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Euratom Directive on MRI Safety and Protection of Workers' Health

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What is the Directive About?

Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 lays down minimum requirements for the protection of workers from risks arising from exposure to electromagnetic fields (EMF) and waves. All Member States are required to incorporate this Directive into their national law by 2008. However, it has dramatic implications for interventional magnetic resonance (MR) imaging, because workers who are close to the MR scanner while scanning are exposed to levels substantially above the exposure limits. This is especially the case for timevarying magnetic fields in the 110 Hz–5 kHz range, which includes the field from the imaging gradients.

Scope of the Directive

The measures provide a minimum basis of protection for all workers in the EU, thus giving the Member States the option of keeping or adopting more favourable provisions. Its main aim is to provide a minimum standard of protection for those working with electromagnetic fields (EMF) and to ensure that industry is competing on an equal basis.

The Directive applies to time-varying electromagnetic fields with frequencies varying 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. But 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 will be reconsidered when the Directive is reviewed in 2009).

Employers' Obligations

The Directive lays down various types of obligation with which employers, such as hospitals, have to comply with:

• assessment, measurement and calculation, by the appropriate services and at regular intervals, of the levels of electromagnetic fields to which workers are exposed;

• saving results of this assessment on a suitable data storage medium, to be consulted

• considering in the assessment of risks (e.g. the level, frequency spectrum, duration and type of exposure), the indirect effects, such as interference with medical electronic equipment and devices, fires and explosions resulting from ignition of flammable materials.

Provisions Designed to Avoid or Reduce Risks

If action values are exceeded, employers must develop and implement an action plan which would prevent exposure from exceeding the exposure limit values. This could include changing working methods, choice of appropriate work equipment, better design of work stations, etc. But, employers are not obliged to do so if they can prove that there are no risks to the workers' health.

The Directive also provides a number of other provisions including health surveillance, reports and sanctions. The health of exposed workers has to be monitored in order to prevent any adverse effects due to exposure to electromagnetic fields. If exposure exceeds the limit values, a medical examination has to be carried out. Both the worker concerned and the doctor responsible for the health surveillance have access to the health records. Member States must provide for adequate sanctions in the event of infringement of the national provisions transposing the Directive.

In addition, Member States must provide a report to the Commission every five years on the practical implementation of the Directive, indicating the points of view of the social partners.

Every five years, the Commission must inform the European Parliament, the Council, the European Economic and Social Committee and the Advisory Committee on Safety and Health Protection at Work of the content of the reports of the Member States.

Concerns from Medical Community

The medical community across the EU has expressed concern that the implementation of Directive 2004/40/EC could have severe implications for medical and research use and for maintenance and testing of MRI equipment. Some medical professionals claim that it could restrict and or even prevent the use of MRI. The main concern is the over-exposure of operators and appears to relate mainly to static magnetic fields and low frequency time-varying magnetic fields.

The Directive sets out minimum health and safety requirements regarding the exposure of workers to the risks arising from EMFs, but does not apply to patients or volunteers undergoing MRI examination.

Current Use of MRI

Over the last few decades, MRI scanners have been in increasing use throughout Europe and the rest of the world. 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.

At several hospitals in the United Kingdom, MRI is used instead of X-rays. In 2006, the NHS bought 100 new MRI scanners, at nearly 1,5 million euros a piece, making the UK a leader in MRI usage as well as research. 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.

Other concerns voiced regarding the Directive point out that the implementation of the regulations threatens to reverse pioneering advances in MRI as it would be more difficult to use high field scanners. Diagnosis and treatment of anaesthetised, frail or anxious patients, and children, will be particularly affected. Additionally, patient and staff safety will be put at greater risk from X-rays.

Lending her voice to this debate is Liz Lynne, Member of the European Parliament's Employment Committee, who warned about the impact of a European Directive on MRI Scanners. The Electromagnetic Fields Directive will not only limit the time that operators will be able to spend near MRI machines when they are in use but also prohibit new uses of MRI technology which let doctors see how treatments are working.

According to Lynne, "The evidence from the medical profession, then as now, was overwhelmingly against restricting the use of MRI scanners. These are vital machines which can save lives; limiting their use will leave doctors reliant on less successful, more dangerous procedures. The European Commission and Governments across the European Union are beginning to realise the severe implications of this Directive on medical treatment. I am strongly urging the Commission to amend this piece of legislation before bodies are laid at its door.The sooner this situation is remedied the better."

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