

12 August 2003

Mr. Jose Biosca de Sagastuy  
EU Commission  
DG Employment D 5  
Rue de la loi 200  
1049 Brussels  
Belgium

RE: Alarm Over the "Draft Directive for the Protection of Workers from Exposure to Electromagnetic Fields and Waves"

To Whom It May Concern,

The International Society for Magnetic Resonance in Medicine (ISMIRM) needs to alert you to our serious concerns regarding the "Draft Directive for the Protection of Workers from Exposure to Electro-magnetic Fields and Waves." The ISMIRM is a non-profit, non-affiliated international society of more than 5,000 members advancing the science and development of Magnetic Resonance in the medical and biological sciences. Our Annual Scientific Meeting of more than 4,000 participants conducts an extensive international educational and scientific program in Magnetic Resonance. We publish two scientific journals, host many global workshops, support the SMRT (our registered technologist society), and serve as an international resource for all issues in magnetic resonance.

We firmly believe that the draft Directive is an ill-informed endeavor. There already exist many international guidelines and standards regulating magnetic resonance in general and magnetic resonance imaging in particular, which are much more specific about the potential hazards of working with MR and which require permanent training of staff and special procedures to be followed. The existing standards already in place have advanced MRI in the EU (indeed worldwide) as a premier health care tool of immense value. The draft Directive would completely render the entire health care system throughout the EU inoperable, in that the Directive will cripple the very MRI instruments that are key to many diagnostic and image-guided therapeutic procedures, creating havoc in international health care standards for all EU citizens and the many thriving EU MR-manufacturers. We further are convinced that crippling MR within the EU will have a ripple-effect felt worldwide.

The ISMIRM supports the rising conviction that the present draft is "ill conceived and has been re-activated without any consideration on its implications on business or employment." At our recent international meeting in Toronto, the ISMIRM Safety Committee voiced concerns that the EU directive is restricting the use of MRI as a medical modality without solid proof that a risk for patients or MR system operators truly exists. The ISMIRM further supports the WEM/ORGALIME position that the Directive could have the effect of restricting or even preventing the use of MRI scanners used in health care, creating a problem not only for industry but as well for health care professionals depending on MRI for medical diagnosis. The ISMIRM asks that the Directive should

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**International Society for Magnetic Resonance in Medicine**

exclude medical devices (such as MRI) 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 harmonized European standards (EN 600601).

We vigorously voice our concerns that the present draft is unbalanced and does not consider the tremendous implications on the medical diagnosis of diseases in particular, the whole development of MRI in general and the economic impact to the EU. The ISMRM would be very happy to address further inquiries and is eager to contribute to the discussion for "Draft Directives for the Protection of Workers from Exposure to Electromagnetic Fields and Waves."

Sincerely yours,

A handwritten signature in black ink, reading "Michael E. Moseley". The signature is written in a cursive style with a large, sweeping initial "M".

Michael E. Moseley, Ph.D.

President

International Society for Magnetic Resonance in Medicine