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Regulatory issues in protection of workers exposed to static magnetic fields generated by Magnetic Resonance scanners

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***Abstract*—International regulations for protection of workers exposed to intense static magnetic fields like those in close proximity of Magnetic Resonance scanners present some problematic aspects which will be herein discussed.**

***Index Terms*— Health effects, MRI, Occupational exposure, Safety risks.**

I. Introduction

In 2013, the Directive 2013/35/EU was issued [1] laying down minimum health and safety requirements regarding the exposures of workers to electromagnetic fields, including those used in Magnetic Resonance Imaging (MRI), which has to be transposed by 1 July 2016. As regards static magnetic fields (SMFs), [1] was based on the 2009 guidelines of the International Commission on Non Ionizing Radiation Protection (ICNIRP) [2] which recommended exposure limits introducing a "flexible approach" based on the distinction between sensory and health effects, allowing in some occupational circumstances that unpleasant sensory effects can be experienced by the exposed workers.

Notwithstanding the adoption of the ICNIRP's flexible approach, Directive 2013/35/EU foresees the possibility of derogations with respect to exposure limits, in particular for MRI, in which case protection of workers has to be demonstrated "including by ensuring that the instructions for safe use provided by the manufacturer in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices are followed" [1].

Other protection issues are related to health and sensory effects associated to the movement of workers in the SMF which are not completely addressed in [1,2]. As a matter of fact, directive [1] refers to the planned publication of ICNIRP specific guidelines for a comprehensive assessment of the movement-related effects that should have been inserted by the European Commission in the annexes of the directive itself. ICNIRP actually published these guidelines in 2014 [3], but their insertion in the directive has not yet occurred. The application of these guidelines presents some difficulties, that will be hereinafter addressed.

II. Stray SMFs Generated by MR Scanners

An MR scanner generates a uniform SMF (B_0) within the imaging volume, but outside this central region and outside the bore, where the staff can operate during normal job activities, the stray SMFs are highly non uniform. Some data on the SMF spatial distribution for different typologies of scanners show that the exposure limit for general public recommended by ICNIRP [2] is exceeded for 1.5 T – 7 T scanners at distances below 1 m from the bore entrance. Issues relevant to protection of MRI workers against SMFs are therefore limited to the close proximity of the higher B_0 scanners.

III. Health effects of SMFs

SMFs interact with the biological matter through several established physical mechanisms such as magneto-mechanical effects, electron spin interactions, electrodynamic interactions with moving electrolytes (Lorentz forces), the induction of electric fields and currents according to Faraday's law (applying to temporal variations of the SMF perceived by a moving subject).

Based on the above mechanisms, ICNIRP states that the major potential concerns with respect to limiting exposure to SMFs are cardiovascular and neurological effects, but studies on humans exposed to SMFs up to 8 T do not provide evidence of any irreversible or serious adverse health effects [2]. ICNIRP recommends to restrict exposure below 8 T because for higher exposures there is no human experience and therefore there is lack of knowledge.

Similarly to what happens in the case of exposure to low frequency fields, motion-induced electric fields can stimulate electrically excitable tissues like nerves and muscles. However, in 2009 ICNIRP discounted the possibility of this health effect below the 8 T exposure limit since frequencies associated with body movement are likely to be less than 10 Hz, and below this frequency the electrical excitability of nerve tissues decreases due to the slow inactivation of the voltage-gated sodium ion channels [2].

IV. Sensory Effects of SMFs

Exposures to SMFs can induce transient sensory effects such as vertigo, nausea, metallic taste, and phosphenes which may be annoying and impair working ability, possibly posing

risks for safety but not for health.

Sensory effects such as vertigo and nausea are probably due to motion-induced electric fields, even if the Lorentz force on ionic currents in the vestibular organ could contribute to them also in a stationary subject in a SMF. On the other hand, phosphenes are due to micro-currents in the retina deriving from the electric fields induced by movement in the SMF.

V. ICNIRP RECOMMENDATIONS FOR MOVEMENTS IN SMFS

In the 2014 guidelines [3], both health and sensory effects due to movements in an SMF are addressed by ICNIRP, differently from the previous 2009 guidelines. Indeed, ICNIRP recognizes that, although the threshold for peripheral nerve stimulation is unlikely to be reached for normal movements in an SMF below 8 T, for very fast movements the basic restrictions for peripheral nerve stimulation set by the 2010 guidelines [4] may slightly be exceeded. These qualitative considerations (moreover referring to ICNIRP 2010 guidelines that apply only to frequencies greater than 1 Hz) are specified in quantitative terms by recommending, for prevention of peripheral nerve stimulation, basic restrictions (BRs) on the induced internal electric field, along with the corresponding reference levels (RLs) on the external dB/dt, for frequencies up to 1 Hz (Table I). If the spectrum of the motion-induced electric field extends above 1 Hz, ICNIRP states that it is necessary to apply also the BRs and RLs recommended in its 2010 guidelines [4].

Table I
BRs and RLs for controlled exposures (peripheral nerve stimulation)

	Basic restrictions	Reference levels
Frequency (Hz)	Internal electric field strength ($Vm^{-1}_{(peak)}$)	dB/dt ($Ts^{-1}_{(peak)}$)
0 - 1 Hz	1.1	2.7

BRs and RLs for health effects apply in all situations, even for controlled exposure conditions where workers are able to control movements in order to prevent annoying and disturbing sensory effects [3]. For uncontrolled exposure conditions, where sensory effects have strictly to be avoided, similar but more restrictive BRs and RLs are recommended in order to avoid the induction of phosphenes (Table II).

Table II
BRs and RLs for uncontrolled exposures (phosphenes)

	Basic restrictions	Reference levels
Frequency (Hz)	Internal electric field strength ($Vm^{-1}_{(peak)}$)	dB/dt ($Ts^{-1}_{(peak)}$)
0 - 0.66 Hz	1.1	2.7
0.66 - 1 Hz	0.7/f	0.8/f

Moreover, in order to prevent other sensory effects like vertigo and nausea, a specific BR is recommended directly on the external magnetic flux density B (making pointless a corresponding RL) whose change ΔB (as experienced by the moving subject) should not exceed 2 T during any 3 s period. Even if not explicitly stated by ICNIRP, we have to assume that the change ΔB (as expressed in [3]) is equal to $|\Delta \mathbf{B}|$. Indeed, the hypothesis $\Delta B = \Delta|\mathbf{B}|$ has to be excluded because it would be incoherent with its physical basis, the Faraday's law.

VI. DISCUSSION

Implementation of Directive 2013/35/EU as it is (without the insertion of [3]) would not address protection of workers against health effects related to movement in the SMF. Moreover, the possibility of derogations from the compliance to the 8 T limit opens questions about how to demonstrate the protection of workers against health effects of the SMF.

A problematic aspect of 2014 ICNIRP guidelines appears to be that, in order to verify compliance with BRs and RLs recommended to prevent sensory effects, an *a priori* knowledge of all the possible movements of workers in the SMF may be necessary. Actually, these BRs and RLs are set for uncontrolled exposures, where no training of workers is foreseen about sensory effects and how to control movements to avoid them. On the other hand, the same BRs and RLs can be useful in the case of controlled exposure conditions in order to provide procedural advices to control movements in the SMF.

In the case of the BR for prevention of vertigo and nausea, a possible simplification of the procedure of exposure assessment can be found on the basis of the following considerations. In order to have a possible violation of the BR ($|\Delta \mathbf{B}| > 2$T in any 3 s period), it is necessary to have $|\mathbf{B}| > 1$T at least in one point in the space: in such a case, a 180° rotation of a moving subject can lead to a perceived change of the magnetic flux density from $\mathbf{B}$ to $-\mathbf{B}$ whose modulus $|\Delta \mathbf{B}|$ is > 2 T. This allows a possible simplification of the procedure of risk assessment, as long as the effects of nausea and vertigo are concerned: 1) if it is verified that $|\mathbf{B}|$ is everywhere ≤ 1 T, the BR for prevention of nausea and vertigo cannot be violated, and the risk assessment can stop; 2) if somewhere $|\mathbf{B}| > 1$ T, but it is everywhere ≤ 2 T, instead of proceeding to a complex evaluation relevant to all the possible movements of workers, the same measures foreseen for controlled exposures could be taken (access restriction to properly trained workers able to control their movements in order to prevent annoying and disturbing sensory effects).

However, it has to be underlined that the above described simplified evaluation cannot be applied as long as phosphenes are concerned.

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