

## **MRI safety in practice: The EU directive on work in electromagnetic fields – practical and clinical aspects**

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### **Highlights**

- The adopted EU directive 2004/40/EC has severe consequences for the use of MRI. If implemented in the current form, it will drastically affect approximately 5-8% of examinations, and will limit employee's movement near scanners.
- Interventional MRI and examinations of patients requiring special attention (e.g. due to age or anaesthesia) will be most affected. So will research and development, and scanner maintenance/cleaning procedures.
- If MRI procedures become impractical, the cost-benefit ratio goes up as will the use of alternative modalities involving ionizing radiation increasing the risk of cancer.
- Before implementation, the directive will likely be modified to reduce detrimental effects for MRI.

### **Problem summary**

The current paper addresses the practical consequences of the EU directive 2004/40/EC<sup>1</sup> passed in 2004 concerning protection of workers from electromagnetic fields (EMF). These consequences were evaluated in detail only after the directive was passed, and they were found to be severe. Consequently, the directive has not yet been implemented fully in the EU member state's legislation, and a revision is expected before this happens in October 2013, the latest<sup>2</sup>. The revised directive is expected to be based on revised recommendations<sup>3,4</sup> of the *International Commission on Non-Ionizing Radiation Protection (ICNIRP)*, and may in other ways limit the detrimental consequences for MRI, but this is uncertain. Hence the presented summary of consequences is based mainly on the current directive, representing a realistic worst-case scenario, except for a static field limit that will likely be introduced in a revised directive. An estimated 5-8% of current examinations will be severely affected<sup>5</sup>. The inadvertent effects include reduced access to interventional MRI, and to procedures involving personnel in the scanner rooms during scanning, e.g paediatric examinations, and scanning conducted under anaesthesia. Other consequences are increased use of alternative imaging modalities including X-ray based techniques, hindered development of improved MRI techniques, and general consequences of increased complexity and cost.

### **Background**

The EU directive 2004/40/EC on protection of workers from electromagnetic fields (EMF) was adopted in 2004 despite concerns expressed by MRI stakeholders. At that time, the consequences of the directive were largely unknown since studies including complex field modelling for worst-case situations were absent. The concerns of the MRI community proved to be warranted since the exposure limits of the directive were exceeded significantly for a range of established MR procedures. Limiting the use or development of MRI was not an intention of the legislators, since MRI has proven to be of immense clinical value with no established safety hazards that would be mitigated by the directive. In contrast, it is widely accepted that the norm for MRI equipment, IEC 60601-2-33, ensures sufficient protection of MRI workers<sup>6</sup>. Relative to patients, for which the norm aims at zero risk, the workers are typically exposed to much less EMF.

The directive should initially have been implemented in the EU member states in 2008, but due to the inadvertent consequences for MRI, the deadline for transposition of the directive was delayed by the EU, first to 2012, and latest to October 31<sup>st</sup>, 2013<sup>2</sup>. A revised directive largely exempting MRI was proposed by the EU Commission in June, 2011, but it was rejected by the European Council since exemptions for specific applications were deemed unfortunate. Hence, this summary of consequences is based mainly on the current directive 2004/40/EC<sup>1</sup>. A status report from 2012 describes the progress during the Danish EU presidency where a new model for a partial MRI derogation was introduced<sup>7</sup>.

A study of the EMF exposure in MRI environments was commissioned by the British Health and Safety Executive<sup>8</sup>. The report and accompanying journal articles were published in 2007 and included computational field modelling and experimental dosimetry. It was found that the ICNIRP guidelines for occupational exposure would be exceeded during normal MRI procedures, including movement in the fringe field of MRI scanners, and bending over patients during scanning. Similar conclusions were reached in a study commissioned by the European Commission to illuminate the field exposure of MRI workers<sup>9</sup>. Guidelines were exceeded by factors up to 10-50 during established MRI procedures that are perceived as unproblematic by the MRI community.

The consequences of the directive have been reviewed in several papers. A report from the British Institute of Physics summarized the earlier studies<sup>10</sup>. A report from June 2010 written by experts in the field of MRI<sup>11</sup> was issued by the European Science Foundation and endorsed by the European Medical Research Councils representing 30 national research communities. A working paper on the impact (including financial) of different versions of the directive was published by the European Commission in 2011<sup>5</sup>.

### **Consequences of the EU EMF directive**

According to an EU impact assessment of the current directive, the following measures are adequate in most situations involving scanners up to 3T<sup>5</sup>.

- do not come closer than 0.5m from the entry of the bore when not absolutely necessary to assist the patient.
- just walk normally in the MRI room (~ 4km/h except close to the scanner).
- do not stay close to the bore when (image) acquisition is in progress.
- do not remain in the room when it can be avoided.

Phrases such as “necessary” or “can be avoided” offers little comfort: In the current directive, the exposure limits are strict, and the well-being of the patient is not of relevance. If exposure limits are exceeded, the affected personnel are entitled to medical examinations, which makes little sense in the case of transient dizziness, peripheral nerve stimulation or visual phosphenes which are the anticipated harmless effects that may result if the above advise is ignored (unfortunately not an option). Obviously, special problems pertain to maintenance and cleaning of MRI systems.

Especially the third point above is a major problem for interventional MRI and procedures involving anaesthesia where close monitoring of patients is needed. Also scanning of groups requiring special attention during scanning, e.g. children, confused patients, or patients in pain becomes highly problematic. The needed unnatural behaviour of staff in the scanner room, and discordance between staff behaviour and patient information, will cast suspicion on a technique that is well tolerated except for the uncertainty and claustrophobia felt by many patients. Telling the patients that they are safe while not being able to assist them near the scanner, will add to the already large fraction of scanings terminated because of anxiety. It is unlikely that all patients will understand or appreciate that the discordance is simply due to unfortunate EU legislation.

In the same EU impact assessment, estimates from the British Health Protection Agency were used to calculate costs associated with cancers resulting from increased use of ionising radiation as a direct consequence of the directive. A cost of 2.5M Euros was found contrasting another estimate by the Alliance for MRI of 175M Euros<sup>5</sup>. While these numbers may not seem high for the entire EU, they are not acceptable considering that they reflect inadvertent suffering inflicted on patients for political reasons only: The partial MRI derogation from the directive was rejected since derogations for a particular application could be used to question the *raison d'être* of the EMF limits for other applications, though it is widely accepted that MRI is already sufficiently regulated.

Also development and research requiring full scanner access and flexibility will be affected. It is difficult to imagine, for example, how the novel motion tracking methodologies providing much needed insensitivity to patient motion could have been developed if the directive had been implemented, thus limiting employee's access to moving in the bore where sensor systems are located. Also, the advice above pertains to 3T scanners, but clinical applications are emerging for scanning at 7T where e.g. the phase contrast and spatial resolution is much improved compared to lower field strengths. The field exposure limits are basically show-stopping at 7T.

Even if a partial exemption for MRI is introduced, extra requirements for training and documentation will likely be needed<sup>5</sup>:

- reinforced information measures
- reinforced training of workers
- documented and practicable working procedures favouring exposure limitation whenever possible
- strict administrative procedures for access to MR rooms
- consultation of personnel on improvements
- monitoring

The EU cost estimate is 325 Euros per installation for risk evaluation and formulation of procedures. 75 Euros per employee is estimated for ½ day of training. An increased focus on safe procedures, that will also reduce the significant risk of projectile accidents, is not necessarily bad, of course. Example material supporting such training is produced by Dutch stakeholders<sup>12</sup>.

### **Consequences of the norm for MRI equipment vs. the EU EMF directive**

The MRI community is used to restrictive exposure limits that apply to patients and employees. The international norm for MRI equipment<sup>6</sup> imposes severe restrictions on the fields that can be applied, and on the rates of field switching. Based on scientific evidence, the norm sets limits aimed at protecting the patients from *any* health risk resulting from MRI procedures. Recently, also staff protection was included in the scope, which was relatively simple since employees are generally exposed to much less EMF than patients. The norm is widely accepted even though it indirectly sets lower limits for the scan duration and upper limits for the technical scan quality for a large fraction of the examinations. These limits are conservative, but are well perceived since they have proven to protect both patients and staff from inadvertent effects of EMF without imposing overly strict limits not based on scientific studies. Some of the limits of the norm have been relaxed somewhat over time as warranted by the steadily growing knowledge on EMF effects. Many ingenious methods have been developed to partially overcome the limitations imposed by the norm. Low SAR techniques, for example, are generally used to maintain quality of diagnostic information while operating at the SAR limit, in situations where this is reached.

The situation may seem similar for the restrictions imposed by the EU directive 2004/40/EC<sup>1</sup> as they may appear conceptually similar to those of IEC 60601-2-33. Both are based on scientific evidence, so the fuss over the EU directive may seem exaggerated. That is not the case, however. Reducing EMF exposure limits will likely drive MR innovation towards techniques reducing exposure, but in analogy to the low-SAR example above, improved techniques can typically only reduce the disadvantages partially. Since exposure limits are exceeded by e.g. a factor 50 during routine procedures, the negative effects will be drastic. Also there are other clear differences between the restrictions imposed by the norm and the directive. The former are established limits based on scientific evidence and much experience, and they have proven sufficient. They don't mitigate all EMF effects, such as metal taste or dizziness, for example, that may occur for patients and staff. These effects are well-understood and harmless short-term effects, that are felt differently by different persons, and are generally well tolerated by the staff. Dizziness can be avoided simply by moving at a pace in the scanner room where it cannot be felt (normal movement for most people). Since the effects are very subjective and harmless, it makes little sense to avoid them via limits that are way too strict for almost all people. Large safety factors are not needed when the well-understood implications of exceeding thresholds for physiological effects are of minimal importance, and when inadvertent effects of the limits are severe.

### Summary

The consequences of the currently adopted EU EMF directive are drastic. Revisions providing partial derogations are badly needed.

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