The Role and Responsibilities of the Medical Physicist in MRI in Europe

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The Legal Framework

Responsible for the Health and Safety at Work Directives


Directive 2004/40/EC on the exposure of workers to the risks arising from physical agents (electromagnetic fields)

Directive 2006/25/EC of the European Parliament and the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)
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The Problem


Calculations suggest that to remain below the Exposure Limit Values set by the Directive, workers would have to move their bodies and heads slower than 0.4 ms\(^{-1}\) near a 1.5T scanner and 0.2 ms\(^{-1}\) near a 3T scanner.

Workers would need to remain more than 1 m away from the scanner during imaging.
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The Problem
The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 April 2008. They shall forthwith inform the Commission thereof.

For almost three years scientists that realised that this Directive would create problems in the use of MRI attempted to convince the European Organised Stakeholders to act in order to stop the transposition of this Directive into National Law.

Already a small number of Member States have transposed the Directive into National Law.
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The MRI Alliance
The Alliance was founded by the European Society of Radiology, the European Federation of Neurological Associations and Dr. Swoboda MEP, Vice-Chairman of the Socialist Group in the European Parliament.

The Alliance for MRI was officially launched in March 2007 in response to the implementation of the EU Physical Agents 2004/40/EC (EMF) in April 2008.

EFOMP has officially joined the Alliance for MRI on the 13th of March 2008.
The MRI Alliance
Already in October 2007 the European Commission proposed the postponement of the implementation deadline from April 2008 to April 2012 to allow more time for the evaluation of new data on EMF and its short-term effects on the human body.
The Commission stated that it was never the intention of this Directive to impede the practice of MRI and the postponement was approved by the European Parliament and the Council.
The Alliance for MRI was instrumental in raising awareness of the threat posed to MRI and obtaining the postponement of the Directive.
The MRI Alliance


**Article 1:** In Article 13(1) of Directive 2004/40/EC, the first subparagraph shall be replaced by the following:

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than **30 April 2012.**
The MRI Alliance

During the past four years a lot of scientific evidence was gathered and a large number of presentations, lobbying and other events took place with the initiative of the Alliance for MRI, that convince the European Commission to place before the European Parliament and Council a new Directive that proposes a derogation for the application of the Directive in the use of MRI.

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Article 3, paragraph 4 states:

By way of derogation, paragraphs 1 and 2 shall not apply to medical applications using the magnetic resonance effect and the following related activities: integral system testing before release for shipment, installation, cleaning, maintenance, research and development activities. In these particular cases, specific protection measures shall be put in place. For this purpose the Commission shall consult the existing working groups and proceed according to the measures set out in Annex IV.

Article 15, states: Directive 2004/40/EC is repealed.
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ANNEX IV: Specific measures for activities falling under article 3(4)

In accordance with Article 3(4), and in order to ensure harmonised and adequate protection of workers and whilst taking due account of existing precautionary and protective measures, the following principles will be followed and tasks carried out.

1. Objectives

   a) The first objective is to develop, with the parties concerned, a consistent and practicable methodology to protect workers exposed to EMF during activities falling under Article 3(4).
b) The second objective is to include, in the developed methodology and related tools, aspects such as:

- **Effective information measures and dynamic consultation mechanisms**
- **Efficient training measures**, also for external personnel having access to the MR area (MR installation room, control room, any related adjacent room)
- **Documented working procedures** (and review mechanism)
- **Strict rules for access to MR rooms**
- **Monitoring of the quality of implementation**.
The third objective is to involve all the representative organisations in the dissemination of information to their members to ensure effective implementation of the good practices in a harmonised manner in all the MR installations of the Union.

2. Tasks
The tasks will be to:
• collect good practices already in place in Member States or in specific installations;
• examine existing guides and working procedures;
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- identify and describe risks (EMF, noise, flying objects, cryogenic liquids);
- identify the maximum-exposure scenarios
- define typical working situations;
- define appropriate rules of conduct for each typical working situation;
- establish a standard training programme and its content;
- establish any other means to fulfil the objectives;
- for future establishments, produce recommendations to improve safety (design of department, access management to MR room, design of rooms, etc.).
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3. Duration of work and reporting

a) The work will start immediately after adoption of this Directive and will be finalised no later than the date mentioned under Article 14(1);

b) The Commission will prepare a report explaining the outcomes achieved. The report will be transmitted to the Council and European Parliament not later than 9 months after the date mentioned under Article 14(1).
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In meantime:

In the period of March to May 2011, EFOMP has carried out a survey on the safety recommendations and regulations for MRI installations in European countries.

This survey showed that there was a wide variation in procedures within Europe, ranging from compliance with national legislation that is more restrictive than international guidelines to reports of no regulation.
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Due to the results of this Survey, in June 2011, EFOMP has decided to appoint a Task Force with the mandate to prepare a Policy Statement on:

The Role of the Medical Physicist in the Management of Safety within the Magnetic Resonance Imaging Environment.

The Task Force has finalised their work and presented the Draft Policy statement to the EFOMP Officers in December 2011.

Before being published, this Policy Statement will be send to the NMOs for comments and approval.
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The main recommendations of the Draft Policy Statement are:

*MR Safety Management*

It is essential to ensure the safety of staff, patients, volunteers, and visitors within the MR environment.

EFOMP suggests that a 2-level approach to the management of MRI Safety which distinguishes between the roles of the person responsible for MR safety on a day-to-day basis and those of an expert level professional with a higher degree of scientific and technical expertise in MRI is adopted.

This mirrors the case of ionising radiation where the new revised EC Basic Safety Standards directive mandates the existence of two levels, an Officer level and an Expert level.
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The MR Safety Officer

The MR Safety Officer (MRSO), must:

- be competent to assess and manage dangers caused by MR equipment
- be responsible for monitoring the measures taken to protect against such dangers
- ensure that appropriate measures for minimizing risks to health that arise from the use of the MR equipment are implemented and monitored
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The required knowledge and competence include the general principles of good safety management, the need to develop, document and introduce safe working procedures, and possession of adequate technical understanding and management skills to carry out the administrative responsibility delegated, and these should be acquired through formal, recorded training.

The MR Safety Expert
The MR Safety Expert (MRSE) - requires the skill, knowledge and competence to provide high level advice on the engineering, scientific and administrative aspects of the safe clinical use of MR devices.
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In particular the MRSE should be responsible for:

- the development and continuing evaluation of a safety framework for the MR environment
- the development of local rules and procedures to ensure the safe use of MR equipment
- safety advice regarding the selection and procurement of MR and related equipment
- advice on the design for accommodation and facilities for MR equipment.
- advice regarding non-routine MR procedures for individual patients and specific patient
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In early December 2011, EFOMP was informed that the responsible bodies of the European Union will vote on the new Draft Directive as follows:

The Public Health Committee of the European Parliament will hold its vote on 24/25 January 2012.

The European Parliament Employment Committee will have its vote on 13th February 2012.

The plenary vote of the European Parliament (all MEPs) is foreseen for March 2012.
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Also according to our latest understanding, the Member State positions are as follows:

- **Opposing MRI derogation:** Poland, Germany, Italy, Portugal, Austria, Lithuania, Czech Republic, Sweden, Denmark, Ireland, Spain

- **Supportive of MRI derogation:** UK, Netherlands, France, Latvia, Hungary, Finland, Luxembourg, Malta, Belgium, Slovenia
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In an effort to support the positive outcome of the above voting, on the 16th of December 2011, I have send, on behalf of EFOMP, personalised letters (87) to all the MEPs of the opposing Member States.

A request was also send to all the Presidents of the NMOs asking them to contact their local Minister responsible for the Directive (Health or Labour) to persuade them to vote positively at the European Council of Ministers.
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Last week we were informed that:

1. The Public Health Committee of the European Parliament has voted positively for the MRI derogation.
2. The European Commission will request from the European Council of Ministers a postponement of another two years for the transposition of Directive 2004/40/EC, due to the large opposing opinions in the European Council Working Party.

If consensus is not reached at the European Council in the next two years, we run the danger of the implementation of Directive 2004/40/EC as it is, with the problems it will bring to the MRI community.
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Reference Websites

Alliance for MRI

EFOMP
http://www.efomp.org/