



COCIR

SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR comments on the European Commission's proposal of 14 June 2011 on the EMF Directive and Member State discussions

1. Discussion of the inclusion of Magnetic Resonance applications (MR) within the EMF Directive has been on-going for more than 10 years. **Throughout this period, considerable uncertainty and concern over MR's future has disrupted its use and development in Europe to the detriment of patients and economic activity.**
2. **Following concerns from the European Parliament, Member States, the Commission, MR users and patient groups, the European Union was convinced in 2007 that the unintended consequences of the EMF Directive on MR were sufficiently serious, that it took the most unusual step of postponing the implementation of the Directive for 4 years until 2012.** Since then, the Commission has consulted widely amongst Member States and all interested parties and undertaken research and literature reviews on the possible effects of EMF on workers and specific aspects relating to MR.
3. After this extensive work, **the Commission proposed on 14 June 2011 that activities involving MR be exempted from the Directive's exposure limits,** and remain covered by other provisions of the Directive and in particular the comprehensive safeguards for workers and patients specified in the new Annex 3 to the Directive.
4. **COCIR fully supports the Commission proposal of 14 June and urges all Member States and MEPs to endorse the Commission proposal** in order to bring to an end the uncertainty over the future of MR in Europe and allow the Directive to be implemented without further delay.
5. **EU policies in areas such as medical research, medical innovation, healthy and active ageing and economic competitiveness in a high tech business sector are encouraging and in some cases funding the increased use of MR** as the technique is developed to diagnose cancers, neurological, cardio vascular, muscular and many other diseases at an earlier stage, advancing scientific understanding and improving patient outcomes.
6. **The use of EMF in MR is intentional and is conducted in a strictly controlled environment** to safeguard patients and workers. The **maintenance of MR machines** is complex and in most instances requires the static magnetic field to remain on – a mechanic cannot diagnose a car engine fault with the engine turned off. Also, restoring MR to operational level after turning off the magnet may take several days, a downtime hard-pressed hospitals and waiting patients cannot afford. **For these reasons, proposals that the exemption for MR may only be applied to clinical staff are unworkable.**
7. Similarly, **research activities in Europe to develop new uses for and the next generation of MR must not be unnecessarily hindered in what is already a global marketplace.**
8. **A proposed compromise that Member States be allowed to decide whether to include MR use in the Directive's exposure limits seems to COCIR to be wholly against the rationale and ethos of EU legislation** – that of equality between and within all Member States. COCIR supports legislation based upon grounds of a competitive European marketplace.
9. **COCIR concludes that the most practical, sensible and scientifically justifiable action that will enable this complex and long running issue to be resolved is for Member States and the European Parliament to accept and support the Commission's carefully considered proposal of 14 June.**