# Unwarranted caution from the EU will affect MRI use and patient care

A recent European Union (EU) Directive which comes into force in 2008 could have potentially unforeseen and damaging effects on clinical magnetic resonance imaging (MRI). The scientific basis for the Directive is weak, and leans heavily on the 'precautionary principle' in deciding its restrictions, while having little or no substance to support them.

In April 2004, the EU Parliament enacted the first of three Physical Agent Directives, in this instance dealing with occupational exposure to electromagnetic (EM) radiation (EU Directive, 2004). Legislation implementing this Directive has to be taken on board by all EU member countries – including the UK – by 30 April 2008.

The Directive is concerned with the permitted exposure levels of staff operating, maintaining or manufacturing equipment which produces EM radiation in the frequency range 0–300 GHz. The basic exposure limit values are defined in terms (e.g. the current density possibly calculated over a small area induced in the head or trunk in the frequency range up to 10 MHz) that are impracticable to measure in almost every instance, and so a set of 'action values' are also prescribed. These are couched in terms which can be used in practice (e.g. the amplitude of time-varying electric or magnetic fields) and are very conservative to guarantee that limits cannot be exceeded in practice.

## Relevance to hospitals

The most significant piece of equipment in a typical hospital which produces EM radiation is the MRI system, and this is most likely to be affected by the new Directive. While the relationship between the prescribed action values and frequency is complex, there are three key aspects to the restrictions. These relate to the static magnetic field from the MRI magnet, the time-varying fields produced by the gradient coils, and the radiofrequency (RF) fields. Since the Directive relates only to staff operating and maintaining equipment, the RF limit is largely irrelevant.

Staff do not get close enough to the RF coils during machine operation to receive any significant radiation dose, and as averaging over time and tissue mass is allowed it is difficult to see how limits might be exceeded. The RF limit conforms to widely accepted radiation levels, and is basically the same as the level for patient exposure.

No exposure limit value is prescribed for the static magnetic field, although the action value is set at 0.2Tesla (T). A static field limit of 2T was considered during negotiation of the Directive, but wiser counsels prevailed. However, since current National Radiation Protection Board (NRPB) advice on occupational exposure gives limits to the whole body of 2T and 5T to the limbs, the indication that UK regulators might impose such a limit unilaterally would be devastating, making emerging 3T MRI systems essentially impossible to clean or maintain.

A more subtle problem which has been overlooked by legislators is the limits imposed for time-varying fields within the audio frequency range (the range occupied by the magnetic resonance (MR) gradients). The action values can be as low as 25 μT. This is about 400 times lower than the threshold for the only known acute biological effect of EM radiation in this frequency range: peripheral nerve stimulation (McRobbie and Foster, 1984).

The existence and nature of peripheral nerve stimulation has been known for a long time, both in the context of MRI exposures (Shaefer et al, 2000) and as a clinical tool in its own right in transcranial magnetic stimulation. Fields of the levels set by the action values extend for a considerable distance along the axis of modern clinical scanners while they are operating. These values will prevent staff from being in close proximity to the scanner bore. This will make the servicing of MRI systems much more difficult; and anaesthetists and sedation nurses will be unable to get close to their charges while they are being imaged. Moreover the development and application of MR-guided interventional procedures will become impossible. Perversely this will lead to greater ionizing radiation exposure for both staff and patients in future as procedures that might otherwise have been transferred to MRI guidance continue to be performed using X-ray or computed tomography.

It is reasonable to question why such safety issues have not been raised in the past, and whether the introduction of the new limits is not long overdue, if they are needed to protect staff who use this equipment. However, there has never been any demonstration (or even suggestion) that there is any hazard to patients or machine operators from any of the fields involved in MRI.

The known hazards with RF doses – which have the potential to exceed proposed limits – are catered for by manufacturers building systems that comply with the relevant international standard (International Electrotechnical Commission, 2001) and obtaining approval under the Medical Devices Directive. In any event, staff are almost invariably, and inevitably, further from RF sources than patients – and the same limits apply to both.

The problems with the static and audio frequency fields arise from an over-zealous and scientifically unjustified application of the precautionary principle. This can only be responsibly applied in circumstances where there are known risks, even if their magnitude is unknown – and not, as seems to have happened in the case of the scientific justification for the Directive, on the basis of 'scientifically plausible' effects that have never actually been observed.

A great many things are plausible – but have no actual reality. The case supporting the proposed levels for the various fields seems concerned with the possibility that people might be 'disturbed' by effects arising from them – even if the effects are completely non-hazardous. As noted in the NRPB justification (National Radiological Protection Board, 2004) for the adoption of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines – and those Guidelines themselves (International Commission on Non-Ionizing Radiation Protection, 1998) – the case leans heavily on the possibility that some people may be 'hypersensitive' to one field or another (without demonstrating, or attempting to demonstrate, that such people exist). The same argument could be used to ban planes, trains, automobiles or any other domestic, agricultural or industrial mechanical device on the grounds that some people might be hypersensitive to the noise they emit. That would have a rather better scientific justification.

## Guidelines for patient exposure

NRPB was the first regulatory body in the world to issue guidelines for patient exposure in 1980. Subsequently, the Food and Drug Administration (FDA) in the USA produced more restrictive guidelines, which prompted NRPB (National Radiological Protection Board, 1983) to revise its suggestions and bring them into line with the FDA version, although they added a 'dose dependent' component (8 hours exposure at 0.2T or pro rata in each 24-hour period).

Over the years, the FDA has steadily increased its guideline limits for patient scanning – they are now substantially greater than NRPB's levels for both main and gradient fields. NRPB maintains it sees no reason to change its guidelines in spite of multiple demonstrations of the improved diagnostic performance of higher specified systems. Presumably, improved patient benefit is not regarded by UK regulators as a worthwhile reason for changing their position. These guidelines apply to patients, but provide the background to what is now happening with staff, and the current ICNIRP and NRPB views about risks to operators are clearly coloured by their antecedents in patient regulation. Much of the literature cited and the committees evaluating it involve the same small group of people, and there should be an independent evaluation of the scientific basis on which the EU Directive is founded.

It is not possible here to give a detailed critique of the underlying scientific basis for the Directive, although it is extraordinarily weak, and, on occasion, is actual nonsense. The only way to reverse what has been done is to demonstrate through good research how misguided the approach is, but the aim must be to persuade those who will enforce the Directive that a commonsense, proportionate approach is more sensible than a gung-ho demand for instant conformity.

MRI has enormous value as a diagnostic method and, as far as is known, in none of the 400 million or more studies performed worldwide, has any operator or patient been affected by any of the fields used – even though, under the International Electrotechnical Commission standard, patient exposure to gradient fields may be up to 100 times the level at which the Directive insists 'instantaneous, detectable, adverse health effects' occur.

Hazards in MRI have almost all involved the 'projectile effect' (things containing iron being sucked into the magnet) and RF burns from inadequately insulated RF coils, and inappropriate or badly placed monitoring devices, with very few being the result of cryogenic problems. Vulnerable, elderly, often very ill patients do not experience any of the problems perceived by the regulators and they are mostly in much higher fields than the Directive permits for fit, relatively young operational staff.

## Conclusions

It seems perverse to diminish the efficacy of this vital clinical tool, in view of the complete lack of evidence of any hazard, and particularly when alternative imaging approaches would almost certainly involve staff and patient exposure to harmful ionizing radiation. Further discussions involving government, regulators and the MR community as a whole (users, maintainers and researchers) are now urgently needed so that the advances made in MRI over the last 30 years are not squandered. BJHM

### KEY POINTS

- The European Union enacted a directive in 2004 which must be implemented in the UK by the end of April 2008 which lays down limits for the exposure of staff to electromagnetic radiation.
- The levels prescribed by the Directive will affect current methods of operating magnetic resonance imaging systems, and could result in some of the most modern scanners being shut down.
- The scientific basis for the levels which have been set is very weak indeed, and the values chosen have been almost entirely guided by over-enthusiastic application of the 'precautionary principle'.
- Perversely, the Directive will tend to raise the exposure of staff and patients to ionizing radiation (a known hazard) at the expense of exposure to fields with no known adverse effects at all.
- Urgent action is needed to persuade those implementing the Directive to do so with understanding and a light hand, rather than operating the letter of the law.

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