrier to innovation. I am pleased to say that subsequently, along with others, the MRC was invited to participate in a workshop organised by the HSE held on 5 January.

9. However, the report I have received from the workshop indicates that the HSE is interpreting the EU Directive in a way that will severely limit the use of MRI in both clinical and experimental settings. It appears that the HSE is taking a overly cautious approach based on the report of an NRPB Working Party that I chaired in 2001, and an associated conference, the proceedings of which were published in 2003. I have written to the HSE, explaining our concerns, in particular that the evidence for harmful biological effects in vivo is non-existent, and that they have misinterpreted our precautionary views. A copy of this letter is attached, for information (Annex).

10. In summary, the Government is now consulting more widely on the possible impact of the Directive, but this has come rather late. Earlier consultation would have reduced the risk of the UK introducing regulations that would limit the valuable use of MRI.

January 2006

Annex

23 January 2006

Dear Mr Denham,

Physical Agents Directive

I am writing to follow up the Workshop on the EU Physical Agents Directive (PAD) that the HSE arranged on 5 January at Skipton House. You kindly invited me to attend the Workshop, but I was unable to do so. I nominated Professor Derek Hill and Professor Jo Hajnal to attend on behalf of MRC and they have now reported back to me.

At the PAD Workshop, I understand that there were several references to the Report of the (then) NRPB Weak Electrical Fields Group, which met in 2001, and the associated conference on Weak ELF (Extremely Low Frequency) Electric Field Effects in the Body, the proceedings of which were published in *Radiation Protection Dosimetry*, volume 166 (2003). I believe that the conclusions of the Weak Electrical Fields Group and the Report of the conference were cited at the PAD Workshop to support the exposure limits for ELF fields that are proposed in the Directive.

I chaired the Weak Electrical Fields Group, and my colleague, Professor Denis Noble, chaired the associated conference. I am writing with the agreement and on behalf of Denis Noble and all the external expert members of the Group to express concern at the possibility that our cautious conclusions might be transformed into regulations curtailing the use and development of technology that offers proven benefits for patient care and biomedical research.

First, I wish to mention again some points I made last September in my letter on this issue to your colleague, Norman Smith.

Magnetic Resonance Imaging (MRI) and Magnetic Resonance Spectroscopy (MRS) are technologies in which the UK has been a world leader—as recognised for example in the Nobel Prize awarded to Sir Peter Mansfield—and the UK remains at the cutting edge of development of both the technologies and their application. The MRC and other funders are supporting development of 7-Tesla (7T) imaging and spectroscopy in Nottingham, one of only two Universities in Europe with these facilities. MRI, which has been described as the most important diagnostic advances of the twentieth century, is now routinely employed in many areas of clinical practice, with a huge benefit to patients. The technology for clinical scanners continues to develop, with 3T machines set to become the standard and with the growing prospect of a range of new clinical applications, including the use of ligand markers for the examination of biochemical and metabolic function, and for use as biomarkers in diagnosis and clinical trials.

MRI has revolutionised many aspects of fundamental and applied brain research, and is also widely employed in research on cancer, cardiovascular function, metabolism and obesity. New methods and uses are constantly emerging (functional MRI, event-related fMRI, Diffusion Tensor Imaging, 3He diffusion MRI etc). Increased and innovative use of MRI forms an important part of the national strategy for strengthening clinical research. For instance, the MRC is funding a number of 3T whole-body MRI machines for dedicated research use as part of a coordinated funding plan to create new clinical research facilities and to strengthen experimental medicine.

Use of MRI in animal experiments is not only improving the range and quality of information obtained, but also, in some cases, reducing the numbers of animals used. The result of work in animals is driving new applications of MRI, both experimental and clinical, in humans. Also, in some areas, the use of MRI is actively decreasing risk to patients by substituting for the use of ionising radiation, for example by providing alternatives to Positron Emission Tomography.

My colleagues and I were alarmed to learn that the conclusions of our discussions and the proceedings of the associated conference might be taken to support the implementation in 2008 of new regulations that could limit or forbid certain current MRI applications and inhibit the advance of this important field.

The remit of the Weak Electrical Fields Group was to speculate on possible effects of time-varying electrical and magnetic fields below 100 KHz on the human body, especially the nervous system, and to review the evidence for any effects. The emphasis was on ascertaining the lowest field strength at which effects might occur, and it is important to note that the existence of effects need not imply that they are harmful.

We considered three areas in which there is evidence for effects of ELF fields (typically <1 KHz) at relatively low field strength:

(i) influences on the growth and guidance of axons in the developing nervous system and on axonal regeneration;

(ii) the induction of phosphenes by stimulation of the retina with time-varying fields; and

(iii) subtle changes in the patterns of firing within interconnected circuits of neurons (and/or glia), with possible implications for network processing functions.

There is a good deal of evidence that direct current (DC) electric fields can affect nerve growth and nerve regeneration. However, most studies report effects only at high fields (of the order of 10–100 V m-1) and they require prolonged exposure to DC.

Phosphenes provide an easily-determined, reproducible end-point for the establishment of thresholds, but these are not necessarily representative of other situations because of the particular sensitivity of the eye. Although there is a degree of uncertainty about the relationship between external current density and internal fields, and about the frequency selectivity of such effects, there is general agreement that an internal field of 100 mV m-1 or even less can evoke phosphenes. Phosphene induction is highly frequency-dependent, with threshold rising rapidly above about 20 Hz because of the time constant of the neuronal elements that are stimulated.

Eye movements and sudden head movements within static magnetic fields above about 2T can induce phosphenes. However, the Group knew of no evidence that the induction of phosphenes per se carries any associated risk. Phosphenes are, after all, simply visual sensations produced by the activation of neurons in the retina—a process that occurs continuously, whenever we look at visual scenes. The Group simply concluded that the threshold for phosphenes might indicate the threshold for influences on neurons in the brain itself, which could conceivably have adverse effects.

Regions of the brain with highly ordered layers of neurons, such as the cerebral cortex, hippocampus and cerebellum, would favour interactions with electric fields. Effects of ELF fields on the firing patterns of networks of neurons have indeed been described for slices of brain tissue, mainly hippocampus, studied in vitro. Fields of the order 4 V m^{-1} can affect excitability and synchronicity of activity in neuronal tissue, and subtle effects have been seen with fields as low as 100 mV m^{-1}. The Group considered that such interactions might occur for frequencies up to 1 KHz or so, ultimately being limited by the temporal characteristics of voltage-gated ion channels. However, recent evidence (from the laboratory of Professor Jeffreys at Birmingham) has in fact shown that effects on network properties also decline very rapidly above 20 Hz, just as for phosphenes. This particular frequency-dependence for the excitation of phosphenes and for effects on brain neural networks might be different to the frequency-dependence assumed by those drawing up the EU PAD, when calculating the thresholds for effects at the frequencies used by MRI machines.

The Group did speculate, in its discussion, on possible adverse effects of any influences on neuronal network activity, if they were to occur in the human brain. Although, it is conceivable that they could exacerbate epilepsy, disturb memory processes or modify cognitive processes, such as perception or attention, there is no hard evidence for such effects. There have been a few studies of cognitive performance during exposure to weak, time-varying fields, but the results are negative, equivocal or uncertain as to dosimetry. A similar conclusion was reached in the NRPB (2004) Review of the scientific evidence for limiting exposure to electromagnetic fields (0–300 GHz). (*Documents of the NRPB* 15 (3), p 56):

> "Substantial numbers of laboratory experiments with volunteers and animals have investigated the possible consequences of exposure to weak EMFs on various aspects of nervous system function, including cognitive, behavioural and neuroendocrine changes. These studies have been reviewed by NRC (1997), NIEHS (1998), IARC (2002) and ICNIRP (2004). In general, very few effects have been established, and even the more robust field induced responses tend to be small in magnitude, subtle and transitory (Sienkiewicz *et al.* 1993; Crasson *et al.* 1999)."

We urge the HSE, in considering how to draft the UK regulations on exposure levels, to take full account of the enormous benefits of clinical and experimental MRI. Moreover, we believe that it is impossible to estimate the risk of harm, if any, without further research. There is an urgent need for:

- proper, quantitative dosimetric modelling of internal fields created by exposure to the real-life conditions of MRI;
- experimental work to make quantitative assessments of any cognitive effects produced by such fields, and their dependence on exposure duration; and
- rational consideration of whether any such effects might be hazardous.

We understand that the Health Protection Agency Centre for Radiation, Chemical and Environmental Hazards at Chilton (former NRPB) has the expertise and the capacity to undertake the necessary dosimetric work, if funding can be provided. A number of research groups in the UK have had extensive experience in the study of cognitive functions during exposure to EMFs, including that of Professor Alan Preece at Bristol and the Biomedical Sciences Department of Dstl at Porton, and it might be possible for relevant research to be undertaken quickly and at modest cost.

We hope that funding can be forthcoming for this urgently needed research, the results of which could inform rational decisions about future UK regulations.

The HSE will know of considerable concern, over the past few years, about the possible risks from so-called "non-thermal" effects of radiofrequency fields associated with mobile telephony. The Stewart Committee (of which I was a member) urged a precautionary approach, but this has taken the form of better public communication and the funding of research, rather than restrictive regulations. It is salutary to note that the research that has subsequently been performed through the Mobile Telecommunication and Health Research Programme, and through a programme of work sponsored by the Home Office on the new police communication system (TETRA), has generally failed to replicate early indications of such "non-thermal" effects. It would be very unfortunate if MRI, with all its proven benefits, were to be curtailed, simply because thresholds for biological effects can be defined, but without clear evidence that such effects are hazardous.

I am copying this letter to the Clerk of the House of Commons Science and Technology Committee, as part of the MRC's evidence to the Committee for its inquiry on "Scientific advice, risk and evidence".

Colin Blakemore

On behalf of:

Professor David Attwell FRS (University College, London)

Professor John Jefferys FMedSci (University of Birmingham)

Dr John Tattersall (Dstl, Porton Down and University of Southampton)

Professor Denis Noble FRS (University of Oxford)

APPENDIX 14

Memorandum from David Grainger MSc, Senior Medical Device Specialist (MR & X-ray Imaging) Device Technology and Safety Medicines and Healthcare products Regulatory Agency (MHRA)

MRI Incidents Categorised

Static Magnetic Field

- Ferromagnetic projectiles;
- Patients scanned with shrapnel fragments;
- Pacemakers patients scanned accidentally.

Gradient Magnetic Field

- Excessive noise;
- Physiological effects.

Radiofrequency Magnetic Field

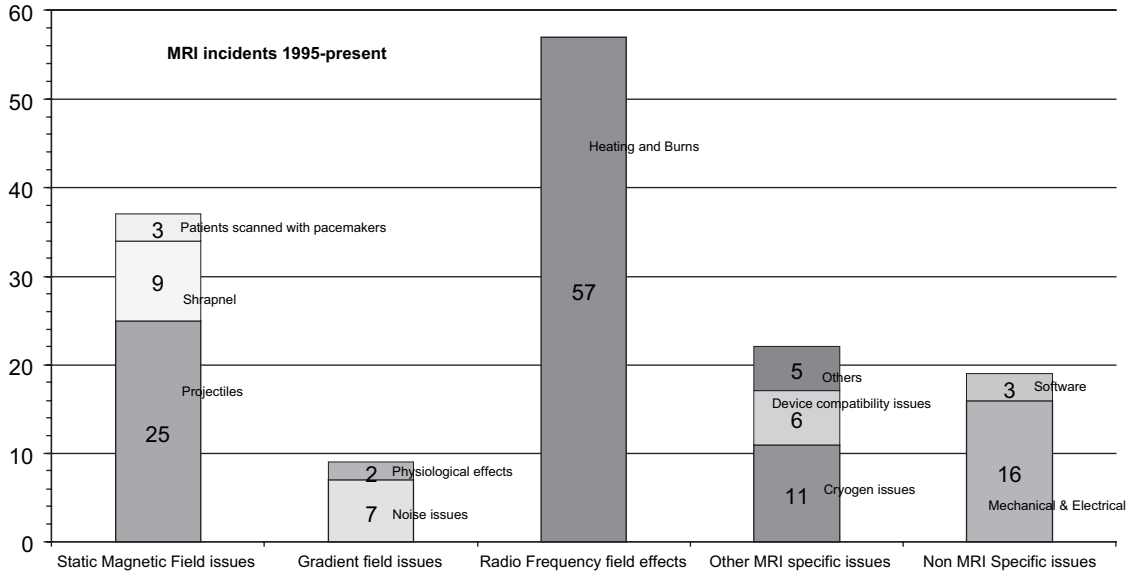
- Heating & burns.

Other MRI Specific Issues

- Cryogen issues;
- Device incompatibility.

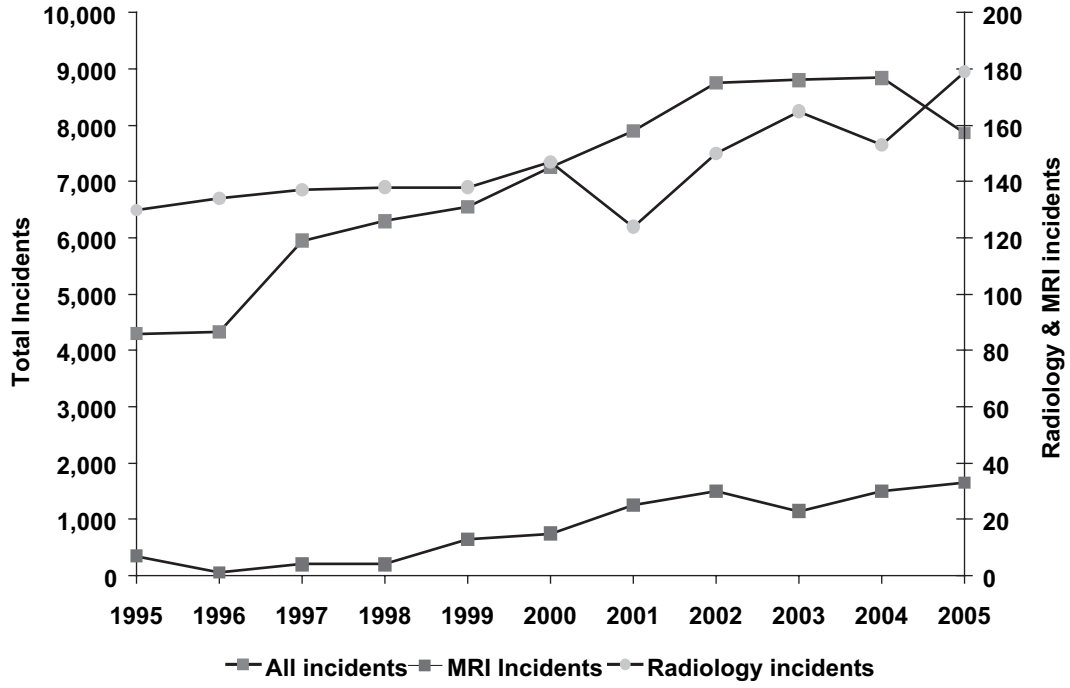
Non MRI specific issues

- Mechanical and electrical problems;
- Software problems.



Incident Trends 1995–2005

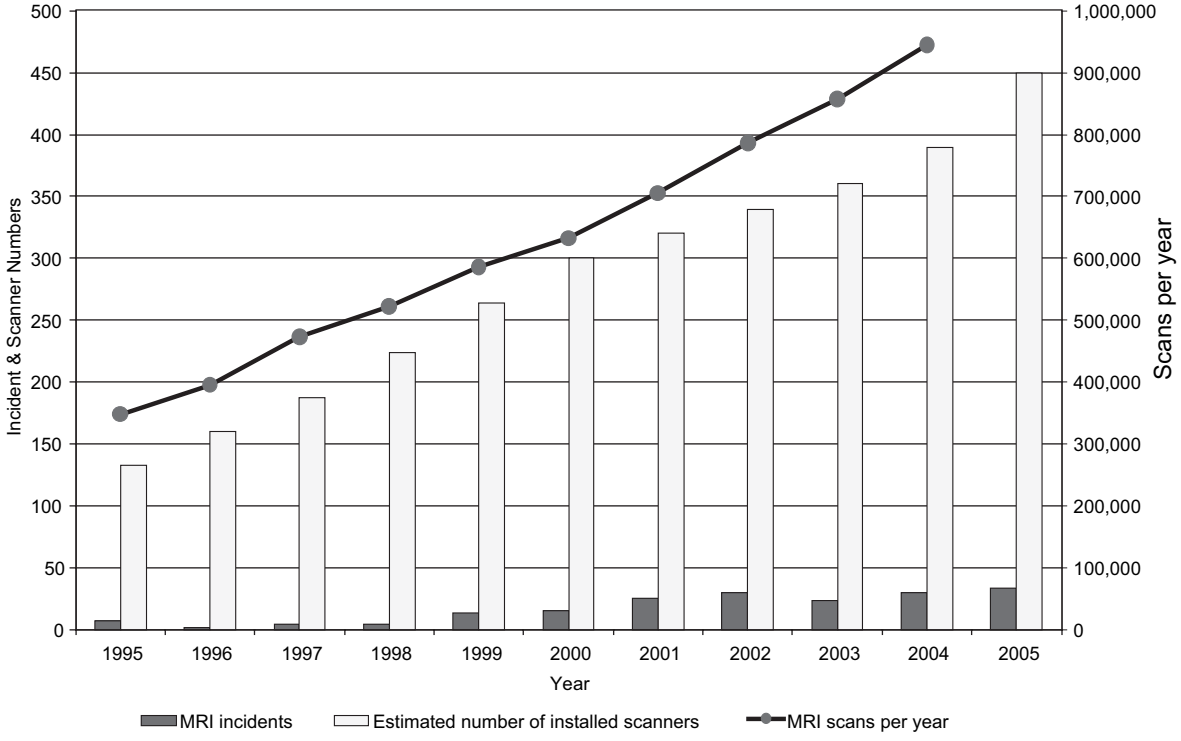
- MRI Incidents;
- X-ray equipment incidents;
- All incident reported to MHRA.



SCAN NUMBERS

Scan data from: http://www.performance.doh.gov.uk/hospitalactivity/index.htm

Scanner Numbers from MagNET (a PASA device evaluation centre).



April 2006

APPENDIX 15

Memorandum from Siemens

MR MANUFACTURERS' ADVICE ON ELECTROMAGNETIC FIELD (EMF) EXPOSURE

General Principle

All safety aspects of MR equipment are dealt with in the MR safety standard IEC/EN 60601-2-33 (MEDICAL ELECTRICAL EQUIPMENT—Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis). Especially the EMF exposure of patients covers a major part of this standard. The standard also defines requirements which safety information the system user manual has to contain. All MR systems on the European market are in compliance with this safety standard otherwise they would not get market approval.

EMF information provided in user manuals (Please refer to Siemens example attached) (not printed):

The user manual begins with a special safety section. This section contains general information about EMF effects generated by MRI and discusses various potential risks or physiological effects, especially for patients. These include short term physiological reactions such as dizziness, which can be observed in strong static magnetic fields, the possibility of peripheral nerve stimulation, the warming of tissue due to RF exposure. Potential hazards of persons (patients and operating personnel) with implants are discussed and stray field plots of the static magnetic field are provided, especially in light of the main hazard of any MR system, that ferromagnetic objects get attracted and might become dangerous projectiles when coming close to the magnet (missile effect). There are also warnings given about the effect of quenching in superconductive magnets and of currents induced into electric cable loops, which can lead to burns.

Also the necessity of compliance with national regulations is stated. Some of these are specifically referenced, for example the German Accident Prevention Regulation which sets EMF exposure limits for workers. However, the user manual does not list each applicable regulation of each individual country in the European Community.

Involvement of Manufacturers with the Development of the EC Directive 2004/40/EC

MR manufacturers were first informed about the development of the regulation towards the end of 2002, with the first draft circulated in December of that year.

MR manufacturers immediately started to analyse the possible impact on the application of MR. Under the leadership of COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry), a first position paper was created and published in Spring 2003, explaining the threat for themedical application of MR. The aim was to get a general exemption from the scope of the directive for people working with MR.

The MR medical community was then informed aboput this threat by approaching national and international radiological organizations such as ISMRM Safety Committee (Int Soc of MR in Medicine), ESMRMB (Eur Soc of MR in Medicine and Biology), ECR (European Congress of Radiology). Information has been provided on several web sites (eg:
http://www.ismrm.org/safety/EU_Safety.htm, http://www.esmrmb.org,
http://www.magres.nottingham.ac.uk/safety/eu/).

In Aug. 2003 COCIR invited members of the SQWP (Social Question Working Party), who were involved in the development of the directive, to visit an MR site in Leuven, to demonstrate the potential conflict with clinical practice.

The further development of the directive was carefully monitored. The EC commission was contacted several times by manufacturer organisations as well as MR organisations. The directive became an issue on national and international annual radiological conferences.

The early drafts of the EC directive had stipulated exposure limits for the static magnetic field, which at that time were the major focus of concern. Eventually the proposed limit was dropped by the EC commission, as a result of protests and lack of scientific evidence.

In April 2004 the EC Directive was published as 2004/40/EC, with no limit values for the static magnetic field, but with exposure limits for RF fields and, most critically, for low frequency magnetic fields (gradient fields), which were in conflict with MR practice and equipment design, without exemption for medical use. (The conflict only applies to operators, not to patients).

MR manufacturers have lobbied and will continue to lobby in line with medical MR users for an exemption for people working with MR in medicine.

MR manufacturers have initiated an attempt to amend the MR safety standard IEC 60601-2-33 for assuring safety of "MR-workers" even when exposed by EMF exceeding the limits given in the EC directive. The draft of this amendment has been prepared by the IEC working group MT 40 and will be distributed shortly for comments.

April 2006

APPENDIX 16

Memorandum from Mr Nikolaus Van Der Pas, Director-General, Employment, Social Affairs and Equal Opportunities, European Commission

Was the Directive based upon the precautionary principle and, if so, what definition of the principle was used?

The directive provides protection against the established health effects in the human body that may result from exposure to electromagnetic fields. It does not address other potential health effects, like possible carcinogenic effects, for which there is not, as yet, conclusive scientific evidence establishing a casual relationship with electromagnetic fields exposure. The Committee is kindly referred to recital 4, Article 1§2 and Article 2 b) of the directive.

In the event of the working group set up to look at the impact of implementation on MRI proposing some amendment to the Directive, what possibilities exist for making such an amendment before its scheduled implementation, or for otherwise mitigating its impact?

The directive was drafted and approved by the European Institutions after extensive public consultation in accordance with the rules provided by the EU Treaty. Scientific evidence has been an essential element in this comprehensive process. Following observations which have come forward after the adoption of the directive, ie from Members of the European Parliament, Mr Spidla, Member of the European Commission responsible for Employment, Social Affairs and Equal Opportunities, has invited a working group to measure the real exposures of health personnel in following current medical protocols for using MRI equipment and to compare those with the exposure limit values established by the directive in order to verify whether the claim that the directive will impair the use of MRI equipment is founded or not. The European Commission will examine the results of this study and draw the appropriate conclusions. Until then, the question as to whether the directive should be modified before it's entry into force remains a hypothetical one.

May 2006

APPENDIX 17

Memoranda from Research Councils UK

What horizon scanning activities UKRO undertake to inform the UK research communities about proposed Directives which may have an impact on them?

What notification was received, and when, from UKRO about the potential impact of the EU Physical Agents (Electromagnetic Fields) Directive?

UKRO is sponsored by the Research Councils and over 150 subscribing organisations (mostly HEIs) and responds to the needs of its funders by providing information and advice relating to the EU's research and training programmes (no government departments sponsor UKRO). The Office therefore has very limited horizon scanning activities on the huge number of directives which emanate from the European Commission. Any calls for proposals for contract work or related research tasks published in the Official Journal of the EU would have been circulated to sponsors and subscribers in the UK through the usual UKRO information management system. As a consequence of this it would not have been expected to pick up on this particular EU Directive. Any future policy analysis undertaken by UKRO will be limited to EU developments directly relating to research and HE such as the ERC, EIT and rules of participation in the Framework Programme.

June 2006

APPENDIX 18

Supplementary evidence from Dr Stephen Keevil, Consultant Physicist, Head of Magnetic Resonance Physics Guy's and St Thomas' NHS Foundation Trust

EU Physical Agents (Electromagnetic Fields) Directive

1. *What indications were given by the MR community that it was content with the Directive following the removal of static fields; and when concerns about the inclusion of time-varying fields were first raised with the HSE or NRPB/HPA? (Q 868)*

To the best of my knowledge no such indications were given. Indeed the question did not arise, since the community was advised that the HSE would seek to retain the static field limit in UK legislation, even after it was removed from the Directive (see Q 905).

Concerns about the time-varying field limits were first raised by the European MR equipment manufacturers in a communication to the Social Questions Working Party in April 2003. I believe that the HSE represented the UK on this working party and therefore would have become aware of the issue at that time. The earliest written record I can find of communication directly between the UK MR community and government agencies on this issue is in a letter from IPEM to MHRA in June 2004, but there were a number of earlier meetings with the HSE, for which there is no written record, where the issue may have been raised (see original submission from MR community, Annex A). The time-varying field issue was certainly discussed at the HSE stakeholder meeting in July 2004 and on a number of subsequent occasions when I was present.

There appear to have been communication problems within the HSE, so that senior policy staff were not aware of what the MR community was being told about the static field issue by HSE representatives, or what the same HSE representatives were being told about time-varying field issues by the MR community at European level.

2. *You undertook to let the Committee have any comments on the transcript of the evidence session the Committee held in Brussels on 11 May.*

Comments are attached as Annex A. I have also taken the opportunity to expand briefly on my answers to some of the questions posed during the session on 17 May, and this is attached as Annex B. I am enclosing with this letter a copy of a manuscript submitted to the Institution of Engineering and Technology Seminar on the Physical Agents (EMF) Directive which addresses the central question of whether there is evidence that the Directive will impact on MRI practice.

Finally, I am aware that the various ways in which EMF in different frequency bands are used in MRI, compounded by the different ways in which exposure limits are set in each of these bands, make detailed discussion of the impact of the limits complex. This situation has not been helped by some confusing statements made in Brussels. I hope the following table may help.

	Frequency	*Exposure limit*	*Action value for magnetic flux density*	*Estimated maximum occupational exposure in the UK*
Static magnetic field (present at all times for mid and high field systems)	0 Hz	None	0.2 T	3 T (clinical) 7 T (research)
	<1 Hz (typical) (generated by movement of subject)	Current density 40 mAm^{-2} to head and trunk	0.2 T	Possibly up to several hundred mAm^{-2}
Switched gradients (present during imaging)	500 Hz (typical)	Current density 10 $mAm^{-2}$to head and trunk	50 μT	2,000 μT (to head) (60 mAm^{-2} approx?—possibly higher)
RF field (present during imaging)	10-400 MHz	SAR 0.4 Wkg^{-1} whole body average, averaged over six minutes. SAR 20 Wkg^{-1} to the limbs, averaged over six minutes.	0.2 μT	<0.4 Wkg^{-1} whole body average in most conceivable situations. Local SAR may approach limit in some instances.

MRI uses EMF in three distinct frequency ranges—a static magnetic field, time-varying magnetic fields in the frequency range 100s–1000s Hz (known as switched gradients), and radiofrequency (RF) fields (10s–100s MHz). Typical frequency values have been shown in the table in the case of time varying fields, as the limits are frequency dependent in this part of the spectrum. In the case of the static field, there is no exposure limit in the Directive but concern arises because movement through the field exposes staff to a slowly time-varying field which induces currents that almost certainly exceed the limits at 3 T and quite possibly also at 1.5 T. Where possible, references supporting the figures in the right hand column are given in Annex B in relation to question Q 810.

May 2006

Annex A

Comments on uncorrected transcript of oral evidence taken before the Science and Technology Select Committee, 11 May 2006

The expertise of the MR community

1. In a number of places (Q 678, 683, 777, 788, 794, 797) Mr Biosca seeks to draw a distinction between, on the one hand, an expert scientific community that supports the ICNIRP limits and, on the other, a community of medical users of MRI who he implies are ignorant of the issues around exposure to EMF in their practice.

2. In fact the MR community is a diverse body of medical practitioners, clinical and basic scientists with a wide range of relevant expertise and experience. Those who have made representations about the Physical Agents Directive in the UK comprise physicists, medical physicists, biochemists, physiologists and other biological scientists, many of them of professorial status. They include a Nobel Prize winning physicist (Sir Peter Mansfield) and both the present Chief Executive of the MRC (Professor Colin Blakemore, a professor of physiology with directly relevant research interests) and his immediate predecessor (Sir George Radda, a professor of biochemistry).[23]

3. Regarding input by manufacturers, Mr Biosca states that:

> In my view, manufacturers have not said anything at all, they are very happy with the Directive so far (Q 683).
>
> So far, neither from Siemens nor Philips. We do not have any complaints to the Commission so far from manufacturers of magnetic resonance equipment (Q 684).

4. Although these comments are contradicted later in the evidence (Q 742–749), it is perhaps worth reiterating that Siemens and Philips made representations about the impact of both the static and time-varying field limits on MRI to the Commission's Social Questions Working Party as early as April 2003. I can provide the Committee with a copy of this material if required.

The nature of the ICNIRP guidelines and the evidence behind the limits

5. Mr Biosca presents the ICNIRP 1998 guidelines as justification for the exposure limits contained in the Directive (eg Q 752), implying that the limits are supported by a large quantity of peer-reviewed publications (Q 712–715) and are the settled opinion of the relevant expert community. It is true that there is a large body of published research on EMF exposure, but this literature reveals a wide margin of uncertainty rather than agreement. Most published studies report negative results and many of the positive results, some of which were published over 20 years ago, lack replication. There are some established effects, such as magneto-phosphenes, but these relate to biological effects rather than adverse health effects.

6. Even in 1998, the view of ICNIRP was rather more equivocal than the Directive and Mr Biosca imply.

> In establishing exposure limits, the Commission recognizes the need to reconcile a number of differing expert opinions . . . [to] provide an adequate level of protection from exposure to time-varying EMF[24]

7. By 2004 ICNIRP accepted that:

> Guidelines on occupational and general public exposure limits to all ranges of electromagnetic fields (static, time-varying gradients, radiofrequency) have been published (ICNIRP 1994, 1998). However, these guidelines were written many years ago, and they are now under review.[25]

8. And in the same year NRPB described adoption of the ICNIRP limits as:

> . . . a cautious approach . . . to indicate thresholds for adverse health effects that are scientifically plausible[26]

[23] See original memorandum from the MR community, Annex B.
[24] ICNIRP (1998) *Health Physics 74* 494–522.
[25] ICNIRP (2004) *Health Physics 87* 197–216.
[26] NRPB (2004) Documents of the NRPB Vol 15 (3) p 137.

9. The MR community has consistently maintained that, contrary to the view presented by Mr Biosca, the ICNIRP guidelines represent a cautious interpretation of limited scientific data, and should be treated as *guidelines* to consider alongside other factors as part of a wider risk assessment, rather than used as the basis for statutory exposure limits.[27] In his evidence to the Committee on 17 May, Dr McKinlay (a former Chair of ICNIRP) vindicated this position, stating that

> ICNIRP does exercise caution in coming to its advice on guidelines; that is intrinsic in the way ICNIRP operates. It is dealing with the health of people and it does exercise caution, both in interpreting the signs [sic] and in arriving at the guidelines that we give. I would emphasise that they are guidelines. We do not recommend legislation and we do not recommend—such as in the EC directive—regulations (Q 866).

10. The MR community maintains that there is no evidence that adverse health effects occur at the exposure limits stated in the Directive, and that this assertion is supported by the fact that hundreds of millions of patients have been exposed to MRI over the past 25 years, at gradient field amplitudes up to 100 times the occupational exposure limit, with no evidence whatsoever of harm. This evidence relates to patient exposure, not exposure of workers, but it would be perverse to suppose that the physiology of the two groups differs fundamentally!

11. Later in the session comparison is drawn between the IEEE exposure guidelines (not IEE as stated) used in the USA (set by the International Committee on Electromagnetic Safety—ICES)[28] and those of ICNIRP. Mr Biosca says of the ICES limits that

> They follow the same basic restrictions as ICNIRP but they set what they call the maximum permissible exposure . . . (Q 803).

12. The ICNIRP basic restrictions are referred to as exposure limit values in the Directive. As I stated in oral evidence (Q 828–829), it is not true that the basic restrictions set by the two organisations are the same over the frequency range of concern to the MR community. ICNIRP and ICES express their basic restrictions in different ways, but Reilly[29] has shown that the two sets of limits are quite different in the frequency range up to 3 kHz. For example, at 1000 Hz the Directive exposure limit (ICNIRP basic restriction) is an induced current density of 10 mAm^{-2}, but the lowest ICES basic restriction at that frequency corresponds to approximately 180 mAm^{-2}. The range of uncertainty in the scientific evidence is demonstrated by the fact that two expert bodies working with essentially the same evidence base are able to propose limits differing by a factor of almost 20.

13. ICE's Maximum Permissible Exposure (MPE) is analogous to the ICNIRP reference levels (action values in the Directive), and only of importance as a tool to demonstrate compliance with the exposure limits (basic restrictions). Hence discussion of the differences between how MPE and reference levels are calculated is something of a red herring in terms of exposure limitation.

Static magnetic fields

14. In relation to exposure to strong (7-8 T) static magnetic fields, Mr Biosca states:

> They are doing experiments with volunteers and in order to walk the room with the patient—it is a room like this—they had to spend 20 minutes because if you move fast within the magnetic field you get induced currents in the body and you have disturbances in the brain because there is a migration of calcium ions in the neurons and you become really, really sick and you can fall.

15. I have discussed this point with Professor Penny Gowland, a professor of physics who works with the 7 T MR system in Nottingham (not Norfolk, as stated in the evidence). She assures me that this is completely untrue and staff move in the scanner room at perfectly normal speed without ill effects.

16. It is true to say that currents are induced in the body and the head on moving through a static magnetic field, and the limits contained in the Directive in this regard will be a serious problem for MRI. It is also true that many people report feelings of vertigo on moving through strong magnetic fields. This is a transient and harmless phenomenon, often compared to motion sickness. It is believed to be due to interaction with the organ of balance in the inner ear.[30] I am not aware of any evidence that it is due to migration of calcium ions in neurons as stated, and to suggest that the effect is so serious that it takes 20 minutes to walk across the scanner room is a gross exaggeration.

Time-varying fields

17. Mr Biosca states that the MR community was initially concerned only about the static field limit but has now changed its position to one of concern about pulsed fields in the frequency range 100–500 kHz (Q 770–774).

18. In fact, concerns were raised about the time-varying field limits as early as April 2003. The frequencies involved are up to about 3,000 Hz, not 100,000-500,000 Hz as stated.

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[27] See original memorandum from the MR community, Sections 3.4.1 and 5.1.3.
[28] ICES (2002) IEEE Std C95.6 (New York: IEEE).
[29] Reilly JP (2005) *Health Physics* **89** 71–80.
[30] WHO (2006) Static Fields. Environmental Health Criteria 232 (WHO: Geneva).

19. Mr Biosca states that in this frequency range:

> . . . the only thing you have is electro-stimulation which can go very, very high and induce a current of 1,000 amperes a square metre and you would have fibrillation of the heart (Q 774).

20. It is perfectly true that electrical stimulation occurs at very high induced current densities—peripheral nerve stimulation (PNS) at around 1 Am^{-2} (I assume this is what Mr Biosca is referring to, and that 1,000 Am^{-2} is an error in the transcript), cardiac stimulation at higher levels still. Obviously these effects are highly undesirable in either patients or staff, and MR scanners are designed according to international standards to prevent them.[31] The MR community agrees that PNS is the only effect for which there is evidence in this frequency range, and would have no issue with limits set at the PNS threshold. However, the limit set in the Directive (0.01 Am^{-2} over most of the relevant frequency range) is two orders of magnitude below this level.

21. He also states that:

> At the highest frequencies in the range of 300 KHz and 500 KHz you have burns (Q 774).

22. EMF at these frequencies is not used in MRI. Radiofrequency fields at 10s to 100s of MHz are used, and at sufficiently high intensities they can certainly cause burns. Again, systems are already designed to minimise this risk for patients and hence also for staff. Burns do not occur anywhere near the specific absorption rate (SAR) limit in the Directive—0.4 Wkg^{-1}, which corresponds to a rise in temperature of approximately 0.1°C.

23. Comments were made to the effect that exposure to time-varying fields could be made compliant with the Directive by limiting the time a worker uses MRI equipment (Q 683, 763, 764, 779, 780). It is important to make clear that this is an option only for radiofrequency fields. The MR community's greatest concern is in relation to lower frequency time-varying fields. At these frequencies, up to about 3 kHz, the Directive allows no scope for time averaging, so the exposure limits represent absolute limits that cannot be satisfied in this way.[32]

> The exposure limit values in the frequency range 1 Hz to 10 MHz are based on established adverse effects on the central nervous system. Such acute effects are essentially instantaneous and there is no scientific justification to modify the exposure limit values for exposure of short duration.[33]

Evidence that the Directive will impact on MRI

24. In his evidence Mr Biosca repeatedly and vehemently denied that the Directive will affect MRI practice (Q 678, 683, 690, 691, 693, 717, 733, 735, 759, 794, 797). He claims that the reason adverse health effects have not been observed in MR workers is that they are invariably exposed below the limits (Q 733). The MR community believes that there is substantial evidence that exposure in MRI exceeds the limits, which is summarised in Annex B (additional response to Q 810) and in the attached paper.[34]

25. Mr Biosca said in evidence that ICNIRP have stated "No. In no circumstances do medical personnel with currently installed magnetic resonance equipment in hospitals, which goes up to three teslas, get exposures over the limit values" (Q 678).

26. ICNIRP does not have expertise on MR system design or use. In his evidence to the Committee on 17 May Dr McKinlay stated that:

> I know of no evidence like that, or advice that ICNIRP gave to the Economic [sic] specifically on MRI. As I said at the beginning, we do not concern ourselves with exposure to the particular device with a particular frequency (Q 887).

27. In relation to interventional MRI specifically, Mr Biosca states:

> Even in the operating theatre when they use these machines, the machines that are used for brain surgery or heart surgery are very low powered machines, a maximum of 0.4 teslas. You can go to the manufacturers and they will tell you that (Q 691).

28. This is untrue, as I am sure the manufacturers will readily confirm. There are two 1.5 T MR systems used for intervention in the UK (at Guy's and St Thomas' Hospitals), with two more being installed in the near future (at Great Ormond Street and Queen Square). Similar systems are in place in other European countries, and in the USA intervention is performed using magnets up to 3 T. There are also low field systems (0.2-0.3 T) with open architecture dedicated to interventional use, but these have relatively poor performance and the trend now is towards higher field (1 T) systems even in the open scanner market.

[31] IEC (2002) Standard 60601-2-33 (IEC: Geneva).

[32] See original memorandum from the MR community, Section 3.3, and Annex B of this additional submission.

[33] Official Journal of the European Union L 159 of 30 April 2004, Note 2 to Table 1.

[34] Keevil SF (2006) Proceedings of Institution of Engineering and Technology Seminar on The Physical Agents (EMF) Directive (in press).

29. Describing use of interventional MR systems, Mr Biosca states:

> Secondly, there are machines that when they are permanently installed in operating theatres they are hidden below the table and when the doctor needs to see an image after doing a certain operation it comes out from under the table and it is switched on (Q 691).

30. I am not aware of any installation that fits this description—there may be one somewhere in the world, but it is not the case generally. Most MR systems are based around superconducting magnets, which are always switched on. The switched gradients and radiofrequency field are only present during imaging, but in many cases the intervention is performed directly under imaging guidance.

31. Regarding exposure of interventionalists, he states that:

> There is very limited exposure. Do not ever think that the doctors in operating theatres use the machines continually throughout the whole operation because that is not true. They use it for a very limited amount of time, a maximum of five minutes and no more (Q 691).

I am not sure on what basis Mr Biosca believes he knows more about interventional MRI practices than the professionals who have developed and perform these procedures. For the record, in my own institution, interventionalists are exposed to time-varying fields continuously for up to around 20 minutes. However, since the time-varying field exposure limits that we are most concerned about are absolute, without scope for time averaging, the length of exposure is irrelevant.

MR safety in hospitals

32. Mr Biosca acknowledges that hospitals have stringent MR safety procedures in place (Q 690), and of course these procedures include measures to limit risk due to attraction of ferromagnetic objects (Q 680, 731) (not 'any metallic material' (Q 680)—many metals are not ferromagnetic and are quite safe in the MR environment). Safety procedures also include use of hearing protection by staff who remain close to the scanner during imaging (Q 690). Establishment of these safety precautions in UK hospitals is the responsibility of medical physicists, who have been prominent in the MR community's representations about the Directive.

Annex B

Supplementary material relating to oral evidence taken before the Science and Technology Select Committee, 17 May 2006

Q810 *Dr Harris: . . . Can you help us by identifying that the opinion you give, that these action limits and maximum limits would impact on diagnostic and therapeutic interventional procedures, are published somewhere in the form of evidence, in peer-reviewed scientific journals, with a conclusion to pass muster which states: "These limits would interfere"?*

In answering this question I omitted to mention a number of published, peer reviewed papers reporting the results of simulations of exposure to time-varying magnetic fields in and around MR scanners. Because the exposure limits are expressed in terms of induced current density, which cannot be measured directly, simulation is the only means of investigating compliance with the limits. Work by Crozier's group[35, 36] demonstrates that exposure to very low frequency fields due to movement through the static field will almost certainly exceed the relevant exposure limit at 3 T and very likely also at 1.5 T. This will potentially affect all clinical and non-clinical activities in the vicinity of MR scanners. There is also some work on exposure to the switched gradient fields which, while less directly relevant, demonstrates that the occupational limits are breached for patients inside the scanner and therefore probably also for staff standing close to the bore during imaging.[37, 38] I am appending a recent manuscript that explores this evidence in more detail.[39] The impact of the Directive in MRI has also been discussed in two other refereed publications,[40, 41]

[35] Liu F, Zhao H and Crozier S (2003) *J Magn Reson 161* 99107.
[36] Crozier S and Liu F (2005) *Prog Biophys Molec Biol 87* 267-278.
[37] Gandhi OP and Chen XB (1999) *Magn Reson Med 41* 816–823.
[38] Liu F and Crozier S (2004) *J Magn Reson 169* 323–327.
[39] Keevil SF (2006) Proceedings of Institution of Engineering and Technology Seminar on The Physical Agents (EMF) Directive (in press).
[40] Hill DLG, McLeish K and Keevil SF (2005) *Acad Radiol.* **12** 1135–1142.
[41] Keevil SF, Gedroyc W, Gowland P, Hill DLG, Leach MO, Ludman CN, McLeish K, McRobbie DW, Razavi RS and Young IR (2005) *Br J Radiol 78* 973–975.

Q826 *Mr Flello: I want to pick up on something you said a few months [sic] ago in terms of the dizziness effects that have been noted. You said there was some suggestion that it was to do with calcium ions but then I think you said, "We think it has more to do with the inner ear." Do you have any evidence on which this conclusion is based?*

The reference for this is work by Schenck,[42, 43] cited in the very recent WHO monograph on static field effects.[44] However, while there appears to be consensus that the organs of balance in the inner ear are involved, the precise mechanism of interaction remains uncertain.[45]

APPENDIX 19

Supplementary evidence from Lord Hunt of King's Heath following the evidence session on 17 May 2006

Scientific Advice, Risk and Evidence: How Government Handles Them

EU Physical Agents (Electromagnetic Fields) Directive and its impact upon those working with MRI equipment

I was pleased to give evidence about this Directive with Geoffrey Podger of HSE on 17 May. I said I would write to the Committee on certain matters.

You asked for evidence of the point at which the UK did seek to remove MRI completely from the Directive during negotiation. In the Social Questions working group of the European Council, on 26 March 2003, Germany and the Netherlands proposed a derogation, "for persons working with the magnetic resonance technique in the medical sector." Official European Council papers record the UK (and an increasing number of Member States) supported this proposal from the working group meeting of 13 May 2003 onwards, throughout negotiations.

This continued until static fields were removed from the Directive at the final working group before political agreement, on 17 September 2003.

A page of the draft proposal produced after the meeting on 13 May 2003 is attached,(not published), showing a footnote with UK supporting the proposed derogation. Should you wish copies of the same document produced before or after this date I would be pleased to provide them.

You also asked what specific lessons will be taken into account in the future. I hope it was clear in my answer to the Committee that HSE do want to learn from this experience. The key lesson is to listen and work with all stakeholders and not become complacent that existing networks are sufficient.

I also mentioned that I would provide you with a timescale for our future work to seek a solution to this issue. I mentioned to the Committee that HSE are working with the Royal College of Radiologists and various clinicians with an interest. Indeed I have had a further meeting with them since the hearing, on 23 May, at which we discussed progress. We have agreed to get together again in six months time to assess how the research evidence that will have emerged by then can be used to best effect. We will also be able to review progress with the European Commission expert group, which is expected to meet in June.

May 2006

APPENDIX 20

Memorandum from UKRep, Brussels

What mechanisms and resources UKREP has in place, or has access to, in order to determine whether proposed Directives have implications for, or should be informed by, UK science; and by what means UKREP obtains scientific advice when necessary?

UKRep relies upon, and is instructed by, Government Departments who are responsible for formulating policy and taking the necessary expert advise.

[42] Schenck JF (1992) *Ann N Y Acad Sci 649* 285–301.
[43] Schenck JF (2000) *J Magn Reson Imaging 12* 2-19.
[44] WHO (2006) Static Fields. Environmental Health Criteria 232 (WHO: Geneva).
[45] Glover PM, Gowland PA, Bowtell RW and Cavin I (2006). *Proc. Internat. Soc. Magn. Reson. Med.* 2053.

When UKREP was first asked to seek to remove MRI scanners from the scope of the Directive and what steps it took in support of this request? (Qs 899–901)

In time for the meeting of the Council's preparatory Social Questions Working Party on 13 May 2003. At this meeting the UK along with five other delegations called for a derogation for people working with MRI in the medical field. We pursued this point at the meetings of the Group on 22 July and 2 September. As I explained when we met, this is a matter of public record since the Council Secretariat's record of the meeting 2 September (Outcome of Proceedings Ref. 12207/03) has been published and is on the Internet. Footnote 22 on page 15 refers. The text is available at URL: http://register.consilium.europa.eu/servlet/driver?page=Result&lang=EN&typ=Advanced&cmsid=639&ff—COTE—DOCUMENT=12207%2F03&ff—COTE—DOSSIER—INST=&ff—TITRE=&ff—FT—TEXT=&ff—SOUS—COTE—MATIERE=&dd—DATE—DOCUMENT=&dd—DATE—REUNION=&dd—FT—DATE=&fc=REGAISEN&srm=25&md=100&ssf

When UKREP first made aware of the representations by MR manufacturers to the Commission regarding the Directive?

We were not made aware direct of representations made to the Commission. However, I understand that UK authorities and other delegations' authorities received representations on MRI from a number of organisations in the course of Spring 2003 and I assume that the Commission was also approached.

What links UKREP has with the United Kingdom Research Office in Brussels?

UKRO helps UK organisations participate in the EU research programme and is jointly funded by the seven UK grant-awarding Research Councils and receives subscriptions from its member organisations. UKRO has a particular expertise on the Rules of Participation for the EU research programme. Colleagues in UKRep who deal with negotiations on the framework for the research programme have good informal contacts with UKRO.

June 2006

APPENDIX 21

Supplementary evidence from the Government

SCIENTIFIC ADVICE, RISK AND EVIDENCE: HOW GOVERNMENT HANDLES THEM 2005–06

1. *When the Government first sought to remove MRI scanners from the scope of the Directive, by what method, and what evidence is there to support this assertion? (Qs 868, 871, 899–901)*

In the Social Questions working group of the European Council, on 26 March 2003, Germany and the Netherlands proposed a derogation, "for persons working with the magnetic resonance technique in the medical sector." Official European Council papers record the UK supported this proposal from the working group meeting of 13 May 2003 onwards, throughout negotiations.

This continued until static fields were removed from the Directive at the final working group before political agreement, on 17 September 2003.

A page of the draft proposal produced after the meeting on 13 May 2003 is at Annex 1, showing a footnote with UK supporting the proposed derogation. Should you wish copies of the same document produced before or after this date I would be pleased to provide them.

2. *When consultations were first held with MRI manufacturers about the Directive, and what representations were made by them about its impact? (Q 872)*

Discussions were held with the MR magnet manufacturers on 29 August 2003 and with a group of MRI manufacturers on 16 September 2003 in University Hospital Leuven, Belgium. At these meetings, the focus of concern was on the proposed limits for exposure to static magnetic fields.

3. *What indications were given by the MR community that their concerns about the Directive had been met by the removal of static fields? (Q 874)*

During negotiations only one organisation raised any concerns regarding gradient fields. All other concerns raised with HSE by the MR community focused on static field issues. This included a letter from the MHRA expressing concern about the potential impact of the Directive on MRI scanning. They advised that removal of the static field values would "certainly resolve this issue".

As mentioned in the evidence from the Wellcome Trust (SAM 08), the one organisation which did raise concerns was COCIR, the European Co-ordination Committee of the Radiological, Electromedical and Medical IT Industries. They presented a paper to the European Council Social Questions Working Group very late in the negotiations—just before common position. The paper does mention the possibility of partial body exposure to gradient fields above the limits during interventional MRI procedures. However, the issue of greatest concern in both the paper and the presentation was the static field values. HSE focused on the issue of greatest concern to clinicians and manufacturers—the static fields. When the commission continued to refuse to exclude MRI entirely the presenters of the paper appeared to be content with the removal of static field values only.

After static field values had been removed, a presentation was made to British Magnetic Resonance Radiographers Association meeting at Royal School of Medicine on 19 September 2003. They were told that static magnetic field Exposure Limit Values were removed from the proposal. During discussions after the presentation their only concerns were still over static magnetic fields. No mention was made of switched gradient fields.

HSE accepts that it did not understand at that time the potential implications of gradient field values where there is a need for workers to be present during a small proportion of MRI scans and that, in consequence, effort was not made to resolve this during the negotiation of the Directive. This HSE regrets.

4. *When the HSE first informed Ministers about the concerns of the MR community relating to the Directive? (Q 907)*

Following concerns raised with him by clinicians, Lord Hunt requested a note from HSE. This was submitted on 27 September 2005. This led to a meeting between Lord Hunt and concerned clinicians on 20 October 2005.

5. *What is the timescale for the work being undertaken on the impact of the Directive; who is funding this work; and how it will be linked to the work being undertaken by the Commission on the same issue? (Qs 919–20)*

HSE are working with the Royal College of Radiologists and various clinicians with an interest. Lord Hunt has had a further meeting with them since the hearing, on 23 May, at which progress was discussed.

HSE have set up a working group to oversee a number of workstreams on research and on engagement with the European Commission.

HSE are funding research which will be finally reporting in around 12 months time, but will be providing regular update reports. Other research is being funded by MRC and others, the first of which may be reporting in around 6 months time. The working group will be overseeing the results as they appear to build up an understanding of the extent and nature of the impact the Directive could have on MRI procedures.

Lord Hunt agreed to meet clinicians again in 6 months time to assess how the research evidence that will have emerged by then can be used to best effect. We will also be able to review progress with the European Commission expert group, which is expected to meet in June.

Some of the members of HSE's working group are expected to be on the European Commission's expert group. They can use the evidence already available and feed into it the work being undertaken by HSE, and can update HSE on progress with the expert group. This will enable HSE to find the most appropriate way to influence Europe if the research confirms that MRI procedures would be limited by the Directive.

6. *The Committee has requested the following documents referred to in Appendix A of the joint submission of evidence (SAM 05): a) the letter of October 2004 to MHRA on interventions using MRI; b) the Department of Health response of 20 September 2005 to the letter from eminent scientists raising concerns about the Directive; and c) the letter from HPA of 20 September 2005 in response to these concerns?*

(a) is at annex 2;

(b) is at annex 3; and

(c) rather than a letter, the response from HPA referred to was an interview with the BBC, available at http://news.bbc.co.uk/1/hi/health/4264228.stm. The HPA spokesman states, "The medical professionals are right about the fact that there is a lack of evidence for deleterious effects. But we are dealing with new technology here. The Health and Safety Executive will have to implement this directive and they will need to consider such representations carefully."

7. *What consideration, and when, was given by the Interdepartmental Liaison Group on non-ionising radiation of the Directive, and with what results? What is the membership of this Group?*

The possibility of the Directive appearing was flagged as early as June 2001. Updates were given to each meeting (every six months) and discussions of the possible impact were had. The MRI issue was mentioned to the group in June 2003 but no action agreed.

The group's membership consists of representatives from:

- HSE;
- HPA;
- OfGem;
- Home Office;
- ODPM (to be confirmed since change in Department);
- Welsh Assembly;
- DfEs;
- Medical Research Council;
- MoD;
- DTI;
- DoH;
- Scottish Executive;
- Defra;
- Office of Science and Technology;
- Department of Health, Social Services and Public Safety, Northern Ireland;
- EPSRC; and
- OFCOM.

8. *What methods HSE uses to determine which stakeholders have an interest in proposed Directives; what role the HSE Chief Scientist plays in such decisions; and how such stakeholders are usually contacted? (Q 922)*

HSE would seek to identify the entirety of the population which might be affected by an EU Directive, including but not limited to the scientific community.

There is internal guidance for officials involved in negotiating and implementing Directives. This includes instructions for negotiators to consult widely both within and outside HSE throughout the course of the negotiations, to ensure that that they are well informed about the potential impact on those who will be affected. Consultations should include Government Departments, and a range of stakeholders, with an interest.

The HSE's Chief Scientist's main role has been to embed the Government Chief Scientific Adviser's (GCSAs) 'Guidelines on the use of Scientific Analysis in Policy Making' into HSE practice. He monitors, annually audits and reviews implementation of the Guidelines to ensure that the principles are widely understood and applied. The results of these audits show good compliance with the Guidelines. This reflects the high level of professionalism in HSE with policy makers and scientific advisers working together toward a common goal.

Stakeholders would be contacted though a variety of methods. This might include consulting small business forums and professional bodies by phone, email or letter, raising and discussing the proposals at regular forums or meetings with stakeholders etc.

9. *What plans are there to introduce regulations to implement the Directive?*

As explained under question 5 a number of workstreams have been put into place to find a solution to the problem of MRI use under the Directive.

Current implementation plans include working with all our stakeholders in developing a set of proportionate regulations and accompanying guidance.

We will consult widely on these drafts but cannot give timescales since they are dependent on the outcomes of the MRI working group's workstreams.

The deadline for implementing the Directive is April 2008.

10. *What in-house expertise the HSE has on the medical sciences and MRI in particular?*

HSE has 76 people with expertise in medical science. This group is made up of:

- 14 Medical Inspectors with expertise in occupational medicine,

— two Occupational Health Physicians in HSL,
— 29 Occupational Health Inspectors who are all Occupational Health Nurses,
— three Occupational Health Nurses in HSL,
— three Biomedical Scientists in HSE,
— 22 Biomedical Scientists in HSL, and
— three Occupational Health Technicians.

In addition, HSE has 9 Radiation Technical Specialists. Two of these have expertise in Electromagnetic Fields which can be applied to MRI equipment and HSE also receives specialist advice from the Health Protection Agency—Radiation Protection Division.

11. *What mechanisms the Department and HSE use to identify proposed EU Directives with a potential impact on the scientific community or which require scientific advice?*

HSE have a number of ways of identifying European proposals, which include:

— Maintaining good relationships with the European Commission officials both directly and via UKREP to obtain intelligence of upcoming proposals;
— All proposals on Occupational Safety and Health now go though a lengthy Social Dialogue process. HSE would be included in this process as would European social partners representing both business and workers, who would in turn be expected to consult their constituents and seek scientific advice if needed;
— Formal notification of Member States of a proposal.

As already stated in response to question 8, HSE would seek to identify the entirety of the population which might be affected by an EU proposal, including but not limited to the scientific community.

On scientific advice, HSE follow the GCSA's Guidelines to inform decisions on when to consult external experts, as described under question 8.

Annex 2

David Grainger
MHRA
Hannibal House
London
SEI 6TQ

19th October 2004

Dear Mr Grainger

Conflict between IR(ME)R and PA(EMF) directive

I am writing to draw your attention to the conflict that exists between the Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R) and the Physical Agents (Electromagnetic Fields) (PA(EMF)) Directive, which has recently been adopted by the EU and must be incorporated into UK law by 2008.

In our research and clinical work here at Guy's Hospital, we have developed techniques for performing cardiac catheterisation under a combination of X-ray and MRI guidance, or in a growing number of cases purely MRI guidance, in our integrated X-ray and MRI (XMR) facility. Last year we published results on our first series of patients (Razavi et al 2003 The Lancet 362 1877–1882), demonstrating a mean x-ray dose-area-product of 5.7 Gy.m2 compared to 25.7 Gy.m2 in age-matched controls. In patients whose procedures are performed completely under MR guidance, there is of course no ionising radiation dose at all. Given the young age of our congenital heart disease patients (mean age 8.5 years, with many less than a year old), this reduction in x-ray dose and consequent lifetime risk of cancer is very significant.

In performing these MR-guided catheterisation procedures, the interventionalist is inevitably exposed to time varying magnetic fields due to the switched gradients used in MRI. The manufacturer of our MR scanner has advised that the exposure levels involved are considerably in excess of the exposure limits specified in the PA(EMF) Directive. These limits are derived from recommendations by ICNIRP based on possible effects on central nervous system excitability that are extrapolated from limited work on magnetophosphenes. This phenomenon has never been shown to be harmful, and much of the work has been reported in non-peer-reviewed literature. Having performed these procedures on around 50 patients now, I personally have never experienced any perceptible acute effects of this exposure.

Under these circumstances, it appears that implementation of the PA(EMF) directive will prohibit these MR guided catheterisations from being performed after 2008, and the procedures will then have to be carried out under X-ray guidance instead. Under IR(ME)R, as a practitioner I am responsible for the justification of a medical exposure to ionising radiation (section 5(2)), and in doing so I am required to consider the efficacy, benefits and risk of available alternative techniques having the same objective but

involving no or less exposure to ionising radiation (section 6(2)). Since in this instance I have available to me an efficacious alternative that involves no ionising radiation exposure, I consider that performing these procedures under X-ray guidance is unjustifiable, and that in doing so I would breach IR(ME)R.

Exposing small children to relatively large doses of ionising radiation and a not insignificant risk of fatal cancer in order to avoid effects on staff that are based on flimsy evidence, and almost certainly transient if they exist at all, is an extraordinary prospect. It stands in marked contrast to the considerations that apply in X-ray imaging, when a small risk to staff due to ionising radiation exposure is considered to be justified by the benefit to the patient. Indeed, given the uncertain and transitory nature of the exposure risk in MRI it is probable that the risk to staff is also greater if the procedure is performed under X-ray guidance. Such a situation cannot be justified ethically, and in my view it is also legally unjustifiable in view of the requirements of IR(ME)R. I would appreciate a view from MHRA on the dilemma in which my colleagues and I find ourselves because of the conflict between these two pieces of legislation.

Yours sincerely
Reza Razavi
Professor of Paediatric Cardiovascular Science
Director of Cardiac MRI, Centre for MR Imaging and Intervention

David Granger MHRA
Hannibal House
London
SE1 6TQ.

28 October 2004

Dear Mr Granger,

Re: Conflict Between IR(ME)R and TA(EMF) Directive

I am writing to you to express my concerns about the evolving conflict between the Ionising Radiation (medical exposure) Regulations and the Physical Agents (electro magnetic fields) Directive, which has been accepted by the EU and will be incorporated into UK law within four years.

I have been undertaking Interventional Magnetic Resonance Image Guided interventional work for seven years at St Mary's Hospital using a half tesla dedicated open interventional magnet. Fringe fields near our unit are significant despite the fact that the actual field strength of our magnet is only half tesla and much of the time in many of the portions of the peripheral field the exposure would be very close to those of the guidelines and may at times break them. Potentially this would severely damage this evolving field and prevent us carrying out many of these procedures. Much of our work is dedicated to using thermal ablation techniques to destroy tumours in an entirely minimal invasive fashion, obviating the need for surgery, chemotherapy, radiotherapy and other expensive and unpleasant forms of the therapy with high morbidities substantial complications and significant expense. The principles developing in intervention MR are of immense potential benefit to patients and may allow accurate safe non-invasive treatment of many areas, which are potentially highly problematic at the moment. In many instances comparable procedures do not exist and where they do monitoring of the procedure is very limited and has to be carried out under CT. The ionising radiation exposure associated with CT is large in comparison with none in MR and it would be absurd if practitioners where stopped from carrying out procedures under MR guidance for rather ill defined dubious reasons backed up by extremely poor science and forced to carry out these procedures under CT guidance which unequivocally has a high radiation exposure to practitioners and patients alike. The inconsistency here would definitely breach the IRMER Guidelines which stress that whenever a suitable non-ionising radiation modality is available of equal benefit it should be used.

Having tried to understand the evidence on which the EU formulations are based it is clear that they have evolved out of poor hypotheses with very flimsy evidence. I have absolutely no doubt in my mind which type of procedure is more harmful to the operator let alone the patient and I would far rather carry out a procedure in MR than in a CT scanner.

I believe that there should be an urgent re-evaluation of this whole field to assess this discrepancy which has been created by these new EU guidelines and that the scientific evidence should be completely re-examined so that a sensible compromise can be achieved for the benefits of our patients.

Yours sincerely,

Professor W Gedroyc MRCP ERCR
Professor of Radiology—Imperial College
Director of MRI—St Mary's Hospital

Annex 3

From the Rt Hon Patricia Hewitt MP
Secretary of State for Health

SofS 39359

Professor Ian Young OBE FRS FREng
High Kingsbury
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Marlborough
Wilts SN8 1 HZ

SAFETY OF MAGNETIC RESONANCE IMAGING (MRI) EQUIPMENT

Thank you for your letter of 20th September in which you give your views on clinical magnetic resonance imaging (MRI) applications within the Physical Agents (EM) Directive. You have set out your arguments for proposing a change in the Directive, postponing implementation and initiating research.

I should say that the Directive was published in the European Official Journal on 29 April 2004 and that the UK signed up to its content after extensive negotiations on the part of officials and technical experts. HMG has until April 2008 to transpose the Directive into UK law. This should not be too onerous, as the industry is already required to carry out most of the requirements under existing health and safety legislation (that is, the Management of Health and Safety at Work Regulations, 1999).

I am sure that you will agree with me that the health of NHS workers in MRI, as in any medical practice, is of paramount importance. In this respect, responsibility for matters relating to the protection of workers and practical implementation of the Directive in the UK lies principally with the Health and Safety Executive (HSE).

The Health Protection Agency's Radiation Protection Division (HPA—RPD) has both carried out and commissioned comprehensive reviews of the effects of electromagnetic fields on human health by its own scientific staff, by the independent Advisory Group on Non-ionising Radiation (AGNIR) and other external experts. It has also contributed extensively to the work of the World Health Organization (WHO) on EMF and health and to the International Commission on Non-Ionizing Radiation Protection (ICNIRP). ICNIRP sets the international guidelines for limiting exposure to EMF that have been adopted by many countries including the UK and are the basis for the EMF Directive.

In your letter, you have made some very helpful suggestions for action. There is indeed a case for looking in more detail into the data required to make the best judgements about both the short- and long-term health of those who use MRI. With these considerations in mind, WHO and the ICNIRP held an International workshop, sponsored, among others, by the Department of Health and HSE and organised by the Health Protection Agency at Chilton in April 2004. Two of the conclusions were that the data on the onset of acute effects were well established and those for possible long-term health effects were less so. I have also been informed that WHO is developing a Research Agenda for key studies that will allow an improved assessment of the health effects of magnetic fields.

There are a number of other practical developments already under way. The Department has identified the main issues at its regular non-ionising radiation liaison meetings between Government departments and HSE. HSE has also met with the leading manufacturers of the superconducting magnets. They are working on improved designs to control the magnetic fields around the MR equipment. This is particularly important when considered against a background where new equipment is being developed that uses significantly higher magnetic fields, which will be in use over long time-periods. In addition, as part of the plan to transpose the Directive into UK national legislation, HSE held a series of meetings with representatives of various professional and technical bodies over the past five years or more, and which will continue. In addition to this, HSE is in the process of setting up a roundtable workshop with representatives of stakeholder groups as a start to developing practical, appropriate and proportionate guidance to support the regulations implementing the Directive. I would very much like representatives from your group to be part of this process. My Department is also included in these discussions. Lord Hunt, the DWP Minister responsible for health and safety, is taking a close interest in the outcome.

I thank you again for bringing these issues to my attention. I hope that all stakeholders will be able to contribute to the process of developing the practical means whereby the health of workers is safeguarded whilst, at the same time, patients continue to benefit from the value obtained from the innovative and evolving diagnostic techniques of MRI.

Patricia Hewitt

APPENDIX 22

SUPPLEMENTARY EVIDENCE FROM THE HEALTH PROTECTION AGENCY

QUESTION 1

When ICNIRP first advised the Commission about the inclusion of (a) static fields and (b) timevarying fields in the Directive; and what advice was given about the degree of certainty of the evidence relating to potential adverse health effects in each case? (Qs 888, 893).

Response—advice

Since the early 1990s, ICNIRP has provided advice to the European Commission on a variety of subjects including advice on limiting exposure to static and time-varying fields.

In summary:

- 1990–91—A report (paper) providing a basis for limiting workers' exposure from physical agents for DG V. This was a common project of the UK National Radiological Protection Board (NRPB), the Italian Superior Institute of Health (ISS) and the German Radiation Protection Agency (BfS). Some of the members of the writing group were Europeans who were members of the International Non-Ionizing Radiation Committee (INIRC), the predecessor body to ICNIRP and the results were published in the scientific journal "Physica Medica" in 1991 (reference 1).
- 1992–96—Advice on exposure of the public to NIR for Commission DG V. A report was compiled by an ad hoc working group comprising scientists from NRPB, BfS and ISS and was published in 1996. "Non-ionizing Radiation Sources, Exposure and Health Effects". (reference 2)
- Through the 1990s—Working with the European Committee for Electrotechnical Standardisation (CENELEC). CENELEC is mandated to develop technical standards related to EMF measurements and exposure assessments.
- From 1994—Individual members of ICNIRP have been variously involved with the project co-operation in science and technology initiatives COST 244 and COST 244bis "Biomedical effects of EMF".
- 1996—EC Expert Group, in part comprising some European ICNIRP members who reviewed the evidence for possible adverse health effects related to the use of mobile phones and proposed a European research programme to address the subject (reference 3).
- 1996–97—ICNIRP European and other experts to investigate the occurrence of electromagnetic hypersensitivity for EC DG V (reference 4).
- 1999–2001 Concerted Action—Possible Health Risks to the General Public from the Use of Security and Similar Devices—for EC DG XIII. Report published in 2002 (reference 5).
- 2003 Advice on static magnetic fields, see response to question 2.

ICNIRP's advice on limiting exposure to non-ionising radiations and fields is published in the public domain with the aim of providing science-based Guidelines that health and safety professionals and others might use as part of a system of health protection. In addition, ICNIRP has always recognised that the Guidelines might be used as a basis for national recommendations or even regulations. However, ICNIRP looks to the authority developing or promoting the system of health protection, which could include egulations, to consider aspects related to its practical implementation. This concept is set out in ICNIRP's leaflet "The development of Guidance on Protection", where it is stated "ICNIRP recognizes that the acceptability and adoption of a complete system of protection also requires data and evaluations based on social economic and political considerations. It is ICNIRP's view that these matters are more appropriate to the functions of national governments and their designated authorities. ICNIRP and other advisory bodies may, however, provide background information of relevance for such evaluations."

In relation to the current Directive, ICNIRP did not provide specific advice to the Commission about "the inclusion of (a) static fields and (b) time-varying fields" or otherwise, apart from that referred to in response to question 2 below.

Response—uncertainties

ICNIRP published its recommendations (Guidelines) on limiting exposure to static fields in 1994 (reference 6) and to time-varying fields in 1998 (reference 7). The recommended basic restrictions and reference levels contained in the Guidelines were used by the Commission in formulating the Council recommendations for limiting exposure of the public to electromagnetic fields in 1999 (reference 8) and for the Directive (reference 9). The uncertainties related to the interpretation of the scientific data and ICNIRP's choice of 'safety factors' have been discussed at seminars and conferences and are addressed in ICNIRP's Statement on "Use of the ICNIRP EMF Guidelines" of 32 March, 1999 (reference 10). Here it is noted:

"Thus, summarizing the evidence for health effects for current densities greater than 10 mA m-2, ICNIRP decided to limit human exposure to fields that induce current densities not greater than 10 mA m-2 in the head, neck, and trunk at frequencies of a few hertz up to 1 kHz. As a consequence, the safety factor around 1 kHz may be unnecessarily conservative, but this is the result of insufficient knowledge, and ICNIRP will reconsider this as soon as more scientific data are available. With regard to severe and potentially life-threatening effects such as cardiac extrasystoles, ventricular fibrillation, muscular tetanus, and respiratory failure, the safety factor between these effects and the basic restriction is about 100 or greater. This is the same order of magnitude as safety margins limiting exposure to dangerous toxicologic substances".

Uncertainties and safety factors are also referred to in the ICNIRP guideline publications themselves. For example:

- *Health Physics, Volume 66, pp 100–106 (1994)—Static Magnetic Field Guidelines*
  - Page 103—"Current scientific knowledge does not suggest any detrimental effects on major developmental, behavioural, and physiological parameters in higher organisms for transient exposure to static magnetic flux densities up to 2 T."
  - Page 104—". . . it is recommended that the occupational exposure limit is a time weighted average value of 200 mT during the working day with a ceiling value of 2 T. Because the extremities do not contain large blood vessels or critical organs, a limit of 5 T can be allowed. The restriction of 200 mT is a conservative one based on the present lack of knowledge of long term effects of exposure. For the reasons just given, the exposure limit for the general public incorporates an additional safety factor of 5 resulting in a continuous exposure limit of 40 mT."
- *Health Physics, Volume 74, pp 494-522 (1998)—Time varying Field Guidelines*
  - Page 494—"In establishing exposure limits, the Commission (ICNIRP) recognizes the need to reconcile a number of differing expert opinions. The validity of scientific reports has to be considered, and extrapolations from animal experiments to effects on humans have to be made. The restrictions in these Guidelines were based on scientific data alone; currently available knowledge, however indicates that these restrictions provide an adequate level of protection from exposure to time-varying EMF."
  - Page 495—"These guidelines will be periodically revised, and updated as advances are made in identifying the adverse health effects of time-varying electric, magnetic and electromagnetic fields."
  - Page 508—"General statement on safety factors. There is insufficient information on the biological and health effects of EMF exposure of human populations and experimental animals to provide a rigorous basis for establishing safety factors over the whole frequency range and for all frequency modulations. In addition, some of the uncertainty regarding the appropriate safety factor derives from a lack of knowledge regarding the appropriate dosimetry."

QUESTION 2

For what reason the ICNIRP advice (a) on static fields and (b) on staff was withdrawn in 2003?

Response

The Commission (EC) was advised by ICNIRP in 2003 of the inadvisability of including static magnetic field limits in the Directive. This was because ICNIRP was clear that review of the relevant science was to be carried out in the near future (completed) and, following such review, it was ICNIRP's intention to consider revision of its exposure guidelines for static magnetic fields (underway). The advice was relayed to the Commission at an informal meeting between ICNIRP and Commission representatives in June 2003 and by letter in September 2003, following a request from the Italian EC Permanent Representative.

QUESTION 3

What advice was given by ICNIRP to the Commission on the work that it had done on MR, during discussions on the Directive?

Response

None specifically on occupational exposure and little in general on MRI can be recollected.

ICNIRP's exposure Guidelines deal with all parts of the electromagnetic spectrum and not with any particular device or exposure situation or any specific small part of the spectrum. ICNIRP has however published advice on protection of the patient and volunteers from MRI, but these specifically do not address occupational exposure of staff. This is clearly set out in those Guidelines (references 11 and 12).

QUESTION 4

What contribution HPA and ICNIRP are making to the revision of WHO guidelines on timevarying fields? (Q 893)

Response

It is ICNIRP not WHO which provides exposure guidelines. WHO's principal role in non-ionising radiation protection is through co-ordination of world-wide research efforts and health risk assessment. ICNIRP has recently completed scientific reviews of static and time varying EMF (including epidemiology, biology and dosimetry) (reference 13). Along with other expert bodies, through its publications, ICNIRP has provided input to WHO health risk assessments on both static magnetic (and electric) fields (reference 14) and time-varying extremely low frequency magnetic fields (reference 15). These health risk assessments involve many other WHO-invited experts, providing further breadth to the overall scientific review process, and are valuable to ICNIRP in developing its exposure Guidelines. ICNIRP is currently undertaking a revision of its Guidelines on limiting exposure to static magnetic fields and time-varying electric, magnetic and electromagnetic fields of frequencies less than 100 kHz.

The Radiation Protection Division of HPA has reviewed the scientific basis for the 1998 ICNIRP exposure Guidelines for limiting exposure to time-varying EMF (reference 16) and has recommended their use in the UK (reference 17). HPA has hosted an ICNIRP/WHO International Workshop on Weak Electric Field Effects. The Proceedings of this Workshop (reference 18) should provide significant scientific input into the ICNIRP Guidelines revision process. As a WHO national collaborative institution, HPA will continue to support the WHO through the activities of the International EMF Project by the provision of scientific input and review.

QUESTION 5

When the 2003 consultation on the revised guidelines was commenced; when the responses were first published; and what steps were taken to inform contributors and those affected of the results of this consultation? (Q 913).

Response

The Consultation Document was published on 1 May 2003 on the NRPB website requesting comments by the end of July 2003. All comments received were subsequently considered in formulating the final review document (reference 16) and NRPB's advice to Government (reference 17). The review and advice documents were published on 31 March 2004. All responders to the consultation were sent a thank-you letter on 29 March 2004 enclosing a copy of the NRPB's advice and alerting them as to the intended publication of a response report about the consultation (reference 19). All responders to the consultation were again thanked by letter on 30 July drawing their attention to the publication of the response document on the NRPB website and enclosing a copy of that response document.

June 2006

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