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European Society of Radiology

U.E.M.S.

European Society of Radiology and European Union of Medical Specialists Radiology Section
Position on the EU Physical Agents (EMF) Directive 2004/40/EC

The European Society of Radiology (ESR) is the scientific forum of the National and Sub Specialist Radiological Societies and the European Union of Medical Specialists (UEMS) Radiology Section represents over 40000 Diagnostic and Interventional Radiologists in Europe. Many of these radiologists are at the forefront of research or involved in clinical magnetic resonance imaging (MRI) and hence expose themselves regularly to the magnetic fields associated with MRI. We are convinced of the need for a proper legal framework for scientific research and medical practice.

The EU Physical Agents (EMF) Directive 2004/40/EC, which must be transposed into member state law by April 2008, seeks to define safe levels for equipment operators' exposure to electromagnetic fields (EMF). However, the limits proposed are extrapolations from largely hypothetical possible conditions and are an over-cautious interpretation of very limited data.

Risks to Health

The Directive has consequences for clinical magnetic resonance imaging (MRI), which, while apparently unintended, are potentially dangerous. The Directive will

1. threaten both clinical and research use of MRI
2. make it difficult for staff to care for patients who need help or comfort during scans, such as children, the elderly or those who are anaesthetised. These patients may be forced to use technologies with significant proven health risks, such as X-ray or computed tomography (CT) scanners.
3. stop the use of MRI for interventional and surgical procedures
4. curtail cutting edge research in the field of MRI, denying patients innovative treatments in the future.

There are no known adverse long-term health effects of exposure to magnetic fields. This is not to argue that there should be no limits on exposure, rather that exposure limits should be based on current scientific knowledge. Risk assessment and research into safety aspects of electro-magnetic fields is taken very seriously by the European and international MR community. Progress in the understanding of the biological effects of

magnetic fields is regularly discussed and reported at numerous scientific meetings as well as at dedicated workshops.

The balance between risks to workers and risks to patients has not been properly addressed in Directive 2004/40. The risk assessment data used for the Directive was ten years old and the potential impacts of the exposure limits proposed by the directive were not assessed.

MRI Safety Standards

MRI scanners are built to comply with international safety standards (IEC)[1]. These standards set limits on patient exposure so as to avoid possible immediate and non-harmful effects like peripheral nerve stimulation, flashing lights in front of the eyes, nausea or dizziness. The IEC is currently in the final stages of extending this standard to include MRI workers. This amendment will bring the international standard (which is also a European standard adopted through the European Committee for Electrotechnical Standardization (CENELEC)) into direct conflict with the Directive.

New evidence

Due to our concerns, officials from our organizations and the Directorate General for Employment Social Affairs and Equal Opportunity of the EC have decided to contract an independent expert group to perform an analysis of the implications of the Directive on the clinical use of MRI. However, results will not be expected before Autumn 2007.

In the meanwhile Interim findings from the UK Health and Safety Executive (research undertaken by Professor S. Crozier from The University of Queensland, Australia), already indicates that both exposure to the switched gradient field and movement through the static field become problematic within about 1m of the magnet bore. This would mean that almost all MRI procedures in the EU (approx. 8 million examinations/year) would be affected. The probability of compromised patient care and avoidable serious incidents if treatment is withdrawn is very high indeed. Patient groups, members of the European Parliament, officials in the Directorate General for Health and Consumer Protection of the EC and representatives in charge of the implementation of the Directive in a number of member states share our concerns.

Any decision to severely curtail the use of MRI must be based on firm scientific evidence. MRI has been safely used for over 25 years, with over 200 million patients exposed to time-varying magnetic fieldsat amplitudes up to 100 times the occupational exposure limit, without any evidence of harm to workers or patients.

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[1] International Electrotechnical Commission standard 60601-2-33 (3)

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Recommendation

We strongly advise that the deadline for implementation of the Directive be deferred by at least one year (to April 2009) to allow the results of the impact assessments being undertaken by the European Commission and the member states to be concluded. This delay would allow the new scientific evidence to be taken into account and make an amendment to the legislation possible prior to the deadline for implementation. This is not possible within the current timeframe.

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