COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR Position Paper

on the Proposal for a Directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)

The European Commission adopted a proposal[1] on 14 June 2011 to revise the directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields - EMF). The text includes an exemption for the medical applications using the Magnetic Resonance Imaging (MRI) technique from the exposure limit values set in the Directive.

COCIR welcomes the European Commission's recognition of the strict controls already applied to the use of MRI and hence, the proposal to exempt MRI from the exposure limits. This is the result of the concerns raised by COCIR[2] and many others that the proposed limit values would impede the practice of MRI[3] and it will ensure that this vital medical technology will continue to be available for all patients in Europe.

COCIR remains committed to ensuring high levels of safety for both MRI patients and medical and other staff, and is actively involved in developing international safety standards[4].

Medical applications such as MR have been serving European citizens for more than 25 years with no reported negative health effects related to EMF exposure reported.

The exemption for MRI will ensure:

1. Healthcare professionals to continue to use MRI, a lifesaving technology for the diagnosis and treatment of diseases such as cancer and heart disease.
2. New research and developments in MRI will not be restricted, allowing Europe to keep its innovation leadership position in the development of future medical technology.
3. Manufacturers will continue to provide efficient service and maintenance of MRI equipment guaranteeing patients and users' safety throughout the entire life-cycle of the device.

COCIR is ready to:

- **Offer its expertise to the discussions at the European Parliament and the Council of the European Union in the upcoming months, regarding the use of MRI and the measures the Industry is already taking to ensure the safety of patients and users.**

- **Contribute actively to the development of a consistent and practicable methodology to protect workers exposed to EMF as set out in the annex IV of the proposed Directive.**

[1] *COM(2011) 348 final, 14 June 2011. http://www.cocir.org/uploads/documents/84-1212--1216-final_ec_draft_emf_directive_14_june_2011.pdf*
[2] *http://www.cocir.org/uploads/documents/19-19-newest_validated_cocir_emf_pp_07_may_2007_v0_1.pdf*
[3] *http://europa.eu/rapid/pressReleasesAction.do?reference=IP/07/1610*
[4] *International MRI Safety Standard IEC 60601-2-33, 2nd Edition, amendment 2, specifically developed for protection of MR workers.*

DETAILED BRIEFING

MRI has been safely used for over 25 years, imaging more than 500 million patients without evidence of harm to workers or patients due to exposure to electromagnetic fields.

Exemption of MRI from the limit values represents the best acceptable and responsible solution for the clinical and research use of MRI, since potential risks to workers and patients are managed by other means and will be addressed through the development of the responsible guidance to medical and service personnel on good working practices proposed in annex IV of the new directive[5].

It is clear that without an exemption of MRI from the limit values:

- It will be impossible for healthcare staff to care for fragile patients, such as children, the elderly, those who are anaesthetised or who need help or comfort during scans.

- Some patients may be forced to use technologies with significant proven health risks, such as X-rays. In many cases this will mean computed tomography (CT) scanning, which has significant health risks for the patient and also for workers, such as anaesthetists, who must remain close to the CT scanner particularly in the case of children and uncooperative patients.

- It will severely restrict the use of MRI for interventional and surgical procedures. These procedures will revert to X-ray and CT guidance, with potential for high exposure to ionising radiation for workers.

- It will curtail cutting edge research in the field of MRI, denying patients innovative treatments in the future.

- It will interfere with careers in MRI by imposing limitations on MRI training and education.

- It will severely interfere with the construction, installation and maintenance of research MRI systems in Europe, and with the development of new systems, often performed in collaboration with academic laboratories. European MRI manufacturers could be forced to relocate these activities outside the EU, with serious impact on European industry and research.

1. MRI is an essential technique for diagnostic and treating illness.

MRI is a medical diagnostic tool in which EMFs are used intentionally to provide high-resolution images of soft tissues in the body. It produces detailed pictures of the inner structure and function of patients' bodies using strong magnetic fields and radio waves, and is central to important treatments and research programs for many illnesses, in particular cancer and heart and neurological diseases.

MRI has moved to the forefront of medical imaging in recent years covering almost all areas from neurological and cardiovascular imaging to imaging needed for interventional procedures.

[5] *Annex IV: "Specific measures for activities falling under article 3 (4)."*

Without an exemption, it is clear that this directive would have a major negative impact on the use of MRI in the clinic, hindering the diagnosis and treatment for patients with life-threatening diseases such as cancer, myocardial infarction and stroke.

2. **MRI is an essential tool in biomedical research.**

MRI is a leading example of where the EU is in the forefront of cutting edge research, and as such contributes to an innovative and competitive Europe.

MRI is central to fundamental brain research as well as research in areas such as cancer, cardiovascular diseases, neurodegenerative and psychiatric disorders or alterations of the loco-motor system.

In the newly emerging field of molecular imaging in biology and medicine, MR is likely to play a pivotal role as the most comprehensive imaging modality combining the capabilities of high-resolution visualization with information at the molecular, functional and metabolic level.

The promotion of analytical tools and technologies for biomedical research, diagnosis and follow-up of diseases, for drug development, and for monitoring and guidance of therapeutic interventions, in all of which MR play a crucial role, are also supported under the EU's 7th Framework Program.

Without an exemption, it is clear that this directive would threaten Europe's position as a world leader in MRI research and consequently seriously limiting the use of MRI for research purposes and prohibiting research that has clinical and public benefit.

Without an exemption, it is clear that this directive would severely impact on the ability of MRI manufacturers to undertake product development in Europe, resulting in transfer of knowledge and activities outside the EU, and thus impact the European economy.

3. **The safety of MRI for patients and users is correctly addressed by other means.**

Risk assessment and research into safety aspects of electromagnetic fields is taken seriously by the European and international MR community. MRI scanners available on the market in Europe have to comply with the essential requirements of the Medical Devices Directive, which includes a responsibility towards the health and safety of patients and workers. This is achieved through compliance with the International Electrotechnical Commission (IEC) standard IEC/EN 60601-2-33.

In addition, MRI systems are used in a controlled environment, including access controls, safe working practice guidelines and staff training programmes.

Our Industry is fully committed to the protection of workers and will actively contribute to the development of a consistent and practicable methodology to protect workers exposed to EMF as set out in the Annex IV of the proposed Directive by developing and adopting harmonised standards, working practices and safety in MRI across Europe. This might include defining different working situations according to EMF exposure and level of risk. We believe that this approach would provide a more sensible and workable solution to the issue of exposure to electromagnetic fields.