Implications of Directive 2013/35/UE on Protection of MRI Workers

Mariangela Tomaiuolo[*], Rosaria Falsaperla[**], Alessandro Polichetti[*]

[*]*Technology and Health Department, National Institute of Health, Viale Regina Elena, 299 00161 Rome (Italy),*
mariangela.tomaiuolo@guest.iss.it, alessandro.polichetti@iss.it
[**]*Occupational Hygiene Department, Italian Workers' Compensation Authority,*
Via di Fontana Candida 1 00040 Monte Porzio Catone, Rome (Italy), r.falsaperla@inail.it

Abstract – Directive 2013/35/UE about protection of workers against electromagnetic fields allows derogations from compliance to exposure limits in the case of MRI workers. Some critical issues are here discussed.

I. Introduction

Magnetic Resonance Imaging (MRI) workers may be exposed to three different types of magnetic field used for diagnostic images formation:

- a static magnetic field;
- time-varying gradient magnetic fields;
- a radiofrequency (RF) electromagnetic field.

Workers, unlike patients, are generally exposed only to the static magnetic field. However, there are special situations where operators may also be exposed to time-varying fields (gradient and RF fields), like in interventional MRI or when patient management is required.

Potential negative impact of Directive 2004/40/EC about protection of workers against electromagnetic fields [1] on some operating practices, mainly related to MRI, led to the publication, in June 2013, of the new Directive 2013/35/UE [2] which repeals the previous one.

This paper analyzes how the new directive deals with protection of MRI workers, highlighting some critical issues.

II. Directive 2013/35/UE and its derogations

Consistent with the flexible approach adopted in ICNIRP guidelines for static magnetic fields [3] and for low frequency electric and magnetic fields [4] published after the previous directive, Directive 2013/35/UE sets two different types of Exposure Limit Values (ELVs), namely the sensory effects and the health effects ELVs, allowing the overcoming of the first ones under certain conditions.

However, this flexible approach was not considered sufficient in order to limit the impact of the new directive on certain activities, therefore the possibility of derogations has been foreseen in the Art.10 of the directive itself. In particular, paragraph 1, point a) of Art.10 establishes that, as long as MRI equipments for patients in the health sector are concerned, exposures may exceed ELVs if some conditions are met. It has to be underlined that these ELVs are those related to health effects, as the directive itself allows to exceed sensory effects ELVs under certain conditions, whatever be the sector or activity involving occupational exposures to electromagnetic fields.

Among the conditions to be met in order to derogate from the compliance to health effects ELVs, the following is particularly relevant: *"the employer demonstrates that workers are still protected against adverse health effects and against safety risks, 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"*.

It has to be noted that the manufacturer has the possibility to declare that the product (the MRI system) is in accordance with the essential requirements of Directive 93/42/EEC [5], including the health and safety requirements for the users, if (but not only if) the prescriptions of the relevant harmonized technical standards have been followed.

In the case of MRI, the European standard EN 60601-2-33, "Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis", which includes also the prescriptions relative to the instruction for use, is particularly noteworthy. It is therefore a key point to understand how the requirements of the EN 60601-2-33 can assure the protection of workers against electromagnetic fields.

Below, some critical aspects related to derogations are described. Being the critical issues identified differentiated with respect to the static and time-varying fields, they will be treated separately.

III. Static magnetic field

The health effect ELV for the static magnetic field, relative to controlled working conditions, laid down by the Directive 2013/35/UE, is equal to 8 T, as recommended by ICNIRP in 2009 [3]. As mentioned above, according to the Art.10 of the Directive 2013/35/UE, exposures may exceed this limit, if some conditions are met.

It is therefore necessary to ascertain if the instructions for use, drawn up by the manufacturer according to the EN 60601-2-33, are sufficient to guarantee protection of workers against the adverse health effects of static magnetic field levels higher than 8 T.

First of all, according to EN 60601-2-33, the instructions for use should explain the possible effects that MR workers can experience when the main static magnetic field is above the level of the normal operating mode (3 T), including those related to the head's movement (vertigo, nausea and a metallic taste in the mouth). Moreover, instructions should explain the health effects related to the increased static magnetic field and that adequate training shall be given to MR workers to minimize them.

In addition, the instructions shall explain that *"when the main static magnetic field is higher than 4 T, MR workers shall not be allowed to access the MR equipment without special authorization"*.

In the informative part of the standard explaining the rationale behind the instructions for use, it is stated that *"exposure to the static magnetic field for the MR worker is allowed up to 4 T in this standard"* and *"for both the patient and the MR worker exposure to higher values than 4 T requires approval following local regulations"*. However, the latter statements have no practical consequences, not being included in the instructions for use that are delivered to the employer.

Consistently with current scientific knowledge, instructions for use do not provide indications about how to manage an overcoming of the health effects ELV (possible if in the examination room the static magnetic field is higher than 8 T in points accessible to workers). Therefore, the mere following the instructions for safe use does not guarantee that workers (even if authorized) are still protected against adverse health effects.

Derogations from the compliance to health effects ELVs should not apply to the static magnetic field ELV if workers' protection against adverse health effects should rely just on observance of instructions for use.

IV. Time-varying magnetic fields

As regards time-varying fields, the most important aspect of the protectionist approach of the standard EN 60601-2-33 is that it extends to the MR workers the same exposure limits fixed for the patients, therefore exceeding the limits set by ICNIRP for workers, implying that workers could experience some minor biological effects.

The rationale of this choice can be found in the essential requirements of Directive 93/42/EEC (Annex I) where it is stated that the devices must be manufactured in such a way that any risks (not only for patients, but also for users) which may be associated with their intended use are acceptable when weighed against the benefits to the patient. On the contrary, ICNIRP does not consider the need to balance health risks of MR workers with benefits to the patient because social (and economical) considerations are outside of the remit of ICNIRP.

According to EN 60601-2-33, the instructions for use should include information on maximum levels of exposure in areas accessible to MR workers along with a description of ways for the MR worker to mitigate the risks related to the exposure. Nonetheless, some questions are still open.

The standard defines three different operating modes (normal, first level controlled and second level controlled) at which different prescriptions for patient's safety have to be applied. At these different operating modes defined for patients, the standard foresees different prescriptions even for worker's protection.

At the typical frequencies of the gradients used during the MRI scanning, the EN 60601-2-33 foresees provisions aimed at protecting against stimulation effects, distinguishing between cardiac stimulation and peripheral nerve stimulation, stating that "*MR worker exposure limits are the same as the maximally allowed limits for the patients*". In order to prevent cardiac stimulation, the standard sets one unique exposure limit, that therefore applies to any operating mode. On the contrary, limits related to minimizing peripheral nerve stimulation are differentiated for normal and first level controlled operating modes, while no limits for patients are set for the second level controlled operating mode.

It is not clear if for the second level controlled operating mode the above mentioned "maximally allowed limits for the patients", that have to be applied to workers, are those set for the first level controlled mode, or if no limits are defined for workers, too. In the latter case, the standard would not guarantee workers' protection against excessive peripheral nerve stimulation induced by gradient fields.

In the case of RF fields, for which thermal effects are considered, in the standard is stated that "*allowed values for the temperature rise of the MR worker caused by the MR equipment are equal to the values for the patient as defined in Table 201.104 for the normal operating mode and the first level controlled operating mode*". As regards SAR limits, the standard specifies that "*MR worker exposure limits are the same as the maximally allowed limits for the patients*" as in the case of gradient fields.

Therefore, the same considerations, relative to the absence of a clearly fixed limit for the second level controlled operating mode, expressed previously about gradient fields, can be extended to RF fields.

V. Conclusions

The present analysis has highlighted some critical issues related to the possibility, foreseen by Directive 2013/35/UE, that MRI workers' exposures may exceed the limits fixed by the directive itself.

Hopefully, these aspects will be kept in mind when the directive will be transposed by EU Member States in national regulations, even in view of future developments in MRI area which could give rise to workers' exposure higher than the current ones.

References

[1] Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). *Official Journal of the European Union*, L184: 1-9.

[2] Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC. *Official Journal of the European Union*, L179: 1-21.

[3] International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines on Limits of Exposure to Static Magnetic Fields. Health Phys, 96: 504-514, 2009.

[4] International Commission on Non-Ionizing Radiation Protection (ICNIRP). Guidelines for Limiting Exposure to Time-Varying Electric and Magnetic Fields (1 Hz to 100 kHz). Health Phys, 99: 818-836, 2010.

[5] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. *Official Journal of the European Union,* L169: 1-60.