



COCIR informal Contribution to European Commission's Second Stage Consultation of Social Partners on the Protection of Workers from the risk related to Exposure to Electromagnetic Fields at Work

Preamble

COCIR welcomes an amendment of the EU Physical Agents Directive 2004/40/EC (hereafter: EMF Directive) and the specific measures to guarantee safe and unrestricted access to Magnetic Resonance Imaging (MRI), along the lines of the proposals announced in the second Social Partners Consultation document published by the Commission on May 25, 2010.

The need for revision lies in the fact that adopted limit values will prevent the use of MRI, a lifesaving technology for the diagnosis and treatment of many patients, now and in the future. The medical profession, wherever possible, prefers the use of imaging modalities which do not use ionising radiation, such as MRI, to those which use ionising radiation e.g. X-Rays. The current Directive however, prevents healthcare staff from assisting or caring for patients during MR imaging of life threatening diseases such as cancer and heart disease. Furthermore, it would make it impossible for service personnel to install and maintain systems in an efficient manner. In the 30 years' history of the use of Magnetic Resonance for medical purposes with more than 500 million patients treated, no negative health effects have been reported for patients or workers that relate to EMF exposure.

COCIR is convinced that exemption of MRI from the limit values in the EMF Directive is necessary to ensure the future unimpeded use of MRI, particularly for cutting edge research and MR-guided interventions. In respect to this major advance in healthcare technology, concerns can certainly be better addressed through responsible guidance to medical and service personnel than legislation.

COCIR also welcomes the fact that the benefit of patients has been balanced with the risk assessment concerning EMF exposure by and for medical professionals. Safety of MRI workers, already regulated by the EU Medical Devices Directive 93/42/EEC and MR safety standard IEC/EN 60601-2-33¹, requires collaboration between industry and social partners.

COCIR members are committed to setting and implementing the highest standards of safety for their equipment. We vigorously support continuing professional development through guidance and training for MRI workers in order to maintain and develop high quality MRI procedures to the benefit of all.

COCIR calls upon the EU Institutions for a swift adoption of all necessary amendments to the current Directive to ensure implementation by April 30, 2012 at the latest. This is the only way to ensure that health professionals across the EU will not violate the terms of the present Directive while providing high quality care for citizens.

¹ The IEC standard has been published in OJEU as a harmonized standard, prescribing "state of the art" protection of patients and workers against electromagnetic fields, establishing conformity to the Essential Requirements from the Medical Device Directive 93/42/EEC.

Detailed Contribution to section four of the Consultation

4.1 Coverage of all sectors of activity

COCIR supports all sectors to be in scope, provided that good medical practice with Magnetic Resonance (MR) equipment for patients and future innovation which is vital to citizens' healthcare is not hampered. Safety for workers (and patients) is the most important consideration for COCIR and its members.

4.2 Precise definitions

COCIR understands that quality and type of work relates to training and workers guidance. At the same time, safety of workers is adequately addressed: The MR manufacturer is required to instruct the hospital following the IEC 60601-2-33 standard². The instructions of the standard include amongst others the need for training of all personnel allowed entering the "controlled access area".

4.3 Exposure limit values

COCIR has no concern with the principle of zoning, however if adopted it must be internationally harmonised.

4.4 Measurements and calculations

COCIR has no problem with measurement and calculation of the device aspects as they are covered in IEC 60601-2-33. EMF in MR is intentionally generated and therefore well characterised if expressed in directly measurable quantities. It is not clear however how measurement and calculation can be achieved in vivo.

4.5 Guidance for risk assessments

COCIR members are committed to maintaining high levels of safety for both patients and workers. Generally all manufactures of MR equipment apply ISO 14971:2007, the international standard on the application of risk management to medical devices. This type of medical equipment is also complying with European Directive 93/42/EEC which includes post market surveillance.

4.6 Due flexibility in a controlled working environment

The installation of an MRI scanner is subject to strict installation requirements which also affect the access to the scanner. An MR system is always located in a "controlled access area". It encloses the space with a static magnetic field strength exceeding 0.5mT to protect even people with active implants. This controlled working environment is a closed area with access control, i.e., permitting access only to properly informed and trained personnel.

4.7 Medical surveillance

COCIR is of the opinion that the proposals for medical surveillance are not yet mature and need further discussion of all stakeholders.

² The IEC standard has been published in OJEU as a harmonized standard, prescribing "state of the art" protection of patients and workers against electromagnetic fields, establishing conformity to the Essential Requirements from the Medical Device Directive 93/42/EEC.

4.8 The specific case of medical applications and related activities (research, cleaning, maintenance) using nuclear magnetic resonance (MR) technology

COCIR fully supports the Commission's intention of exempting the medical MR sector and activities related to the use and development of medical MR techniques from binding exposure limit values.

This decision well reflects the results of the study of April 2008, impact assessment conducted by the FICETTI consortium and opinion of the entire MR community. Compulsory compliance with the exposure limit values would hamper the future use of MR.

None of the proposed limit values (except IEC 60601-2-33) does address the issue of the use of MR for vulnerable patient groups. The existing ICNIRP limit values heavily restrict movement in the vicinity of the magnet. A practical workflow would be impossible. Assessing the best proposed limit values reveals that a gap remains to fulfil the requirements for MR. Examples of procedures that will be excluded are those where staff is required to monitor the patient, such as small children, anesthetized or cardiac patients. In addition, progress of medical sciences is prohibited if interventional radiologists or cardiologists are not allowed to work in the close vicinity of the MR machine. As a result, they will have to continue working with harmful X-rays.

9. Non-binding measures

COCIR agrees that both employers and workers organisations have an important role to play and is ready to work together on non-binding measures and their successful implementation. Thus, COCIR fully supports the idea of a "European good practice guidance" drafted by workers and employers of all stakeholders which is implemented in all Member States. The Dutch paper "Practical Rules for Employees" from July 2008 or the American College of Radiology (ACR) "Guidance Document for Safe MR Practices" could serve as starting point for safe and responsible practices in clinical and research MR environments.