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The Threat to MRI Throughout Europe?

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In 2004, the European Commission issued a Directive concerning physical agents with the laudable aim of protecting workers from possible health risks associated with electromagnetic radiation in the workplace. The Directive lays down a minimum safety requirement for all EU nations, and has to be implemented by all member states by April 30, 2008. Although there is little to take exception to in the Directive itself, the values laid down in the Annex to the Directive are exceedingly conservative and may impinge on the practice of MRI in a number of crucial situations.

Aims of the Directive

The Directive sets out a range of action values for magnetic fields as a function of frequency. If the action values are exceeded then the employer is obliged to determine whether the associated exposure limits are also exceeded. Action values, given in units of Tesla, reflect field exposure, whereas exposure limits are given in terms of the current density induced within the body, and are more difficult to calculate. After intense lobbying the exposure limit for static magnetic fields was removed, and there is hence no limit for exposure to the main magnetic field of the MRI system. However, limits for time-varying magnetic fields in the kHz range remain. Such magnetic fields are generated by the switched magnetic field gradients used for spatial localisation in MRI. Furthermore, motion in the gradient of a static magnetic field inevitably results in exposure to a time-varying field, and is covered by the terms of the Directive.

What Effect will the Directive Have?

The Directive will impact the following:

' The field of switched magnetic field gradients used within the MRI system extends outside the magnet bore. Any professional in the vicinity during an investigation may be exposed to fields in excess of the exposure limits. This will impinge on those providing a comforting presence to easily stressed patients during an exam, as well as any exams involving anaesthetics or injection by hand

' The stray magnetic field of modern systems ranges from a few to hundreds of milli-Tesla over the first metre from the end of the magnet bore. Hence a person moving even at a modest speed of about a metre-per-second will be exposed to significant changes in magnetic field. Dependent on the field strength, magnet design and speed of motion, exposure values may be exceeded. Effects in this situation are particularly severe for very high-field systems, particularly with a self-shielded magnet design. Although no static field limit was imposed in the Directive, this regulation will make it difficult or impossible to use some systems

' In interventional MR the interventionalist may be exposed to a combination of the above effects. Precise details depend on the system, but they may be exposed to the same switched magnetic field gradients as the patient, and also move in strong static field gradients.

Why are Thresholds Too Low?

The Directive applies to any exposure, however brief. Exposure limits and action values are taken from recommendations of the International Commission for Non-Ionising Radiation Protection (ICNIRP) made in 1998. Careful reading of the ICNIRP publication reveals that limits were set to avoid physiological effects in general, and not specifically harmful effects.

In contrast, limits for patient exposure are set to avoid peripheral nerve stimulation, which, if induced in extreme form, can result in pain. ICNIRP

thresholds are set at about a factor 50 below those for patients. The main physiological effect that ICNIRP guidelines seek to avoid is magnetophosphenes, harmless artifactual flashes of light induced at the retina, interpreted as a possible indicator for effects of magnetic fields on the central nervous system. Magnetophosphenes have been induced in subjects at very high static magnetic fields, but the sensitivity of the visual system falls rapidly with increasing frequency. Magnetophosphenes have not been induced by switched magnetic field gradients in the context of MRI investigations, i.e. if the patient never experiences them it does not seem logical to protect employees from magnetophosphenes at thresholds of around a factor 50 lower amplitude!

Addressing the Situation

In March 2006, representatives including the EAR, ECR, EFOMP, ESMRMB, ISMRM and UEMS visited Brussels for discussions with Commissioner Spidla, the EU Commissioner responsible for Employment, Social Affairs and Equal Opportunities. The delegation received a sympathetic hearing, but changing an established Directive can be a lengthy business. Further contacts between the Commission and representatives are foreseen.

The ESMRMB will run a web-based safety survey to quantify the impact of the Directive on radiological practice. The ICNIRP is at present revising recommendations, and the best hope lies in an increase of thresholds in line with current knowledge. In the short term it is important that the MR user community makes its voice heard. Change to the Directive will be most easily achieved if the European Commission, Council and Parliament all agree that it is necessary, and this will only be achieved by concerted action to bring our case to the Commission, national representatives and MEPs.

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