05 de junio de 2006
Sociedad Española de Radiología (SERAM)

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La Sociedad Española de Radiología es una organización científica y profesional que agrupa a más de 3800 radiólogos en España. En las últimas décadas la Resonancia Magnética (RM) ha generado un avance espectacular de la Medicina, contribuyendo muy notablemente a la salud de la población y al conocimiento médico de la enfermedad.
En los últimos años, los desarrollos tecnológicos y el uso globalizado de esta técnica diagnóstica ha salvado innumerables vidas y acortado la morbilidad de la enfermedad. Los últimos equipamientos de alto campo han permitido una mejoría sustancial en la calidad de la imagen y en la fiabilidad de los diagnósticos al aumentar de forma considerable la señal de la imagen y la rapidez de su adquisición.
El personal sanitario de los servicios de radiología está muy acostumbrado al beneficio para los pacientes de esta técnica de exploración, cuidando mucho de eliminar los riesgos de trabajar con estos campos magnéticos (controlando la presencia de material ferromagnético y evitando la introducción en la sala de dispositivos eléctricos no compatibles).
Dado el importante riesgo que para la salud de la población tendría el límite propuesto por la directiva de la EU (European Directive 2004/40/EC), esta sociedad se adhiere a las quejas de las sociedades internacionales más relevantes (European Society of Magnetic Resonance in Medicine and Biology; International Society of Magnetic Resonance in Medicine, Food and Drug Administration) y de las sociedades radiológicas europeas.
Como representantes del uso adecuado de la RM en sanidad, creemos muy necesario que considerara el enorme e irreparable daño que una directiva como la que puede aprobarse generará en la salud de la población y en el avance de la medicina.
Quedando completamente a su disposición para cualquier información adicional,

Muy atentamente

Firmado:	**Firmado:**	**Firmado:**
Dr. Francisco Tardáguila Presidente	Dr. Luis Martí-Bonmatí VicePresidente	Dr. Lluis Donoso Presidente Saliente

DOCUMENTOS

Directive for the protection of workers from exposure to electro-magnetic fields and waves (EMF)

The EU have just released this statement on the progress of negotiations:

'Static Magnetic Fields (and implications for magnetic resonance imaging (MRI)

Static Magnetic Fields have been removed from the exposure limit values but there will still be a requirement to undertake a risk assessment at the Action levels according to Table 2.

This is because the Council feels that it is not yet possible to address the health effects resulting from occupational exposure to static magnetic fields while there are still uncertainties in existing knowledge. An updated review of the scientific evidence has not yet been completed but the International Commission for Non Ionising Radiation Protection (ICNIRP) are currently undertaking work to address these issues and developments will be monitored. This could eventually lead to amending the Directive.'

This means that there are now no plans to limit exposure to static magnetic fields in the short term. Thank you to everyone who helped to raise the profile of this problem and to ICNIRP. It did also highlight the continuing need for human research in this field.

However, it does set an exposure level for current density 40 mA/m2 rms.

Proceedings from the Council of the European Union, 17-18 September 2003

Amended proposal for a Directive of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields and waves) - Update on Negotiations - September 2003
On this page:

The directive

History

Some versions of the Draft document are linked here:

- 10th December 2002
- 23 May 2003.
- Records of discussions July 2003 Comments, Minutes

The proposed limits are based on International Commission on Non-Ionizing Radiation Protection (ICNIRP) [1,2] guidelines (although there are apparently some important deviations from ICNRIP concepts). As we understand it, the ICNIRP guidlines were closely linked to UK NRPB guidelines [3,4]. The ICNIRP is currently preparing a statement on MRI, but it is unfortunately confidential at this stage. The UK National Radiological Protection Board (NRPB) is has a published a consultation document on its existing guidelines, proposing no change, and have said that they will continue to take comments on it passed the date for final date for comments that they mention, which is the 28th July.

Time scale:

This directive is currently being discussed by the member states, and apparently the Italian presidency is keen to complete the discussions during its term. It is possible that member states will reach a common position by the end of the year (although this is the earliest that this may occur). The directive will then have to be read and passed by the European Parliament. If the Parliament passes this into law, the Directive will then have to be adopted into local law by member states within 3 years.

Exposure limits and Action values

The directive defines two sets of values. The following statements are shortened qutoes from the text:

- **Exposure limit values**: Limits to exposure to EMFs which are based on established health effects and biological considerations. Compliance with these limites will ensure the workers are protected against known adverse health effects.
- **Action values**: The magnitude of directly measurable parameters (E,H,B etc) at which one or more specified measures in the Directive must be undertaken. Compliance with these values will ensure compliance with the exposure limits.

Frequency range (Hz)	rms Current density for head and trunk (mA/m^2)	Whole body average SAR (W/kg)	Localised SAR (head and trunk) (W/kg)	Localised SAR (limbs) (W/kg)	Maximum contact current (mA)	Power density (W/m^2)	Magnetic flux density B (T)
0	-	-	-	-	-	-	2 (5 for limbs) Time weighted average: 0.2T
>0-1	40	-	-	-	8.0	-	-
1-4	40/f	-	-	-	8.0	-	-
4-1000	10	-	-	-	8.0	-	-
1-2.5k	f/100	-	-	-	8.0	-	-
2.5-100k	f/100	-	-	-	5x10^-4f	-	-
100k-10M	f/100	0.4	10	20	50	-	-
10-110M	-	0.4	10	20	50	-	-
110M-10G	-	0.4	10	20	-	-	-
10-200G	-	-	-	-	-	50	-

Action Values

Frequency range (Hz)	E (V/m)	H (A/m)	B (10^-6T)	S (W/m^2)	Contact current (m/A)
>0-1	-	1.63 x10^5	2x10^5	-	1.0
1-8	20000	1.63 x10^5/f^2	2x10^5/f	-	1.0
8-25	20000	2x10^4/f	2.5x10^4/f	-	1.0
0.25-0.82 k	500/f	20/f	25/f	-	1.0
0.82-65 k	610	24.4	30.7	-	4x10^-4f
0.065-1M	610	1.6/f	2.0/f	-	40
1-10 M	610/f	1.6/f	2.0/f	-	40
10-400 M	61	0.16	0.2	10	40
400-2000 M	3f^(1/2)	0.008f^(1/2)	0.01f^(1/2)	f/40	-
2-300 G	137	0.36	0.45	50	-

Who to contact:

Whilst the Directive is still being discussed, you should send any comments that you have

1. Most importantly on the science being used to establish these limits since the EU rather have their hands tied by the advice they are getting from their scientific advisors.
    - ICNRIP: They are currently revising their exposure limits. If the new document is put out for consultation we will inform you here.
    - NRPB (UK) They recently published a consultation document on this matter.
    - Please let me know the appropriate organizations for other member states
        - Copies of letters sent to national regulatory bodies: UK NRPB(BIR)
2. On the directive to (they are meeting again on the 4th September)
    - Your national negotiators
    - Appropriate members of the Council of the EU (please let me know of any changes)
    - Appropriate ministers in your own government. (In the UK individuals will have most impact by writing to their MP and asking them to raise the matter with the Secretaries of State for Industry (re. magnets), Health and Europe). Please let me know the situation elsewhere in Europe.
        - Copies of some letters that have already been sent to national negotiators are available here:
            - UK(BIR).
            - Memos prepared by MR manufacturers, highlighting the huge benefits of MRI to society and the affects of the proposed directive. First Second
3. The EU Commission: The European Agency for Health and Safety at Work
    - Reply from the EU to the ESMRMB

If the Directive reaches the EU parliament, we will email you again to let you know. At that point you may wish to contact your MEP. As far as I can see, there is little point in contact MEPs yet..
We suggest that you send you letters by post (not email) and ask for them to be acknowleged.

ISMRM position:

ISMRM statement.

FDA position:

The FDA only deals with exposure of patients (not staff) in the USA, but it is interesting to note that they have recently published on this matter, and have just increased their 'significant risk level' from 4 T to 8 T for adults (and to 4T for neonates).

Other organizations with an interest in this matter:

- European Agency for Health and Safety at Work
- Metal trade organizations: WEM and Orgalime: Their joint statement
- Society for Radiation Protection
- Health and Safety Commission
- COCIR, the European Coordination Committee of the Radiological, Electromedical and Medical Information Technology Industries: Letter, Paper Memo First, Memo Second

References and other documents related to safety:

1. Guidelines on limits of exposure to static magnetic fields, International Commission on Non-ionizing Radiation Protection. Health Physics, 66, 1, 100-106, 1994. Page 1 2 3 4 5 6 7
2. Guidelines on limiting exposure to time varying electric, magentic and electromagnetic fields (up to 300 GHz). International Commission on Non-ionizing Radiation Protection. Health Physics, 74, 4, 494-522, 1998.
3. National Radiological Protection Board statement on Clinical Magnetic Resonance Diagnostic Procedures, 2, 1, 1991 (Chilton, Didcot, Oxon, OX11 0RQ)
4. National Radiological Protection Board statement on Restriction of Human Exposure to Static and Time Varying Electromagnetic Fields and Radiation, 4, 5, 1993 (Chilton, Didcot, Oxon, OX11 0RQ)
5. IEC EN 60601-2-33: MEDICAL ELECTRICAL EQUIPMENT - Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. (It does not contain any occupational limits).
6. American College of Radiology White Paper on MR Safety, Kanal et al, AJR, 176, 1335-1347, 2002.
7. Guidelines for Magnetic Resonance Equipment in Clinical Use. Medical Devices Agency, UK, December 2002.
8. Schenck, Safety of strong, static magnetic fields. JMRI, 12, 2-19, 2000.

Comments on this page to penny.gowland@nottingham.ac.uk. Last updated 23 July 2003.

COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry Position Paper:

http://www.cocir.org/uploads/documents/-9-cocir_emf_position_paper_06042006.pdf

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European Directive for the protection of workers from exposure to electro-magnetic fields (EMF)

Position of the ESMRMB

The text of the European Directive (ED) 2004/40/EC of the European parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), dated April 29, 2004 and published in the official journal of the European Union including the corrigenda, can be found on:

http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_184/l_18420040524en00010009.pdf

A short explanation of the consequences of this new European Directive:

The new ED limits the Electro Magnetic Field (EMF) exposure for workers in general in the frequency range of 0Hz till 300GHz. This therefore includes the relevant frequencies for MR (the static magnetic field at 0Hz, the dynamic gradient magnetic field around kHz and the RF in the MHz range).

The ED specifies exposure limits values (never to be exceeded) and action values (when exceeded, it must be demonstrated that for this situation the related exposure limit values are not exceeded). The exposure limit values are expressed in relevant physics parameters, whereas the action limits values are expressed in 'directly measurable' parameters.

Unfortunately, a number of the proposed limit values exceed those required for present and future (interventional, high magnetic fields) MR applications. When introduced into national law, the ED requires the employers of the different type of MR workers (hospital, industry, university) to ensure that the employees are not exposed to any EMF values higher than the exposure limits values specified in the ED.

The conflicts arise especially when Interventional MR is performed, mainly because the proposed limits in the kHz range are in conflict with the stray field of the dynamic gradient fields produced by the scanner during scanning, just outside the MR system, at the position where the interventional Medical Doctor is working. Also other workers may be affected. The EMF generated by the RF transmit coils is in general well below the proposed limit values and therefore creates no problem. In the near future major problems can however occur with respect to the static magnetic field. For the time being no limit values are proposed in the European Directive but within 4 years from now this will be corrected and it is not clear at this moment what the proposed limit values will be.

ESMRMB statement:

ESMRMB 2004 Roundtable on Safety Aspects (Presentation)
ESMRMB statement dated July 3, 2003
ESMRMB statement dated October 27, 2003

Other organisations with an Interest in this matter:
ISMRM
COCIR

What has happened the past period?

As a result of the acceptance of the European Directive 2004/40/EC, the European Commission has given a Mandate M/351 to CEN/CENELEC, dated June 2004, to develop harmonized standards for the assessment, measurement and calculation of workers' exposure to static magnetic and varying electric, magnetic and electromagnetic fields with frequencies from 0Hz to 300GHz.

CEN/CENELEC is the European branch of the IEC, the International Electrotechnical Commission, responsible for standardization for all types of electrotechnical equipment, thus including medical systems and more specifically MR scanners.

In discussion with the Technical Committee from CENELEC, TC 106x, it has been agreed that the IEC Maintenance Team (IEC MT40) responsible for the IEC 60601-2-33, the IEC standard that describes the particular requirements for the safety of MR equipment for medical diagnosis, will accept this mandate specifically for MR. Up till now the IEC60601-2-33 only addressed patient safety. It now will be extended by IEC MT 40, to include also the safety of MR workers.

IEC MT40 organized a meeting in March 2005 in The Netherlands, to discuss this mandate. During this meeting an expert from ICNIRP (International Commission on Non-Ionizing Radiation Protection), Mr. R. Matthes, was invited to discuss possible conflicts. ICNIRP is an international organization supported by the WHO and is well accepted as the source for guidelines for EMF exposure limits. ICNIRP has formulated the exposure limits for EMF for workers, which are taken over in the European Directive (apart from the exposure limits for the static magnetic field!). At this meeting in March:

- IEC MT 40 has decided to start working on a 2nd amendment for the current 2nd edition of the IEC 60601-2-33 standard. This 2nd amendment is only directed towards the inclusion of regulation for EMF exposure for MR workers. This amendment must be published before April 2008 (when the European Directive for EMF exposure for workers will become active in all countries in the EU) and preferably earlier since some countries of the EU may decide to introduce the European Directive even earlier then 2008.

  - The discussion with Mr. Matthes, the ICNIRP expert, was fruitful and open. We have identified two possible openings, which would allow IEC MT 40 to deviate from the ICNIRP numbers included in the ED.

First of all Mr Matthes expressed that ICNIRP guidelines are formulated for 'workers in general', not taking into account the special situation of specific categories of workers, for which other risk/benefits arguments may apply. Since such a statement was not clearly spelled out in the publications of ICNIRP it was suggested to ask ICNIRP to issue a statement along this line.

Secondly, specifically the ICNIRP limits in the gradient output frequency range are based on a visual phosphenes, a physiological effect which has never been observed as the result of gradient switching on the MR system (it is observed however by subjects moving in the static magnetic field). ICNIRP has extrapolated these limit values to the somewhat higher frequency range relevant for gradient waveforms, which results in too low limit values not realistic in view of the gradients applied for MR. ICNIRP did not acknowledge the physiologic process resulting in Peripheral Nerve Stimulation for workers (in a separate statement for MR patients ICNIRP did acknowledge this PNS effect for the gradients). The somewhat higher frequencies (then for visual phosphenes) and the special gradient waveforms applied justify also the use of PNS as limiting effect for workers. Again it was suggested to ask ICNIRP to issue a statement to support this conclusion.

- A special letter to the chairman of ICNIRP requesting for such statements was send. In his reply Prof. Vecchia indicated that 'ICNIRP is aware that benefits, both at an individual and at a social level, may be associated to EMF exposure, and that a balance with possible health risk may be needed. However, such balance requires social and economical considerations that are out of the remit of ICNIRP'. Prof Vecchia did not react to the second issue (PNS versus visual phosphenes)

- - During the recent ISMRM conference in Miami the IEC MT 40 members discussed a concept text for the 2nd amendment. This text proposes limit values for the static magnetic field exposure for MR workers (in spite of the fact that these numbers are not included in the European Directive) and exposure limits in the kHz frequency range based on the absence of Peripheral Nerve Stimulation for MR workers. The kHz limits therefore deviate from the ICNIRP numbers (which are included in the ED). The 2nd amendment text will be sent to the IEC member countries for comments in the summer of 2005. The comments will then be discussed during the next meeting of the IEC MT 40, which is planned for November 2005 (in conjunction with the ISMRM Safety Workshop in Washington DC). If we come to an agreement in November, publication in 2006 or early 2007 seems to be possible.

A number of related specific topics are:

- On the static magnetic field ICNIRP claimed that its guideline is still valid in spite of the fact that this guideline was not taken over in the ED. A new literature review has been done in the past years by special WHO workgroup. Publication of its report and subsequently an update of the ICNIRP guideline for the static magnetic field can be expected still this year. Mr. Matthes indicated that it was very well possible that the original limit value of 2T will remain, although a new value of 4T was also considered to be possible.
- The MR experts of IEC MT 40 claim that in fact not the static magnetic field but more specifically the movement of subjects in the static magnetic field (or even the movement of the subject in the gradient of the static magnetic field) results in the observed effects (dizziness, nausea, ...), but that clear literature on this subject is still not sufficiently available. ICNIRP indicated that its decision can still be 'influenced', when experimental results become available in the short term.

For RF the ICNIRP limit values (and thus the ED) are not a major hindrance and the discussion in IEC MT 40 concentrated more on recent new insights (as a result of simulations done) with respect to the local SAR. These local SAR values may become relevant for MR workers.