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From: Borbonus, Monika [mailto:Borbonus@ZVEI.Org]
Sent: 11 April 2003 15:38
To: To the members of Social Questions Working Party & National Experts - Electromagnetic Fields and Waves
Cc: Bursig, Hans-Peter; Strattner Günter; Bätzel Andreas; Schröder, Adolf; philippe.portalier@orgalime.org
Subject: [COCIR] - Draft Directive for the protection of workers from exposure to electro-magnetic fields and waves

[COCIR] - Draft Directive for the protection of workers from exposure to electro-magnetic fields and waves

Dear Ladies, dear Sirs,
COCIR, the European Coordination Committee of the Radiological, Electromedical and Medical Information Technology Industries, would like to draw your special attention to the serious concerns of the European Electromedical Industry with regard to the "Draft Directive for the Protection of Workers from exposure to electro-magnetic Fields and Waves".
COCIR supports the WEM/ORGALIME position, which states that industry feels that the present draft is "ill conceived and has been re-activated without any consideration on its implications on business or employment."
The WEM/ORGALIME position also points at the specific problem for the Medical Device Industry, especially regarding the use of Magnetic Resonance Imaging (MRI) equipment. The current proposal could have the effect of restricting or even preventing the use of MRI scanners used in health care, which creates a problem not only for industry but as well for health care professionals depending on MRI for medical diagnosis. COCIR therefore recommends to exclude medical devices as defined in Directive 93/42/EEC, from the scope of this draft Directive for the reason that specific electromagnetic fields and waves may be required to achieve the desired medical outcome. Safety requirements for electrical medical devices are sufficiently covered by harmonised European standards (EN 600601).
Additional information about the situation with regard to MRI equipment is contained in the attached paper. The current safety requirements for MRI equipment, as defined in EN 60601-2-33 are being regarded as sufficient to protect patients as well as users of such equipment.
Additional information on the specific situation with regard to MRI equipment and other medical devices could be provided through a visit to a European manufacturing facility for such equipment. Such a visit could be arranged on short notice. COCIR experts would also be ready to present information to the Social Questions Working Party on invitation.
The COCIR Secretariat General is available for further questions on this issue.
Best regards
Hans-Peter Bursig
COCIR Secretary General

Encl.
cc: Mr. Portalier, ORGALIME

COCIR Secretariat General
c/o Fachverband Elektromedizinische Technik im
Zentralverband Elektrotechnik- und Elektronikindustrie (ZVEI) e.V.
Stresemannallee 19 D-60596 Frankfurt am Main
Phone: +49 (0)69-6302-206 Fax: +49 (0)69-6302-390
<http://www.cocir.org/> <mailto:office@cocir.org>