

**EU EMF Physical Agents Directive EC/40/2004
Implementation into UK National Legislation**

**Report of Roundtable Discussions
5th January 2006**

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January 2006

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Report History

This document has been prepared by Galson Sciences Limited for the Health and Safety Executive. This document accounts for comments made by the HSE on Version 1.0 Draft 1.0 dated 19 January 2006.

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Executive Summary

Background

The Health and Safety Executive (HSE) has responsibility for taking forward the implementation of the EU Electromagnetic Fields Directive, EC/40/2004, that has to be transposed into regulations by April 2008.

In order to address concerns that the Directive will have a serious impact on the current and future use of magnetic resonance imaging equipment, HSE held an independently facilitated stakeholder roundtable meeting attended by representatives from key stakeholder bodies. The aim of the event was to enable concerns regarding the implementation of the Directive to be clearly established and to identify proposals for the way forward.

The roundtable discussions took place on Thursday 5th January 2006 at the HSE headquarters, Rose Court, Southwark Bridge, London. The event was attended by approximately 50 stakeholders (Appendix A).

The discussions were structured around an introductory session in plenary, which included opportunities for representative stakeholder organisations to set out their key issues. This was followed by facilitated group discussion, which allowed key themes to emerge. These themes were explored in greater detail by four separate break-out groups. Having considered the key topics related to implementation of the Directive, the break-out groups reported back to the roundtable. A final plenary session aimed to determine any areas of general agreement and agree areas for further action.

HSE assured participants that the aims of the event were to listen to stakeholders' views, to continue dialogue and to encourage progress, with open thinking. The majority of participants welcomed the opportunity for dialogue presented by the roundtable discussions and expressed an interest in continued engagement with HSE to achieve a satisfactory resolution of the issues.

The key points of discussion are presented thematically below, for ease of reference.

Exposure Limits

There is concern amongst clinicians, radiologists and radiographers that interventional Magnetic Resonance Imaging (MRI) procedures could cease as healthcare workers would be exposed to electromagnetic fields (EMFs) greatly exceeding the limits in the Directive.

It was suggested that the limits in the Directive were inappropriate for application in MRI as they are based upon prevention of effects on the central nervous system. Several participants suggested that the exposure limits for workers and patients should be based upon the same physiological processes and these should be relevant to the MRI exposure context.

A number of participants noted that there is a risk-benefit trade off between protecting staff from unknown, or possibly uncertain risks, of possible effects of exposure to electromagnetic fields from MRI, whilst necessitating use of procedures with known health benefits for patients. While there is support for the introduction of safety measures to protect workers, ceasing interventional MRI is considered to be illogical if it necessitates the use of medical procedures with greater known risks for patients, namely, through exposure to ionising radiation from X-rays.

Evidence Base

Several participants argued strongly that the evidence basis underpinning the International Commission on Non Ionising Radiation Protection (ICNIRP) exposure guidelines is not of an adequate scientific standard. Several participants commented that some of the guidelines rely upon only one piece of non-peer reviewed research and that much data is derived from studies in the 1980s.

A medical research stakeholder made the point that the Directive is concerned with acute, short-term effects. The implication of this is that new research can be undertaken and peer reviewed quickly, to provide a more substantial evidence base upon which to set exposure limits.

Some stakeholders reported that there are substantial databases of subject exposure data available for analysis to provide a greater evidence basis. It was suggested by several participants that these are compiled and processed to inform risk assessments and for presentation to the ICNIRP technical review committee.

Some participants also suggested that it might be more appropriate to apply the Institute of Electrical and Electronic Engineers (IEEE) standard rather than ICNIRP levels at the low frequencies used for gradient scanning.

Amending the Exposure Limit Values in the Directive

A number of participants recognised that although there is some scope for technical review and possible change within the Directive, this cannot occur until 2009 and would need to be considered in conjunction with ICNIRP's review of the current evidence base. Participants felt that this might represent a possible window of opportunity to amend the more contentious exposure limit values.

Some stakeholders suggested that it could be possible to demonstrate that due to the pulse shapes of MRI the Directive may be inapplicable to MRI due to the difference in wave form.

It might be possible to argue that MRI should be considered as a special case and to gain a derogation from the Directive. Active lobbying of the European Commission (EC) and European Parliament may be required from a broad range of stakeholders to achieve this.

Confidence

Many participants felt it was important not to introduce over-precautionary safety regulations as this could have the effect of undermining staff and patient confidence in their safety. However, the credibility and implementation of future MRI techniques could be threatened if regulatory controls are based on weak advice and unsound science and this must be considered. One stakeholder felt there is also the possibility that staff confidence in safety regulation could be undermined, if workers perceive the risks of exposure to MRI to be problematic and if they feel they are being required to expose patients to a hazard that has known health risks.

Risk Assessment

Participants recognised that MRI equipment manufacturers can contribute information that will assist risk assessments for exposure to EMFs from MRI. The participants recognised such information would need to be used in the context of the local circumstances and may not be of generic value.

Further Research

Areas for additional research were identified by several groups of participants during the discussions. Computational modelling is considered to be important to determine whether there is in fact a problem in terms of exposure hazard and assessing compliance with the Directive. There was some cautious optimism that there may in practice not be such a problem in complying with the exposure limits.

One workshop group suggested that two simultaneous research projects should be undertaken with the overall aim of identifying staff likely to exceed the exposure limits. This would help to inform how modification of system design, guidance, or working practices might need to develop. There was a general view that a balance has to be achieved between gaining rapid but basic research data, and carrying out high quality but longer timescale research, to provide the necessary health effects evidence.

Additional research needs were identified in relation to static electromagnetic fields, which do not currently have exposure limits under the Directive. Concerns were raised that unless some convincing evidence is produced before the ICNIRP review is completed, the Directive in 2009 may well be modified to introduce a limit for static fields. Plenary discussions led to the suggestion that a workshop or preferably a steering group should be established to take this issue forward

Funding

Funding was seen as the key challenge in trying to meet the identified research needs. Participants suggested that consideration could be given to the creation of an independent funding source, created through matched funding between industry and Government. Alternatively, as the challenges of implementation are not unique to the UK, it was suggested by at least one participant that the EU should fund further research.

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1 Introduction

The Health and Safety Executive (HSE) has responsibility for taking forward the implementation of the EU Electromagnetic Fields Directive, EC/40/2004, that has to be transposed into regulations by April 2008.

To help ensure that guidance developed to assist implementation of the Directive is flexible and proportionate, taking due account of the needs and wellbeing of patients and staff, the HSE undertook independently facilitated roundtable discussions. The roundtable was attended by representatives from key stakeholder bodies. The aim of the event was to enable concerns regarding the implementation of the Directive to be clearly established and to allow options for implementation to be considered.

In order to support a transparent and credible process, the roundtable discussions were independently facilitated by Dr Ray Kemp, of Galson Sciences Limited.

The roundtable discussions took place on Thursday 5th January 2006 at the HSE headquarters, Rose Court, Southwark Bridge, London. The event was attended by approximately 50 stakeholders (as detailed in Appendix A).

The roundtable discussions were structured around an introductory session in plenary, which included opportunities for representative stakeholder organisations to set out their key issues (Section 2). This was followed by facilitated group discussion, which allowed key themes to emerge. These themes were explored in greater detail by four separate break-out groups (Section 3). Having considered the key topics related to implementation of the Directive, the break-out groups reported back to the roundtable. Facilitated whole group discussion was incorporated into the feedback presentations from each group. The final plenary session aimed to determine any areas of general agreement and areas for further action (Section 4).

This report presents a summary of the key discussion points that took place during the roundtable.

2 Introductory Plenary Session

The roundtable discussions began with an introduction and welcome from Giles Denham, HSE Director of Policy Programmes, who acknowledged the wide range of interests in Magnetic Resonance Imaging (MRI) and the level of expertise present at the roundtable.

2.1 Objectives

Dr Kemp explained that the roundtable discussions were intended to provide an opportunity for stakeholders to express views on MRI related issues linked to the adoption of the EU Electromagnetic Fields Physical Agents Directive EC/40/2004. The HSE assured participants that the aims of the event were to listen to stakeholders' views, to continue dialogue and to encourage progress, with open thinking.

Dr Kemp advised participants that the key points of discussion would be independently recorded by Galson Sciences Limited and drafted into a report for participants to approve. Once finalised, the report will be published on the HSE website for wider distribution as part of the HSE's formal consultation on the Directive. The HSE explained that the intention was to consult formally on the Directive by late Spring / early Summer 2006.

2.2 Stakeholder Perspectives

Dr Kemp asked participants to present the key issues regarding adoption of the Directive, as they currently perceive them, on behalf of their stakeholder organisations. These presentations incorporated facilitated plenary discussion throughout.

A consultant physicist in MRI provided a background briefing paper setting out some of the key potential impacts as perceived by the Royal College of Radiologists. It was explained that interventional procedures are an emerging process using MRI, in which staff will be exposed to electromagnetic fields (EMF) greatly exceeding the exposure limits. The key concerns related to the exposure limits at the frequencies used whilst scanning from the gradient fields, which would prevent radiologists from standing close to the patient during such procedures. The implication of the Directive is that this type of work will be forced to cease. Several participants agreed with this statement. Another participant added that it is not possible to wear protective personal equipment during MRI procedures because it would interfere with the MRI equipment.

A representative of MRI manufacturers put forward a manufacturing viewpoint, supporting the comments made about gradient field exposure limits and adding that it was also proving difficult to accommodate people moving in the static field. The stakeholder suggested that the limits proposed in the Directive were inappropriate for application in MRI as they are based upon prevention of effects on the central nervous system and this in turn has led to inappropriate Exposure Limit Values in the

Directive. The International Commission on Non Ionising Radiation Protection (ICNIRP) apparently acknowledges that patient exposure limits are based upon prevention of effects on the PNS. The aim of the Central Nervous System (CNS) related restrictions are to ensure that effects such as magnetophosphenes do not occur. These are primarily a concern in the 0 to 100 Hz range but the findings have been extrapolated to 500 – 1000 Hz. The participant suggested that regulations for staff exposures should apply the same consideration and limits as used for patients. It was also suggested that it should be acceptable for patients to experience mild sensation / effects since they experience the health benefits of MRI investigation. Workers are different to patients so there is an argument for using the same physiological process but applying a different limit value. Several stakeholders discussed the fact that the Directive is about acute health effects, but PNS is only one effect from gradient fields. The challenge therefore is to initiate research that can identify what effects may occur.

A representative of the Institute of Physics and Engineering in Medicine supported the view that the physiological process currently setting the exposure limit is inappropriate. The participant asserted that the physiological process is very important, as the only known effect from field gradient exposure is through the Peripheral Nervous System (PNS). The participant added that the Directive is concerned with acute health effects. This stakeholder explained that PNS has been very well investigated, yet no evidence of harm has been demonstrated. PNS is the most sensitive indicator and therefore it would be very difficult to experience any other health complaints without experiencing PNS effects, as the peripheral nervous system will be stimulated before any core effects are experienced.

One stakeholder suggested that the Directive might be found to be inapplicable to the pulse shapes of EMF from MRI. Given that the exposure limits have been developed for a different waveform, it could prove possible to demonstrate that the Directive is not applicable to MRI. Not all participants agreed that this was the case, some participants commenting that the Directive does apply to all waveforms.

A representative referring to the work of European Committee for Electrotechnical Standardization (CENELEC) and the Institute of Electrical and Electronic Engineers (IEEE) highlighted the differences between ICNIRP and the IEEE standards, and suggested that as ICNIRP protects against synaptic effects, while IEEE focuses more on protection of general nervous system tissues, it may be more appropriate to use IEEE standards as the limit for these shaped pulsed fields.

A Medical Research Council (MRC) representative put forward a view that while ICNIRP guidelines refer to various CNS effects, based on an extrapolation of values for magnetophosphene effects at low frequencies, only one piece of non-peer reviewed research is cited by ICNIRP. The participant added that the basis for the standards may not therefore be of an adequate scientific standard.

Another participant made the point that the Directive is not directly concerned with long-term effects but rather acute, short-term effects. This participant suggested that the implication of this is that new research can be carried out and peer reviewed fairly quickly, to provide a more substantial evidence base upon which to set exposure limits.

A medical researcher commented that the ICNIRP guidelines were published in 1998 and that in 2003 an unpublished ICNIRP document featured a review of the MRI literature and proposed PNS as the correct effect to base the exposure limit on.

One participant made the point that the gradient fields range for MRI does not cover the whole ICNIRP range, and the question was raised whether an opt-out clause could be created for different industries. Another participant asserted that ICNIRP do not see the gradient issue as significant

A representative of the Health Protection Agency (HPA) agreed with the comment that the ICNIRP guidance is dated. This participant suggested that although ICNIRP intends to review the guidance, the science is moving faster than the guidance.

The representative explained that the ICNIRP review committee had been waiting for the outcomes of a World Health Organisation (WHO) task group meeting in October 2005. However, the task group had focused more on environmental exposures and childhood leukaemia and hence the outputs had not been so relevant. Several participants suggested that there were issues in relation to compliance as well as specific research proposals that could help progress knowledge.

One participant reminded the roundtable that regardless of the relevance of the data behind it, the Directive must be implemented and that the Directive clearly states that ICNIRP limits must be used for sinusoidal or pulsed fields. The participant recognised that even though there is some scope for technical review and possible change within the Directive, this will not begin until 2009, following ICNIRP's review of the evidence base. A number of participants agreed that this represented a possible window of opportunity, and a deadline for compiling an updated evidence base. However, these participants acknowledged that there are several issues to address in the meantime.

A representative of MRI manufacturers commented that previous experience has revealed surgeons to have been exposed to fields far higher than those proposed under the Directive, but that no cases of adverse PNS effects among surgeons have been reported. The representative asserted that many studies had previously been started but that due to a lack of reported effects they were discontinued. Another participant commented that there are substantial databases on patients that have been scanned with MRI, including information submitted to the Department of Health, and a great deal of data collected by the National Radiological Protection Board (NRPB – now part of the Health Protection Agency – HPA). The participant suggested that these may provide valuable data, either for presentation to the ICNIRP technical review committee or in risk analysis.

A medical researcher made the point that much research is taking place in the field of MRI. Several stakeholders commented that the introduction of health standards was completely supported and welcomed, but caution was raised that these should be based upon sound scientific evidence. Researchers are also people at work. Practitioners in healthcare are another branch of the MRI community. The guidelines

are based on extrapolation from other frequencies and it is essential to have limits that are based upon good science.

A representative of the British Association of Magnetic Resonance Radiographers (BAMRR) stated concerns regarding the impact on certain medical procedures, such as monitoring patients under anaesthetic. The participant commented that while the magnet is being reduced in size for patient protection, workers were being forced to be located further away. The participant felt this had adverse impacts on patient care. Several stakeholders concurred that there is a risk-benefit trade off in introducing safety measures that limit the ability to carry out successful medical procedures. Another stakeholder from the BAMRR added that risk management measures are already in place to safeguard workers, for example from projectile risk, whilst continuing to enable work practices to proceed.

A representative from the Society of Radiographers commented that whereas health and safety law is usually developed as the result of accidents, it was important to recognise the value of proactive health protection. The stakeholder felt it was important not to undermine safety regulations, as this could have the effect of undermining confidence. The stakeholder also cautioned that credibility of regulation and implementation of new MRI techniques could both be threatened if future developments are based on poorly justified regulations.

A representative of the British Institute of Radiology raised a concern that if interventional MRI cannot be continued, workers would be compelled to use the alternative of ionising radiation (X-ray) procedures. The stakeholder felt that this could undermine staff confidence, if workers feel they are being forced to use a technique that has known risks to both patients and staff.

HSE commented that the regulatory framework for ionising radiation is based on minimising the stochastic risk but that for the EMF Directive the aim is to prevent deterministic risk. The Directive requires that exposures limit values are not exceeded and that risk assessments are carried out. The HSE representative suggested that if the limits do not seem appropriate it might be acceptable to carry out a more relevant risk assessment and comply with that. Another stakeholder commented that risk assessment was felt to be the key factor but it was recognised that it could not be generically applied. The stakeholder added that while manufacturers can provide guidance and advice on performing a risk assessment, it would need to be tailored and carried out at the local level to suit the varying needs of workers and researchers in different establishments.

One participant expressed concern with the fact that the exposure limits are absolute. In emergency situations it was felt that there would be times when the exposure limits would be exceeded, and the participant commented that while it is important to minimise exposure, the absolute limit is overly restrictive.

A representative of manufacturers raised the issue of greater “stray” fields from open MRI systems. From a manufacturing perspective no technical measures could be identified that might tackle this problem. Another stakeholder provided an example of a very open system developed by GE Healthcare some years ago, in which fields were

sometimes greater for workers than those to which the patients were exposed. However, no-one reported PNS effects or visual phosphenes. The stakeholder explained that data were not recorded as no effects were observed. Hence the evidence base is lacking due to discontinued collection of data. One stakeholder commented on the ethical issues that could be associated with gathering research data on these systems.

A representative from CENELEC TC106X raised the question of the level of computational modelling that has been undertaken to investigate current densities in tissues. This participant suggested that there may not in practice be a problem in implementing the Directive. The stakeholder provided an example of the induction heating industry that has faced a similar problem. Here, modelling had demonstrated that actual exposures were in fact below exposure limits. One participant suggested that this is the crucial compliance issue to address, before looking at the fundamental effects data. Several stakeholders agreed that further computation modelling should be performed to determine the actual extent of the problem.

3 Workshop Group Discussions

Following the introductory plenary session, Dr Kemp suggested to the workshop that four key themes of discussion were emerging, namely: quantifying the actual 'problem'; closing the research gap; identifying opportunities for updating the guidance; and determining practical steps that could be taken to support implementation of the Directive.

This interpretation was broadly supported by the participants and four break-out groups assembled to consider each of these topics in detail. It was explained that there were no constraints on what the groups could discuss and that participants could move between break-out groups during the session if desired.

3.1 Group 1: Quantifying the 'Problem'

Group 1 considered how more appropriate limits might be introduced. The group considered who would be exposed and what the likely impacts of exposure were, and determined two projects that they felt should take place to address this.

3.1.1 Modelling of Interactions

Group 1 suggested that one project should examine human presence (moving around, sitting or standing) close to the magnet in both open and closed systems. The group envisaged that such a project would take at least a year to carry out and would incur considerable costs. The HPA Radiation Protection Division was considered likely to have the expertise to undertake the project, or alternatively manufacturers might be able to do so. The group suggested that the project should be put out for programme funding.

Dr Kemp opened the Group 1 proposals out to plenary discussion. One stakeholder suggested that there might be value in undertaking quick and basic research rather than a longer-term study. The stakeholder suggested such research might focus on, for example, gradient fields, so that some early results are available, and which could also inform a second phase of research. This was deemed particularly relevant as some participants commented that the period required for this research would be likely to greatly exceed one year. However, some participants cautioned that undertaking rapid research may not produce credible results.

3.1.2 Audit of Worker Exposure

The other project proposed by Group 1 was a worker (not solely medical) exposure audit. The group proposed that this would be undertaken by all workers in all MRI fields, including manufacturing, pharmaceutical, research and hospital staff, to provide an understanding of who is being exposed and how often. The group suggested that the focus of the audit would not be on time averaging, but rather the extent to which particular groups of staff may exceed limits.

Group 1 explained that the overall aim of the two projects was to identify staff likely to exceed the exposure limits, to help inform how modification of system design, guidance, or working practices might need to develop.

In facilitated plenary discussion, one participant suggested that a small number of 'worse case scenario' modelling exercises would be valuable in determining the contour levels for the audit.

3.2 Group 2: Closing the Research Gap

Group 2 discussed the likely research needs for demonstrating what the exposure limits ought to be under the Directive, and considered how best to develop a convincing evidence base.

The group explained that the research priorities they had identified were not solely aimed at the Directive, with some research requirements having a more general focus. The group stated that their objective would be to obtain published results in the literature within three years. This would require quite rapid research, particularly taking into account the timeframe for securing funding. The group identified some key areas of research that were required to meet immediate needs.

3.2.1 Cognitive Effects

Group 2 considered cognitive effects to be of possible importance as a research focus. The group suggested potential areas for research on volunteers, such as hand-eye response rates and exposures to different frequencies. The group emphasised however that the actual study was of less importance than knowledge of the nature of the exposures to which the subjects were exposed.

3.2.2 Vertigo

Group 2 highlighted vertigo in static fields as an important research area. The group commented that the ICNIRP review may influence the review of the Directive in 2009. The group suggested that unless some convincing evidence is produced before that time, it is probable that a limit will also be introduced for static fields. The group suggested volunteer studies to examine vertigo in static fields and moving in static fields.

3.2.3 Specific Absorption Rate (SAR)

Group 2 considered SAR in terms of its relevance to other aspects of MRI safety, and key populations were identified for SAR research. However, the group recognised that there are uncertainties associated with the limits. The group commented that MRI practice on patients could be affected by modification of SAR limits.

3.2.4 Implementation

Group 2 considered the research areas identified above as the key short term priorities, though the group reported that many more areas of research were identified during their discussions for the longer term. The group suggested that multiple research centres would be required to carry out the studies simultaneously, rather than adopting phased research.

Group 2 felt that the need for research is significant, as the group considers that present exposure limits are not based upon sound science, and therefore evidence is required to justify this assertion. The group also stated that where the research does not as yet indicate known health effects, it is important to consider any unknown health effects, and hence ongoing research is recommended.

Group 2 commented that funding was the key issue to meeting the identified research needs. The group outlined various funding bodies that could be approached to support these works, such as Research Councils (e.g. the Medical Research Council (MRC) or the Engineering and Physical Sciences Research Council (EPSRC)), industry, Department of Health, charities, HPA, and HSE. However, Group 2 felt that most funding bodies would be unlikely to have significant funds available.

Group 2 suggested that a workshop or preferably a steering group should be established to take this issue forward, and that a call for funding may help to focus attention, making it more worthwhile to prepare a research proposal. The group estimated that between £3 million and £5 million would be required for a managed research programme.

3.3 Group 3: Updating the Guidance

Group 3 discussed opportunities for and benefits of seeking to update the ICNIRP guidance, for improved applicability to MRI. The group noted that the Directive is not solely limited to MRI. There is a responsibility to assure the safety of workers with appropriate guidelines.

3.3.1 Influencing ICNIRP

Group 3 suggested that efforts should be made by Her Majesty's Government (HMG) to influence ICNIRP. The group felt that HMG should seek justification from ICNIRP regarding the evidence base used to apply their standards to this subject. The group suggested that HMG should also seek to determine ICNIRP's intentions for review. The group recommended that as an early action ICNIRP should be engaged in dialogue.

3.3.2 IEC Standards Review

Group 3 referred to the International Electrotechnical Commission (IEC) Standards review, which is currently believed to be in draft format. The group considered it

important for the HSE to have sight of this draft document as early as possible, to take account of it in developing the HSE's own guidance.

3.3.3 Building the Evidence Base

Group 3 identified manufacturers as potential sources of data to build up an evidence base to justify amending the guidance. The group reported that Philips Medical Services has data obtained from staff monitoring, and it was believed that some of the other manufacturers would hold similar data sets. Group 3 suggested that this data should be compiled and independently analysed, in order for the findings to form part of a credible, peer-reviewed evidence base.

The facilitator, Dr Kemp, commented during plenary discussion that there was successful experience of the creation of an independent funding source, with matched funding between industry and Government. Such a scheme operates in the UK for Mobile Telecoms Health Research (MTHR) and includes firewalls to avoid any possibility of influence by industry on the research outcomes. A participant added that EPSRC do have a process whereby industry money is matched and then managed independently. One stakeholder commented that this issue is wider than just the UK, and that information should be exchanged between other Member States and even beyond. The European Union (EU) were therefore suggested as the most appropriate funding source, as the challenges of implementing the Directive in the field of MRI are not unique to the UK. The HSE offered to investigate opportunities within the EU Framework funding programmes.

Group 3 concluded that any update to the guidance must be credible and based on sound, peer reviewed evidence.

3.4 Group 4: Practical Steps

Group 4 aimed to determine practical measures that could be adopted in order to address implementation of the Directive.

3.4.1 Modelling Data

Group 4 suggested that the main issue is arguably whether or not to comply with the Directive. The group felt that a health hazard (relating to staff exposure to MRI equipment) has yet to be demonstrated. The group suggested that manufacturers have data available and means of modelling so that it could be collected quickly by an independent organisation and analysed to determine if there is a problem. It was suggested that this could be undertaken by the HPA.

Group 4 suggested that a detailed impact assessment should be produced, which addresses the nature and extent of current exposures, as well as projections into the future. The work should examine both staff and patient exposures.

3.4.2 Lobbying

Group 4 suggested that regulation of MRI should be decoupled from the rest of the Directive, on the basis that MRI is a special case for consideration. The group acknowledged that this would need to be justified to the European Commission (EC). The group suggested this would require a proposal for how any presumed risks would be managed, accompanied by active lobbying of the UK and European parliament and other decision making bodies. Group 4 would prefer this to be undertaken immediately, but it was recognised that such activity would more realistically be required to continue throughout 2006.

In plenary discussion, a participant commented that manufacturers have been lobbying the EC for several years, and manufacturers would welcome involvement from other stakeholders for greater impact.

Group 4 proposed that it is acceptable to gain an exemption to an EC Directive. The group suggested that if the EC could be convinced that there is a problem in using the ICNIRP standards for MRI, it may become acceptable to use the IEEE standards instead. The group believed that the mandate to the European standardisation organisations could be amended to exclude MRI from implementation of the Directive, permitting use of IEEE guidelines

3.4.3 Industry Funded Rapid Research

Group 4 believed that there would be an inevitable and lengthy delay in obtaining funding through HMG. However, the group felt that some results need to be obtained quickly in order to demonstrate to the EC that different standards would be more appropriate. It was suggested that HMG might provide seed corn support and industry could fund a basic research approach that could identify the extent of the problem quickly.

3.4.4 Communications

Group 4 recognised that good communications are vitally important to ensure that the HSE guidance for implementation is accepted. The group also identified a need for improved communications to relate the safety message to all professional bodies. One participant commented during plenary discussion that wider involvement of stakeholders would help to tackle the communication issue.

4 Participants' Concluding Remarks

In the final plenary session, Dr Kemp invited participants to summarise their key points regarding implementation of the Directive and to share any particular issues arising from the roundtable discussions.

One participant raised a query about the time taken to fund research, and whether there would be any leeway for delaying implementation of the Directive in order to accommodate research needs. A representative of the HSE explained that failing to implement the Directive in a timely manner would result in infraction, so that there could be no delay to implementation.

Another participant concluded that a balance is required between high quality research and the quick fix research option. The participant suggested that the ideal approach would be a robust but quick piece of research.

One participant commented that the fundamental interaction between the two research priorities identified by Group 1 was important.

A representative of MRI equipment manufacturers restated the advantage in bringing other stakeholders into the lobbying arena in Europe. However, another participant commented that unless there is very good evidence in support, such lobbying is pointless. Another stakeholder commented that if the Directive is openly criticised without such evidence, then more problems will be created.

One stakeholder suggested that if this were purely UK legislation a judicial review would be possible, and that perhaps a similar challenge could be considered for the Directive. However, other participants felt that this would be unlikely as it would be a challenge to broader European legislation and jurisdiction.

Finally, a participant commented that the roundtable discussions had been very useful and it was hoped that progress would be made on the points raised. A representative of the HSE responded that the HSE is responsible for considering points arising during the roundtable discussions, which are also part of a wider process of consultation and political accountability.

Appendix A – List of Participants

The following participants were expected to attend the roundtable discussions, although on the day some delegates were not able to participate.

Allen, T.	Siemens Magnet Technology Ltd
Baartman, H.	Toshiba Medical Systems
Baranski, S.	Hitachi Medical Systems
Barrett, A.	HSE Radiation Team
Beaumont, J.	Alliance Medical Ltd
Carpenter, A.	Wolfson Brain Imaging Centre
Chadwick, P.	CENELEC TC 106X
Cole, P.	AURPO
Darwent, G.	British Association of Magnetic Resonance Radiographers
Davies, P.	HSE Chief Scientist
Denham, G.	HSE Director of Policy Programmes
Dezonia, S.	GE Healthcare
Ebdon-Jackson, S.	HPA
Elsby, S.	EPSRC
Engels, H.	Philips Medical Systems
Evans, R.	Society of Radiographers
Frese, G.	Siemens
Garas, K.	Society of Radiographers
Glover, P.	Nottingham University
Glover, R.	MHRA
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