

# Electromagnetic Field Exposure Limits in Europe: Is the Future of Interventional MRI Safe?

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## Introduction

The new European Union (EU) Directive [1] is designed to protect workers from adverse health effects of electromagnetic fields (EMF). All EU countries must incorporate it into national law by 2008. The legislation covers all frequencies from 0Hz to 300GHz, therefore encompassing the fixed field ( $B_0$ ), the imaging gradient field, and the RF field. Table 1 shows the new exposure limits and action values (more easily measurable quantities that ensure compliance with the limits). Any MR-guided intervention that involves the interventionalist having part of his or her body inside or close to the magnet bore while scanning will exceed the action value for time-varying magnetic fields by up to two orders of magnitude and will thus be illegal. Interventional MR (iMR) avoids exposure to ionising radiation that results from carrying out a procedure under x-ray guidance [2]. The Directive will prevent this reduction in ionising radiation being realised for both patients and staff. The Directive is based on guidelines produced by the International Commission on Non-Ionising Radiation Protection (ICNIRP) in 1998 [3]. We decided to examine the scientific basis of the ICNIRP guidelines, focusing on the gradient fields, 110Hz – 5kHz range, as this is where the Directive has most impact.

## Method

The ICNIRP report cites over 200 abstracts, scientific and review papers and book articles spanning more than 30 years of research. For each effect used by ICNIRP in creating a case we examined the scientific evidence. Often this involved reading reports from other protection bodies and review articles cited by ICNIRP. Specifically we were looking for known adverse health effects: a biological effect alone is not sufficient for claiming possible health effects, i.e.. *in-vitro* studies alone cannot form the basis for setting limits.

## Results

**Volunteer Studies:** effects reported are magnetophosphenes (an established effect, threshold  $\sim 10\text{mAm}^{-2}$ ); reversal of visually evoked potentials (threshold  $200\text{mAm}^{-2}$ , limited evidence, not observed at lower intensities); and a slight reduction in heart rate at specific EMF intensities (limited evidence). All these effects were recorded at below 100Hz, and are not considered to be health risks but ICNIRP uses them as justification for establishing limits.

**Cellular Studies:** Looking for links between EMFs and cancer, neuro-behavioural, genotoxicity or reproductive effects. Of 85 magnetic field specific studies summarised in [4] just 10 were at gradient frequencies. None could be used as evidence of adverse health risks though ICNIRP appears to use these “tissue effects” as justification for establishing limits.

**Acute vs Chronic Exposure:** ICNIRP states, “The severity and the probability of irreversibility of tissue effects becomes greater with *chronic* exposure to induced current densities above the level 10 to  $100\text{mAm}^{-2}$ . It therefore seems appropriate to limit human exposure to ... no greater than  $10\text{mAm}^{-2}$  ... at frequencies of a few hertz up to 1 kHz.” ICNIRP also states, “above  $100\text{mAm}^{-2}$ , the thresholds for *acute* changes in central nervous system excitability and other *acute* effects such as reversal of the visually evoked potential are exceeded.” The Directive is intended to protect against acute effects and explicitly excludes chronic effects, but the limits it creates for gradient exposure appear to be based on chronic effects.

**Frequency Dependence:** The majority of experiments were conducted at power frequencies but ICNIRP extrapolates data to higher frequencies based on the frequency dependence of (*acute*) peripheral nerve stimulation with thresholds  $\sim 100$  times greater than the effects being considered.

## Conclusions

The EU have taken the ICNIRP guidelines and turned them into legislation without considering that the scientific evidence is limited, the precautionary principle has been applied and weight given to a small number of studies in the guidelines. As a result, most interventional MR procedures will become illegal in the EU. No trade-off between benefit to the patient and risk to the staff is permitted within the EU directive. Clearly there is a need for more research specifically at MR gradient frequencies to establish thresholds for any biological effects and their potential adverse health risks.

Frequency	EU directive for workers		Interventional MR	References	
	Exposure	Action			
Static field	Up to 1Hz	None	0.2T	3T	[1] European Union Directive on Physical Agents 2004/40/EC. [2] Razavi R et al. Lancet 362:1877-1882; 2003. [3] ICNIRP 1998. Health Phys 74:494-522. [4] National Academy of Science. Possible health effects of exposure to residential electric and magnetic fields. Washington, DC: National Academy Press;1996.
Gradients	0.025-0.82 kHz	$10\text{mAm}^{-2}$	$25/f\ \mu\text{T}$	$1 \times 10^4\ \mu\text{T}$	
	0.82-65 kHz	$10f\text{mAm}^{-2}$	$30.7\ \mu\text{T}$		
RF	10 – 400 MHz	0.4W/Kg	$0.2\ \mu\text{T}$	0.4W/Kg (whole body)	

Table 1: Summary of relevant limits in the EU Directive and estimates of maximum values in the interventional MR environment. *f* is frequency in kHz.