

Experience of 8 years with the EU EMF-Directive 2013/35/EU

Documentation of the 1<sup>st</sup> European ElectroMagnetic Fields Forum online conference from November 15<sup>th</sup> to 16<sup>th</sup>, 2021

baua: Report



# **Experience of 8 years with the EU EMF-Directive 2013/35/EU**

Documentation of the 1st European ElectroMagnetic Fields Forum online conference from November 15th to 16th, 2021

This publication is the conference documentation on the occasion of the 1st conference of the European ElectroMagnetic Fields Forum "Experience of 8 years with the EU EMF-Directive 2013/35/EU", which was held online on November 15<sup>th</sup> and 16<sup>th</sup>, 2021. The responsibility for the contents of this publication lies with the authors.

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Publisher: Federal Institute for Occupational Safety and Health (BAuA)

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doi: 10.21934/baua:bericht20220425 (online)

https://doi.org/10.21934/baua:bericht20220425

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#### Konferenzzusammenfassung

- 1. Konferenz des Europäischen ElectroMagnetic Fields Forum (EEMFF)
- "8 Jahre Erfahrungen mit EMF-Richtlinie 2013/35/EU"
- 15. bis 16. November 2021, online

## **Kurzreferat**

Das European ElectroMagnetic Fields Forum (EEMFF) ist ein Europäisches Netzwerk nationaler Arbeitsschutzinstitutionen mit dem Ziel, die Umsetzung der EMF-Richtlinie (2013/35/EU) in den EU-Mitgliedstaaten zu verbessern. Um Fachleuten für Sicherheit und Gesundheitsschutz bei der Arbeit eine Plattform zu bieten, ihre Erfahrungen zu diskutieren und bewährte Praktiken auszutauschen, organisierte das EEMFF im November 2021 eine Konferenz, die von der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA, Dortmund, Deutschland) via Webex veranstaltet wurde.

Um einen Dialog zwischen europäischen und internationalen Fachleuten für Sicherheit und Gesundheitsschutz bei der Arbeit herzustellen, bot die Konferenz mehrere Vorträge, die durch Posterpräsentationen und vertiefende Workshops zu den wichtigsten Themen des Arbeitsschutzes in Bezug auf EMF ergänzt wurden:

- Weiterentwicklung der EMF-Richtlinie 2013/35/EU,
- Neue und komplexe Quellen, Zukunft der EMF-Forschung am Arbeitsplatz,
- Die Rolle der Normung zur Verbesserung der Umsetzung der EMF-Richtlinie 2013/35/EU,
- Besonders schutzbedürftige Beschäftigte, und
- Bewährte Verfahren zur Expositionsbewertung.

Diese Konferenzzusammenfassung enthält ausführliche Zusammenfassungen ausgewählter Hauptvorträge und Posterpräsentationen und gibt einen kurzen Überblick über die Ergebnisse der Workshops. Zusätzlich kann die Konferenzdokumentation online unter www.baua.de/eemff abgerufen werden. Aufgrund der enormen Themenvielfalt ist es unmöglich, die Hauptergebnisse der Konferenz an dieser Stelle verständlich und kurz zu benennen. Für die Zusammenfassung wird deshalb auf das Kapitel "Concluding Remarks" verwiesen.

## **Schlagwörter**

elektromagnetische Felder, EMF, Arbeitsplatz, EMF-Richtlinie, 2013/35/EU, Weiterentwicklung, nicht-sinusförmig, Normung, besonders schutzbedürftige Beschäftigte, Exposition, Ermittlung

Conference Summary
1st European ElectroMagnetic Fields Forum (EEMFF) conference
"Experience of 8 years with the EU Directive 2013/35/EU"
15<sup>th</sup> to 16<sup>th</sup> November 2021, online

## **Abstract**

The European ElectroMagnetic Fields Forum (EEMFF) is a pan-european network of national occupational safety and health institutions aiming to enhance the implementation of the EMF Directive (2013/35/EU) in the EU member states. To provide occupational safety and health specialists with a platform to discuss their experiences and to exchange best practice, the EEMFF organised a conference in November 2021, hosted by the Federal Institute for Occupational Safety and Health (BAuA, Dortmund, Germany) via webex.

To establish a dialogue between European and international occupational safety and health specialists, the conference offered several keynotes supported by poster presentations and in-depth workshops on the most relevant occupational safety and health topics concerning EMF:

- Evolving the EMF Directive 2013/35/EU,
- New and complex Sources, Future of occupational EMF Research,
- The Role of Standardisation to enhance the Implementation of the EMF-Directive 2013/35/EU,
- Workers at particular Risk, and
- Best practice in Exposure Assessment.

This conference summary provides extended abstracts to selected keynotes and poster presentations and gives a short outline of the workshop results. Additionally, the conference documentation can be accessed online via www.baua.de/eemff; please adjust language settings to English. Due to the enormous diversity of topics, it is impossible to summarise the conference's key findings with preserving a meaning to them. Please refer to the Concluding Remarks for a summary.

## **Keywords**

Electromagnetic fields, EMF, workplace, occupational, EMF-Directive, 2013/35/EU, evolving, non-sinusoidal, standardisation, workers at particular risk, exposure, assessment

## The European EMF Forum

The idea to provide occupational safety and health specialists in the area of electromagnetic fields with a dialogue forum was born in 2019.

There are considerable differences in the way, the EU Directive on EMF 2013/35/EU was implemented in the EU member states and in the resources available to inform and support employers and workers. When networking with colleagues from other European Member states, the need to further connect and exchange ideas on how to provide healthy, safe and competitive workplaces with EMF exposure across Europe it became obvious. The necessity to provide such a dialogue forum also arose for those among us who are unable to attend and present work at scientific conferences for various reasons, especially employees of public service institutions like labour inspectorates or labour administrations.

On short notice, a small network connected to discuss the idea of establishing such forum emphasising knowledge exchange and dialogue on a pan-European level to tackle both issues mentioned at the beginning. Apart from comparison of specific implementations, a discussion on novel & upcoming EMF-sources as well as on developments in exposure guidelines and assessment techniques were identified as conference core areas. Soon there were 9 members from 8 different EU member states supporting the idea of such a forum. A suitable name was quickly found and preparations for a new conference format commenced in late 2019.

Due to the Corona-Virus-Pandemic, the original plans were shifted to 2021. The attendance of the first EEMFF conference showed a quite large interest in our niche topics and a desire to collaborate with OSH officials and researchers across Europe and beyond: we welcomed 78 attendees from 29 countries across the world.

We are grateful for your contribution to and participation at the 1<sup>st</sup> EEMFF conference and wish us all an interesting and successful conference "8 years of experience with the EU Directive 2013/35/EU".

PS: We offer and live an inclusive philosophy, open for various input from all sorts of EMF-related occupational safety and health topics. If you are intrigued by our ideas and philosophy and favour a project driven collaboration, you are very kindly invited to join EEMFF! You may contact the chairing institution of EEMFF, the German BAuA, under physical.agents@baua.bund.de.



## Agenda

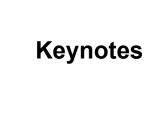
All times are provided in CEWT (Central European Winter Time)

## Monday, 15.11.2021

12:00	Opening of conference and welcome notes	Organising Committee
12:30 chairs: C. Alteköster and K. Schiessl	The EU EMF Directive 2013/35/EU: A brief overview of the history and future of 2013/35/EU	Laura Vicente (EC DG Employment, Social Affairs and Inclusion)
13:00	Overview of the implementation in the member states	Dr. Rianne Stam (RIVM, Netherlands)
13:30	The European Directive 2013/35/EU: "Health surveillance of EMF exposed workers"	Prof. Fabriziomaria Gobba (University of Modena)
14:30–15:30	Workshop "Evolving EMF-Directive 2013/35/EU"	
15:45–16:45	<b>Workshop</b> "New and complex sources, future of occupational EMF research"	
17:00–17:30	Poster Session	
17:45–18:45	<b>Workshop</b> "Role of standardisation to enhance implementation of the EMF-Directive"	

#### Tuesday, 16.11.2021

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08:30 chairs: R. Stam and B. Vatovez	Workers at particular risk:  1. Risk assessment for workers with AIMDs,  2. Risk assessment for pregnant workers and workers with PIMDs.	Dr. Carsten Alteköster (IFA, Germany) Dr. Klaus Schiessl (AUVA, Austria)
09:30	EMF exposure assessment in special situations: 1. Numerical dosimetry and measurement 2. Supporting employers to perform EMF exposure assessment	Dr. Richard Findlay (EMFcomp, UK) Lucien Hammen (INRS, France)
10:30–10:40	Break	
10:40-11:40	Workshop "Workers at particular risk"	
11:40–11:50	Break	
11:50–12:50	Workshop "Best practice in exposure assessment"	
12:50–13:00	Break	
13:00 chairs: J. Karpovicz and K. H. Mild	2013/35/EU – What needs to be done? and the way forward (conference wrap up)	Prof. Dr. Michel Israel (Bulgaria) Dr. Peter Jeschke (BAuA, Germany)
14:00	End of conference	



# The EMF Directive 2013/35/EU: A brief Overview of History and possible Future

Laura Vicente

European Commission, Directorate General "Employment, Social Affairs, and Inclusion"

## **Keywords**

EMF Directive, 2004/40/EU, 2013/35/EU, general aspects, non-binding guides, future evolution, revision

## **Topic**

EMF Directive 2013/35/EU, general aspects

## **History and Origins**

Directive 2013/35/EU [1] on the minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields repeals Directive 2004/40/EU [2] and Directives 2008/46/EC [3] and 2012/11/EU [4], amending it.

The action level values and exposure limit values set out in Directive 2004/40/EU [2] were directly derived from the latest ICNIRP recommendations available at that time. However, since the adoption of the directive in April 2004, a lot of concerns were expressed by the stakeholders, in particular the medical sector using the magnetic resonance imaging technique (MRI) as well as certain industrial activities.

At the same time, new scientific studies on the impact on health of exposure to EMF were made public and ICNIRP started a revision of its recommendations.

In this context, the Commission started a process to analyse the situation and adopt a new directive proposal. It launched a study to reconsider the potential impact of the implementation of the Directive on the use of medical procedures based on MRI and certain industrial activities and took into consideration the latest scientific evidence.

The time required to adopt a new Commission proposal and the directive justified two postponement of the deadline for transposition of Directive 2004/40/EC [2] (by Directives 2008/46/EC [3] and 2012/11/EU [4]).

## **Publication and Non-Binding Guides**

Finally, Directive 2013/35/EU (the EMF Directive) [3] was published in June 2013. In terms of the frequency range, the Directive concerns electromagnetic fields from 0 to 300 GHz. It defines exposure limit values (ELVs) and action levels (ALs), based on the Basic Restrictions and Reference Levels of the ICNIRP guidelines from 1998 [5], 2009 [6] and 2010 [7]. The EMF Directive lays down minimum requirements and

Member States are given the licence to set the same requirements or to adopt or maintain stricter ones for the protection of workers.

The Commission has made available three guides [8, 9, 10] to assist employers to carry out an initial assessment of the risks from EMF in their workplaces and decide whether they need to take any further action. There is a guide aimed at employers [8], a second one for SMEs [9], and a third one presenting several case studies [10] that show employers how to approach assessments and illustrate some of the preventive and protective measures that might be selected and implemented.

#### **Possible Future Evolution**

Regarding the possible future evolution of the EMF Directive, the ICNIRP guidelines from 2020 [11] have incorporated a number of additions and changes to the guidelines from 1998 [5], 2009 [6], and 2010 [7]. Moreover, the new EU strategic framework for health and safety at work 2021–2027 [12] acknowledges that the rapid deployment of wireless, mobile and other advanced technologies requires further analysis of workers' exposure to optical radiation and electromagnetic fields.

In this context, the Commission has started to gather scientific advice about the need of a technical revision of annexes of the EMF Directive. As a first step, it has worked together with ICNIRP to analyse the differences and the practical consequences of the changes introduced by the ICNIRP guidelines from 2020 [11]. In addition, in July 2021 the Commission requested an opinion from the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) [13].

The scientific advice, together with the feedback from stakeholders, would guide a possible revision of the annexes of the EMF Directive.

- [1] Parliament and Council of the European Union (2013) "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 L 179, 1–21.
- [2] Parliament and Council of the European Union (2004) "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 L 159, 1–26.
- [3] Parliament and Council of the European Union (2008) "Directive 2008/46/EC of the European Parliament and of the Council of 23 April 2008 amending Directive 2004/40/EC on 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 L 114, 88–89.

- [4] Parliament and Council of the European Union (2012) "Directive 2012/11/EU of the European Parliament and of the Council of 19 April 2012 amending Directive 2004/40/EC on 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 L 110, p. 1–2.
- [5] ICNIRP "Guidelines for limiting Exposure to time-varying electric, magnetic and electromagnetic Fields (up to 300 GHz)", Health Physics 74 (4), pages 494–522, 1998.
- [6] ICNIRP "Guidelines on Limits of Exposure to Static Magnetic Fields", Health Physics 96(4), pages 504–514, 2009.
- [7] ICNIRP "Guidelines on Limits of Exposure to Static Magnetic Fields and Time-Varying Electric And Magnetic Fields (1 Hz–100 kHz)", Health Physics 99(6), pages 818–836, 2010.
- [8] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields – Volume 1 – Practical Guide", 2015.
- [9] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields Volume 2 Case Studies", 2015.
- [10] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields – Volume 3 – Guide for SMEs", 2015.
- [11] ICNIRP "Guidelines on Limits of Exposure to Electromagnetic Fields (100 kHz to 300 GHz)", Health Physics 118(5), pages 483–524, 2020.
- [12] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "EU strategic framework on health and safety at work 2021–2027: Occupational safety and health in a changing world of work", COM/2021/323 final, accessed 24.03.2022 via ec.europa.eu/social/BlobServlet?docld=24122&langId=en.
- [13] SCHEER Request for a scientific Opinion on potential health effects of exposure to electromagnetic fields (EMF), accessed 24.03.2022 via ec.europa.eu/health/latest-updates/scheer-request-scientific-opinion-potential-health-effects-exposure-electromagnetic-fields-emf-2021-07-12 en.

# The EMF Directive 2013/35/EU: Overview of Implementation in Member States

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## Keywords

regulation; MRI; military; sectoral rules; pregnant workers

## **Topic**

EMF Directive 2013/35/EU, implementation

#### Introduction

Directive 2013/35/EU (Electromagnetic fields) (EMF) [1] was implemented in all EU member states by 2016–17 [2]. The Directive sets minimum requirements for exposure limits, risk and exposure assessment, measures for avoiding and reducing risks, worker information and training and health surveillance, but allows member states to apply more stringent or specific rules. The Directive also offers the scope for certain derogations, which are not compulsory but allow member states some flexibility in whether, and how, to apply them. The first of these is the possibility to exceed the exposure limit values (ELV) related to magnetic resonance imaging (MRI), provided certain safety conditions are met. The second is the possibility to allow an equivalent or more specific system for military installations or activities. The third is the possibility to allow the ELV to be temporarily exceeded in specific sectors or for specific activities apart from MRI or the military, provided certain conditions are met [1]. The aim of this presentation is to provide an overview of how member states have used these possibilities for more stringent measures or for derogations in their national implementation of the Directive.

#### Results

With regard to the ELV and action levels (AL) ([1] Article 3), one member state limits the possibility to exceed the sensory effects ELV, while others have reduced or increased the number of AL to simplify or refine exposure assessment. With regard to pregnant workers ([1] Article 4), some member states apply general population exposure limits to pregnant workers in legislation or sectoral rules. For workers younger than 18 years, two member states specify that AL or sensory effects ELV may not be exceeded. With regard to health surveillance ([1] Article 8), at least one member state has specified the circumstances and symptoms that should be taken into account for EMF, but it is possible that other member states have existing, more general rules for health surveillance under other regulatory statutes.

With regard to MRI equipment for patients in the health sector ([1] Article 10(a)), four member states have not applied a conditional derogation from the ELV, or allow a (temporary) derogation only after a specific request to the authorities. All other member states apply the derogation in national legislation, though some have added extra conditions. With regard to personnel working in operational military installations or involved in military activities ([1] Article 10(b)), seven member states do not apply a derogation, six apply the NATO/IEEE standard (STANAG 2345) [3] and the rest allow for an (unspecified) equivalent or more specific protection system as in the text of the Directive. The majority of member states have not implemented the possibility to allow the ELV to be temporarily exceeded in specific sectors or for specific activities. Two member states have applied this possibility to a specific sector (emergency situations in energy supply, police and rescue personnel). Four member states have copied the general possibility for certain sectors or activities, sometimes with additional requirements ([1] Article 10(c)).

## **Conclusion, Outlook**

Although the Directive sets minimum requirements for all member states, the possibility to apply more stringent requirements or make use of the possibilities for derogations has led to some variation in its implementation. It remains an open question how these variations have worked out in occupational practice and if there is room for improvement in a future revision of the Directive or of national legislation.

- [1] Parliament and Council of the European Union (2013) 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 L 179, 1–21.
- [2] EUR-Lex (2017) "National transposition measures communicated by the Member States concerning 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)", accessed 19-10-2021 via eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:32013L0035.
- [3] IEEE C95.1-2345-2014 "IEEE Standard for Military Workplaces—Force Health Protection Regarding Personnel Exposure to Electric, Magnetic, and Electromagnetic Fields, 0 Hz to 300 GHz".

# The EMF Directive 2013/35/EU: Health surveillance of EMF exposed workers

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## Keywords

Electromagnetic fields, occupational exposure, health surveillance

## **Topic**

EMF Directive 2013/35/EU, health surveillance and overexposure

## Health surveillance of EMF exposed workers

Electromagnetic fields (EMFs) exposure is a widely diffused occupational risk factor: the large majority, if not the totality, of workers is exposed to some level of EMFs at work. As for other occupational risks, an appropriate Health Surveillance (HS) of EMFs exposed workers is needed. In the European member states, HS is mandatory according to the Directive 2013/35/EU [1], transposed in the different member countries. According to Article 8 of the Directive: "With the objective of prevention and early diagnosis of any adverse health effects due to exposure to electromagnetic fields, appropriate health surveillance shall be carried". The "adverse health effects" are defined in the Article 2, and include thermal and non-thermal established effect, such as the stimulation of muscles, nerves or sensory organs and limb current, and indirect effects, as interference. Other effects, as e. g. phosphenes and vertigo and other minor transient changes in some brain function (sensory effects) are considered nondetrimental, so are not considered "adverse health effects". The Directive introduces also Exposure Limit Values (ELVs) that are aimed to the prevention of short-term direct biophysical effects. Explicitly, the Directive "does not address suggested long-term effects of exposure to electromagnetic fields, since there is currently no well-established scientific evidence of a causal relationship."

Considering that EMF are virtually ubiquitous in all working environments, a relevant question is who should be included in HS. According to the Non-binding guide to good practice for implementing Directive 2013/35/EU [2], "in the absence of known risks or symptoms from exposures to electromagnetic fields below the ELVs there is no basis for regular medical examinations". In any case, medical examinations or individual health surveillance are needed if:

- exposures exceeding the ELVs are detected (or expected, in case of Derogations, Art. 10 [1])
- undesired or unexpected health effects are reported (Art. 8 [1]).

An aspect needing specific attention is the problem of workers defined "at particular risk", introduced in Art. 4 of the Directive, where is defined in a generic way ("in particular workers who wear active or passive implanted medical devices, such as cardiac pacemakers, workers with medical devices worn on the body, such as insulin pumps, and pregnant workers"). To date, a comprehensive list of all the conditions inducing a particular risk in case of EMF exposure is not defined. The problem is that in these persons the Exposure Limit Values (ELVs) of the Directive 2013/35/UE cannot be considered adequately protective, and e.g. interference problems, especially in some models of implanted medical devices as pacemakers, may occur at lower levels

Regarding the specific content of HS of EMF exposed workers, no international guidelines or authoritative documents are available but at least an adequate collection of anamnestic data, including occupational history, the possible occurrence of conditions inducing particular risk, and/or the occurrence of symptoms possibly related to EMF exposure should be collected; in this context the availability of widely adopted ad hoc questionnaires should be useful. On the other hand, specific laboratory test and/or investigations should be not considered required, in agreement with the Code of Ethics ICOH 2014 [3], at least not routinely, except on individual clinical basis; in workers at particular risk procedures, possibly including investigations, can be considered based on the specific conditions.

An important point provided by Art. 8 [1], but possibly scarcely considered up now, is the need to preserve the results of HS in a suitable form allowing consultation at a later date.

#### **Conclusions**

To conclude, regarding the Health Surveillance of EMF exposed workers:

- to date no general rules/praxis is acquired, so differences probably exists among different Countries
- an initial medical examination should be considered, at least to screen conditions inducing a higher risk, aimed to identify workers at particular risk; in this context it should be considered also that, in practice, the majority of EMF exposed workers is probably included in health surveillance due to other occupational risk; in these cases there is no need to implement an ex-novo HS, and is sufficient to include such a screening within current HS.
- periodical HS: no agreement exists on the need/on groups who should be involved/on procedures; in any case at least an appropriate HS should be provided if indicated by findings from previous examination(s)
- individual health surveillance/medical examinations are needed in case of exposures exceeding the ELVs, or in case of undesired or unexpected health effects occurrence
- fundamental is the role of information and training of workers (Art. 6 of the Directive), especially on the individual conditions possibly inducing a particular risk, and on symptoms possibly related to EMF, enabling the workers to detect and to refer any occurrence to occupational health professionals; information and training of workers should be considered integral part of HS, and is useful in all workers exposed to EMF levels exceeding population level

 insufficiently considered, if not neglected, to date is the importance of the collection and preservation of the results of HS (Art. 8 comma 2 of the Directive), that, if adequately enhanced, can possibly provide a useful source of data to increase/ complete knowledge gaps

- [1] Parliament and Council of the European Union (2013) "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 L 179, 1–21.
- [2] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields Volume 1 Practical Guide", 2015.
- [3] ICOH "Code of Ethics", Editors: KOGI, K. (Chair); COSTA, G.; ROGERS, B.; IAVICOLI, S.; KAWAKAMI, N.; LEHTINEN, S.; NOGUEIRA, C.; RANTANEN, J.; SANTINO, E. and WESTERHOLM, P.; Monteporzio Catone (Italy), 2014.

## Risk Assessment for Workers with Active Implanted Medical Devices

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## **Keywords**

Cardiac Pacemaker, Implantable cardioverter defibrillator, electromagnetic interference

## **Topic**

Workers at particular risk, Risk assessment for workers with pacemakers or ICDs

#### Introduction

Workplace applications can emit electromagnetic fields (EMF) that are significantly higher than those that occur in everyday applications. Therefore, employees must be protected from hazards due to high EMF exposure at workplaces. A main challenge is the assessment of the risk to employees with active and passive medical implants because interference with external electromagnetic fields can lead to mal-function of those devices. In the context of the European EMF-Directive 2013/35/EU workers wearing implants are attributed to the group of workers at particular risk. Their number is constantly increasing since more and more younger people are be-coming reliant on such medical aids.

Pacemakers and ICDs are by far the most common implants. They differ from other types of implants primarily in their sensing function. Based on the sensed and recorded activity of the heart, the intracardiac electrogram (iEGM), they can decide whether a support (therapy) of the heart by pacing or shock delivery is necessary or not. If the iEGM is influenced by low-frequency EMF, there is a reasonable risk that a needed therapy will be inhibited, or an inappropriate therapy will be triggered. Radio frequency EMF, on the other hand, can heat up the implant so that the sur-rounding tissue is damaged. Static magnetic fields can activate a magnetic switch inside the implant and thus put it into a programming mode.

The EU EMF Directive requires an appropriate risk assessment to be carried out for workers at particular risk and preventive measures to be taken where necessary. However, only action levels applicable to static magnetic fields are provided for this purpose. In addition to the German implementation of the EU EMF Directive, the German Occupational Health and Safety Ordinance on Electromagnetic Fields (EMFV) [1], the research report FB 451 [2] was prepared on behalf of the Federal Ministry of Labour and Social Affairs (BMAS) in order to be able to meet the requirements regarding the protection of workers with implants. The results of the report have been included in the

Technical Rules on EMFV (TREMF) [3], so that the TREMF now contain all the information, including appropriate action levels, needed for a risk assessment for workers with active and passive implants.

According to the TREMF the following steps describes an appropriate risk assessment for workers with cardiac implanted electronic devices (CIEDs), i. e. pacemakers and ICDs.

## Stepwise procedure for a risk assessment

It starts with the analysis of the current situation at the workplace. All the EMF relevant sources, i. e. sources emitting electromagnetic fields, must be determined and information on the work activities have to be collected. An important aspect hereby is how close the worker approaches the EMF-sources during work, bearing in mind that the way of working in theory does not always correspond to the way of working in practice.

Tables from the TREMF can be applied to make an initial assessment. These tables provide information on whether or not an adverse influence on a CIED by a specific EMF-source can be ruled out a priori. If the expected exposure by the identified EMF-sources can be classified as safe in this respect, the risk assessment is finished at this point and the results are documented. Otherwise, proceed to the next step or implement preventive or control measures to reduce exposure.

This next step is to determine the actual level of exposure. This can be done

- by measurements,
- by comparison with existing measurement results of identical sources,
- by modelling or calculation
- or by use of external information, e. g. information from the manufacturer (If these were not supplied, ask for them!).

Once the magnetic flux densities or electric field strengths are known they can be compared to the frequency dependent action levels given by the TREMF. If the levels are met the risk assessment is complete with the documentation. However, if the levels are exceeded, it must be decided whether exposure-reducing measures will be implemented or, as a last option, an individual risk assessment will be carried out.

For the latter information about the implanted device is required, most of which can be taken from the medical device ID card, i. e. manufacturer, model, operation mode (DDD¹, VVI², ...), sensing configuration (unipolar or bipolar) and sensing sensitivity.

The major challenge is likely to be the determination of the so-called "induction area". The induction area is the area enclosed by the electrode probe of the implant and can be obtained from an X-ray image of the implant wearer. The induction area is important because, according to the law of induction, the voltage induced in a loop depends on the size of the area it encloses and through which the magnetic field passes. This

<sup>&</sup>lt;sup>1</sup> DDD refers to the operation mode of a cardiac implant: chamber pacing: dual, chamber sensing: dual, response to sensing: dual; with dual referring to atrium and ventricle.

<sup>&</sup>lt;sup>2</sup> VVI refers to the operation mode of a cardiac implant: chamber pacing: ventricle, chamber sensing: ventricle, response to sensing: inhibited.

means that the smaller the induction area, the smaller the induced voltage, and the lower the probability that this induced voltage will cause a CIED to malfunction. Therefore, it makes sense to take this area into account primarily when low-frequency magnetic fields dominate.

Once all these individual factors have been collected, individual permissible action levels can be calculated based on them, which can then be used for comparison with the determined EMF exposure levels. If these individual levels are not complied with, measures must ultimately be established. Otherwise the risk assessment finally ends with the documentation.

#### Preventive and control measures

It is essential to inform employees about the possible effects of electromagnetic fields as part of an annual safety instruction. Only if the possible effects of electro-magnetic fields are known, they can be recognised and reported. Since there is no general obligation for implant wearers to inform their employers, they should be encouraged to do so. Therefore, the employer should highlight the potential risks to employees with any kind of active or passive medical implants from EMFs. After all, only if the employer knows about the situation, he can act appropriately.

Furthermore, in most cases, it has proven most effective to define a safety distance. Warning signs with additional information on the safety distance, can be used to indicate these distances. Often safety distances of a few tens of centimetres are already sufficient, so that this does not pose a problem for a reasonable workflow. Similarly, clear instructions for safe work practices regarding minimising exposure to electromagnetic fields are a simple but effective measure. However, it cannot be excluded that at particular workplaces, e. g. with equipment for resistance welding or induction heating, additional technical measures or a ban on work for workers active or passive medical implants will ultimately have to be applied.

- [1] German Occupational Health and Safety Ordinance on Electromagnetic Fields (EMFV), BGBI. I S. 2531, 15.11.2016 (in German).
- [2] BMAS, "Elektromagnetische Felder am Arbeitsplatz: Sicherheit von Beschäftigten mit aktiven und passiven Körperhilfsmitteln bei Exposition gegenüber elektromagnetischen Feldern", Research Report FB 451 (2015) (in German).
- [3] Technical Rules on EMFV (preliminary drafts), www.baua.de/tremf (in German).

# Risk Assessment for pregnant Workers and Workers with Passive Implanted Medical Devices

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## Keywords

pregnant workers, indirect effects, metallic implants, implant heating

## **Topic**

Workers at particular risk (assessing passive implants & pregnant workers)

## Introduction and Background

The European EMF-Directive 2013/35/EU, together with its helpful Non-Binding Guide [1], calls for an assessment of any effects on the health and safety of workers at particular risk, who (amongst others) consist of workers wearing passive implanted medical devices (PIMD) and pregnant workers. Special attention on the latter group is backed by the Pregnant Workers Directive 92/85/EEC where attention to all possible effect on pregnancies due to non-ionising radiation such as EMF is demanded. Those demands have not been substantiated by specific limit values on a European level, although some aspects may be more specifically regulated in some member states.

Still, recommendations such as those of ICNIRP [2, 3, and 4] provide a rationale on the applicability of limit values. Due to the need for protection of the fetus, pregnant women, even if they would be exposed to EMF on a workplace, are recommended to be treated as members of the general public. On the other hand, ICNIRP's guidelines unfortunately exclude – and are thus silent on – persons with PIMD. The latter group is defined as those wearing passive devices containing metal such as artificial joints, pins, plates, screws, surgical & aneurism clips, stents, metallic contraceptive implants, etc. and quite apparently may today be a significant fraction of the workforce. Generally, one should also add all other metallic objects within or in contact with the body to the category of PIMD, even if they are not an implant in a medical sense (e. g. shrapnel, body piercings, non-removable jewellery), because the interaction with EMF is in principle comparable. Literature on specific exposure situations is scarce, only a few recommendations exists [1, 5, and 6].

The contribution thus will focus on the assessment of PIMDs and will also give some information on the assessment of EMF exposure of pregnant workers.

## **Approaches to risk assessment for PIMDs**

In time varying fields, metallic implants perturb the induced electric field within the body due to their much larger electrical conductivity (as compared to tissue) and their possible non-zero magnetic susceptibility. This may lead to localised regions of strong fields within the tissue. In addition, metallic implants themselves are inductively heated – in fact, much better than tissue – and implant warming may not be excluded in some frequency regimes. However, at very high frequencies, such as the UHF or SHF regime, the penetration depth is so shallow that typical PIMDs may not be reached within the tissue, and themselves rather reflect EMF instead of being susceptible to warming. The latter 'RF-like' effects are well understood and satisfactorily covered by literature.

Interaction with low to intermediate frequency magnetic fields is less understood. Both enhanced induction of internal electric fields and tissue warming may occur. Where PIMDs are made from ferromagnetic materials, they may also experience torques and forces in the presence of strong, (quasi-)static magnetic fields. An implant's movement within the tissue or a gradually loosing may not be excluded in a workplace assessment.

Recommendations for limit values over the whole EMF frequency range of 0 Hz to 300 GHz are rare. The German research report FB 451 [5] provides 'threshold' values for PIMDs based on a year-long practice. The Non-Binding Guide [1] suggests the application of the reference levels of the Council Recommendation (CR) 1999/519/EC. Recent work [6] reviewed this topic for a set of abundant PIMDs and for frequencies below 10 MHz. Together with experimental validation of thermal effects, the focus was on numerical simulation of the increasingly induced electrical field due to PIMDs. The latter was found to be the dominant adverse health effect and led to reduction factors for exposure (such to ensure the compliance with exposure limit values in the tissue). For frequencies above some 150 kHz, proposed reduced action levels smoothly connect to the reference levels of the CR 1999/519/EC and are thus somewhat lower as those suggested by the report FB 451.

## Approaches to pregnancy risk assessment

Recommendations like those issued by ICNIRP account for pregnancy by demanding the application of limit values for general public in order to protect the fetus. Similar provision is suggested by contributions focussing on EMF exposure on (pregnant) women at the workplace [7]. Thus, limiting exposure of pregnant workers by the reference levels for the general public, with the possible exception for extremities such as forearm and legs, seems to be a straightforward solution.

Nevertheless, it must be noted that limit values for EMF usually account for direct effects in the tissue only, while other hazards and risks, such as, for example, projectile risk and magnetic forces near strong static magnetic fields, in part need to be covered by a set of larger measures identified by an assessment. In addition, literature on female MRI workers has deemed effects on pregnancy caused by the thereby present static magnetic fields unlikely, but could not yet completely rule effects out. Hence, at such particular workplaces some care is still needed and the exemption of pregnant workers from an MRI environment is not uncommon.

#### Outlook

More research on the interaction of EMF and PIMD is needed, in particular near the frequencies of full body resonances as well as for extremely low frequency magnetic fields and ferromagnetic objects, where mechanical forces may be non-negligible.

In case of pregnancy and significant EMF exposure, ongoing monitoring for possible health effects on pregnant workers and their offspring is generally recommended. Specifying explicit limit values for direct effects on pregnant workers will facilitate the assessment. Such limit values (e. g. those of the CR 1999/519/EC) have already been put in place in some EU member states.

- [1] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields Volume 1 Practical Guide", 2015.
- [2] ICNIRP "Guidelines on Limits of Exposure to Static Magnetic Fields", Health Physics 96(4), pages 504–514, 2009.
- [3] ICNIRP "Guidelines on Limits of Exposure to Static Magnetic Fields and Time-Varying Electric And Magnetic Fields (1 Hz–100 kHz)", Health Physics 99(6), pages 818–836, 2010.
- [4] ICNIRP "Guidelines on Limits of Exposure to Electromagnetic Fields (100 kHz to 300 GHz)", Health Physics 118(5), pages 483–524, 2020.
- [5] BMAS, "Elektromagnetische Felder am Arbeitsplatz: Sicherheit von Beschäftigten mit aktiven und passiven Körperhilfsmitteln bei Exposition gegenüber elektromagnetischen Feldern", Research Report FB 451 (2015) (in German).
- [6] HIRTL, R.; SCHIESSL, K.; ÜBERBACHER, R.; JHALA, T. and SCHMID, G. "Evaluation of in situ electric fields and tissue warming in proximity to metallic implants for low to intermediate frequency magnetic field exposure at workplace", Extended Abstract and Poster at BioEM 2019; AUVA project report R78 (www.auva.at).
- [7] SCHMID, G. and TROGER, C. "Vorprojekt: Exposition von Schwangeren gegenüber elektromagnetischen Feldern am Arbeitsplatz", Sicheren Arbeit No. 4 (2013).

## Numerical dosimetry and measurement

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## Keywords

EMF, measurement, modelling, procedures, compliance

## **Topic**

EMF exposure assessment in special situations

#### Introduction

It is now 8 years since the publication of the EMF Directive 2013/35/EU and 5 years since it was transposed into UK legislation, in the form of the Control of Electromagnetic Fields at Work Regulations. Over this period, we at EMFcomp have assessed hundreds of exposure situations for compliance with the Action Levels and Exposure Limit Values, using measurement and modelling methods.

In this study, we attempt to present what we have learnt over this period, with respect particularly to appropriate equipment and methodologies to be employed when assessing electromagnetic fields, and what to do regarding averaging of non-uniform fields, near field vs far field considerations and dealing with multiple field sources.

We will present case studies, based on real assessments, to demonstrate challenges encountered during the assessment process and how these can be overcome, both when measuring and modelling electromagnetic field exposure.

## **Appropriate Assessment Methods**

To measure, quality equipment is required to accurately assess an exposure situation. Probes need to be regularly maintained and calibrated. Additionally, an assessor requires an appropriate range of measurement equipment capable of measuring the static fields, low frequency magnetic, low frequency electric, and radiofrequency fields likely to be encountered when surveying a facility in the industrial sector.

To model, not only are the correct numerical methods required to accurately simulate the interaction between the incident field and the body (e. g., scalar potential finite difference (SPFD) method for low frequencies and finite difference time domain (FDTD) at radiofrequencies), but also anatomically heterogeneous, anatomically realistic human models (phantoms) of adult males and females along with a high-performance computer cluster or workstations.

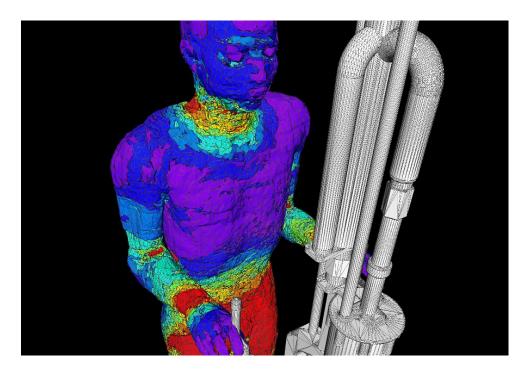


Fig. 1 Spatial distribution of induced electric fields (red-high, blue-low) from spot welding gun exposure.

#### **Correct Assessment Procedures**

An assessor should follow the available guidance in the public domain when either modelling or measuring. In terms of measurement assessments, there are three volumes of good advice in the EMF Directive Practical Guide, produced by the UK's Public Health England and EMFcomp for the European Commission [1].

For computations, there are good European Standards such as 62704-1 'Determining the peak spatial-average specific absorption rate (SAR) in the human body from wireless communications devices, 30 MHz to 6 GHz' [2].

## **Assessment Challenges**

Case studies will be presented for exposure situations where there are significant challenges in exposure assessment. These include automotive spot welding and stud welding, non-destruction inspection methods such as magnetic particle inspection (MPI), plastic (RF) welding, body-worn antennas, demagnetisers and transcranial magnetic stimulation.

## **Summary**

Assessing certain exposure situations can be challenging, but tools have been developed over the last two decades to allow the assessor to examine compliance with the Action Levels or Exposure Limit Values accurately, resulting in competent and proportional EMF assessments.

- [1] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields Volume 1 Practical Guide", 2015.
- [2] IEC/IEEE 62704-1 "Determining the peak spatial-average specific absorption rate (SAR)", 2017.

# Supporting employers to perform EMF exposure assessment: solutions provided by the INRS

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## Keywords

employers, assistance, information, implants

## **Topic**

EMF exposure assessment in special situations

#### Introduction

INRS is a non-profit organization funded by the National Fund for the Prevention of Occupational Accidents and Diseases. Its nearly 600 staff members work in two centres, one in Paris and the other one in Nancy (Lorraine). The mission of the INRS is to contribute to the prevention of occupational accidents and diseases for the 2.2 million companies falling under the general social security scheme and their 18.4 million employees. The Institute offers a wide range of actions in order to identify occupational risks, analyse their impact on health and safety at work and provide solutions. It carries out assistance, conducts studies and research, offers training and provides information.

Regarding the EMF risk assessment, the INRS provides the following services to help companies to comply with the European Directive 2013/35/EU [1], which was transposed in French law in 2017.

#### Information

Companies and occupational safety and health professionals use the INRS productions as a framework and practical support for preventing occupational risks. The INRS offers a wide range of supports available on the website to fulfil the company needs: leaflets, posters, periodicals and multimedia products.

General and relevant information about electromagnetic risk assessment is available on the dedicated page on the INRS website. For more details or specific information, the reader can download or order informative leaflets on various topics:

- General information on EMF physics up to 300 GHz,
- EMF regulation at workplace,
- EMF effects on the human body,
- Principal industrial sources of EMF,

- Pregnancy and EMF exposure,
- AIMD and EMF exposure,
- etc.

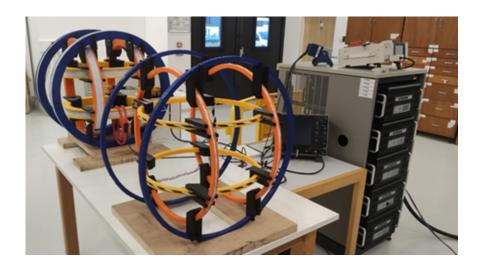
#### **Assistance**

Assistance is an important part of the INRS activity. Requests from companies concern different domains of expertise: medical, technical or legal. The Institute receives more than 10,000 requests each year via its hotline or website. Regarding to the EMF risk exposure, depending on the complexity of the request, the hotline service either answers by sending documentation or transfers the request to an INRS expert.

A web application named OSERAY was developed in order to help companies to fulfil their mandatory EMF risk exposure assessment. It is based on the European Non-binding guide to good practice [2] for implementing the EMF-Directive. OSERAY includes a list of frequently encountered equipments and activities. The user selects the exposure situations to which the employees of his company are potentially exposed. Then he can launch the work situation analysis, which displays for each selected equipment the necessary actions depending on the worker group. There are indeed three categories of workers in the application. Workers with no specific risks, workers with specific risks like pregnancy or wearing passive implants, and workers wearing active implants. For critical cases where exposure limit values could be exceeded, measurements are required. The INRS or one of the 9 "regional technical centres" distributed over the territory are able to perform these on-site measurements.

#### Studies and research

INRS Studies and Research generate new knowledge, methods and tools to prevent occupational accidents and diseases. In 2016, INRS built a new laboratory dedicated to EMF researches. Currently, researches are conducted on two main topics: i) EMF compatibility of Active Implantable Medical Devices (AIMD) and ii) modelling of induced current (dosimetry) in a human body exposed to low frequency magnetic fields.



**Fig. 1** Test bench dedicated to the study of EMF compatibility of AIMDs.

## **Training**

INRS offers a large variety of occupational health and safety training courses. These courses are intended to develop, implement and promote training schemes with a view to making occupational health and safety a professional skill for all company stakeholders. The INRS offers two kinds of training courses dedicated to EMF exposure; the first one is addressed to occupational physicians, the second to preventers.

- [1] Parliament and Council of the European Union (2013) "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 L 179, 1–21.
- [2] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields Volume 1 Practical Guide", 2015.

# The EMF Directive 2013/35/EU: What needs to be done and the Way forward

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## Keywords

acute/short term/long term effects, near field zone, overexposure, multifrequency exposure, averaging time, competence of the specialists, measurement protocols/ measuring equipment

## **Topic**

EMF Directive 2013/35/EU, EMF exposure assessment in special situations

Please note: The full text manuscript can be accessed via the conference website at www.baua.de/eemff.

#### Introduction

There are several problems with the practical use of the Directive 2013/35/EC. Some of them were addressed for the RF frequency region by the ICNIRP 2020 publication on radiofrequency (RF) fields, but many others interfere with the real practice in the working environment. Some of the main questions are discussed below.

## Long term exposure

The EMF Directive does not address long-term effects of exposure to EMFs, since there is currently no well-established scientific evidence of a causal relationship. Many questions arise concerning the type of exposure that continues for months and years, what constitutes dose for EMF, how to evaluate the risk arising by such effect.

There are several publications in peer review journals that discuss low level of exposure and long-term effects on biological tissues. At this time, there is not enough evidence for discussing cancer as a result of EMF exposure, although IARC has classified both exposure to low frequency magnetic field as well as to radiofrequency field as a class IIB, possibly carcinogenic to human. In few countries, the 0.4  $\mu$ T (50 Hz) is a limit when some additional measures are taken as a precautionary measure for the general public. It is a time may be to raise the question: Should cancer be discussed regarding long-term exposure evaluation?

It is, also not clear how the human body reacts to intermittent exposure – high levels of EMF in minutes/seconds, termination of the emission and repetition of cycles.

#### Near field zone

The question of where is "the boundary" between the near- and far-field zones is still open. In the both ICNIRP 2020 and EU Directive, it is accepted to be 6 GHz. But the human exposure standard developed by IEEE (IEEE C.95) proposes this boundary to be at 10 GHz (3 cm wavelength), not at 6 GHz (5 cm). Which of them is more convenient to be used in standards? In the near-field zone, both electric and magnetic field strengths should be measured.

Competence of the specialists performing measurement and exposure assessment.

EU Directive discusses the need of specialists with a knowledge of field measurements and exposure assessment. This is very important because most of the engineers do not have enough knowledge in physics, especially electrodynamics. The competence of the personnel performing assessment and measurement is of utmost importance for the reliability of the results.

To assess the occupational EMF exposure, it is necessary to systematize the criteria for performing measurements, summarizing the methods for measuring EMF, which field parameters should be assessed, to set requirements concerning measuring equipment, and the competence of the personnel performing exposure assessment. A practical guide combining all these issues will serve occupational health services, industrial engineers and other professionals to apply protocols specifically designed to assess EMF exposures in a specific work environment. The uncertainty in EMF measurement at the workplace can be more than 100 % in cases where the competence of the specialists performing measurements is not high enough. There is a need of special requirements for the basic knowledge and training and education for such specialists.

#### Conclusion

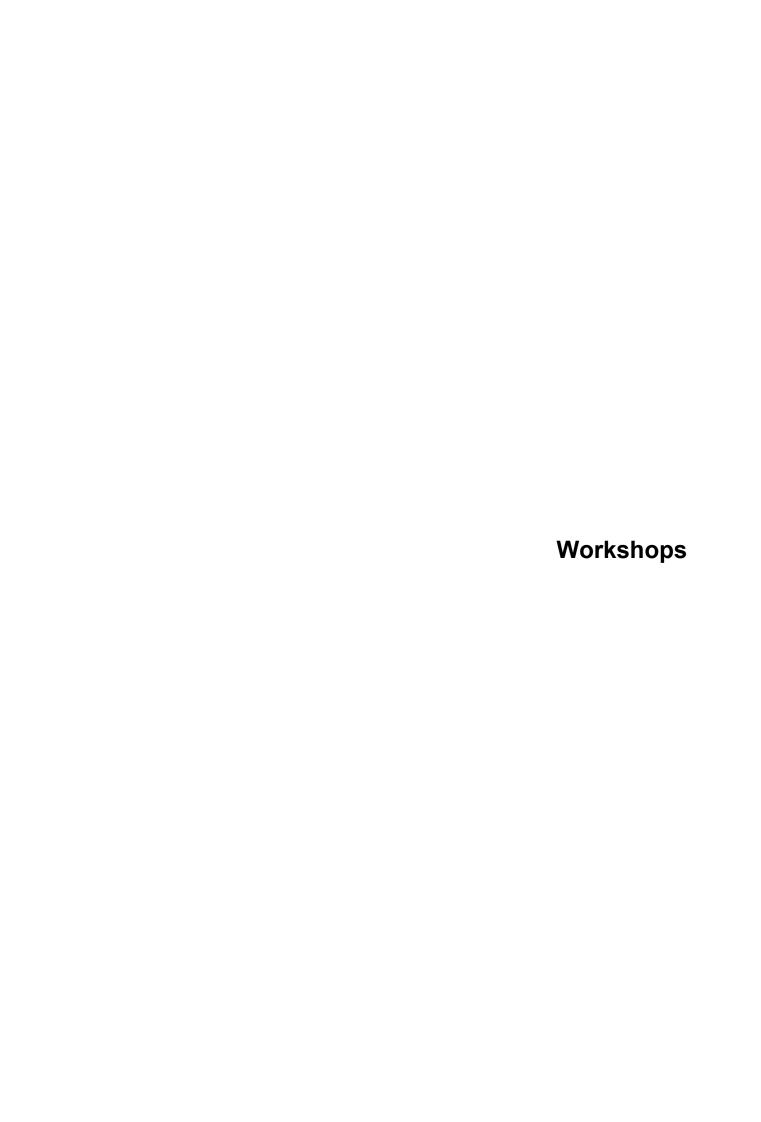
The Directive 2013/35/EU ensuring the minimum health and safety requirements for the workers EMF exposure has been in force over 8 years. The distance of time and the practice we had with the implementation of this document gave us the opportunity to raise some issues that need to be improved.

A review of the new scientific literature made in order to find if there are enough evidence to accept biological criteria in human exposure standards other non-thermal effects or electrostimulation.

There should be discussion of the averaging time/method specially for intermittent emission.

Competence of the specialists performing measurement and exposure assessment is of utmost importance for the reliability of the results.

The obligation of the science is to improve the document to achieve dignified protection for all workers exposed to electromagnetic fields by implementation of all new evidences in the field of risk assessment.



## **Evolving EMF Directive 2013/35/EU**

Rapporteur: Rianne Stam

The discussions in this workshop revolved around four topics:

- 1. Developments in LF limits (Annex II 'non-thermal effects'): ambiguities 0–1 Hz, developments 1–100 kHz
- 2. Developments in RF limits (Annex III 'thermal effects'): ICNIRP 2020, adjustments, new limits brief local exposure
- 3. Developments in derogations, national experiences
- 4. Developments in articles about workers at particular risk, health surveillance

## **Breakout Session 1: Exposure Limits for low Frequency EMF**

With regard to developments in low frequency limits ('non-thermal effects') in Annex II of the Directive, it was suggested that it should be made clearer that the exposure limit values (ELV) in Table A1 ('ELVs for external magnetic flux density (B<sub>0</sub>) from 0 to 1 Hz') are only to be applied to static magnetic fields (0 Hz), since applying them at a frequency of 1 Hz would lead to an internal electric field strength several times the ELV. Instead, for frequencies between 0 and 1 Hz the ICNIRP 2014 reference levels (dB/dt) and basic restrictions (E<sub>int</sub>) could be used as action levels (AL) and ELV respectively (presentation by Dr. Cristian Goiceanu). More generally speaking, it would be helpful if a future revision of the Annexes of the Directive would not just look at the new ICNIRP 2020 radiofrequency limits, but also at the appropriateness of the low frequency limits in the Directive in the context of the work of the ICNIRP Project Group on low frequency guidelines. It would also be useful if the technical annexes of the Directive would be more clearly linked with, and provide explanation for, the scattered elements in the main text (articles) to which they are related.

## **Breakout Session 2: Exposure Limits for Radio-Frequency EMF**

With regard to developments in radiofrequency limits in Annex III of the Directive, the longer averaging time for whole body exposure (30 min) raises questions on accuracy. The averaging periods for whole body and local exposure might be better expressed with the same accuracy (0.5 and 0.1 hour). Similarly, reference levels are sometimes expressed with three or four figure accuracy. In view of measurement uncertainties, it would be better to consistently express them with less (e.g. two figure) accuracy. How to relate the averaging time to duty cycle is also an issue that needs clarification (moving averages?). The magnetic field reference levels from 100 kHz to 30 MHz have become less strict due to new dosimetric insights, leading to a shift in the constant part of the frequency dependence from 10 to 30 MHz. This may create practical problems in exposure assessment, since older instruments refer to the previous frequency dependency. Some participants suggested that a conservative approach would be to retain the old ICNIRP reference levels for frequencies between 100 kHz and 30 MHz. ICNIRP 2020 also removed some limits that were not deemed relevant for health (microwave hearing) or of limited practical use (contact current). It was suggested that the limits for microwave hearing might be retained in the Directive, although doubts were expressed if there were any relevant sources in the workplace. Some national monitoring of this would be useful.

## **Breakout Session 3: Derogations and national Experiences**

With regard to obligations for employers, it was remarked that the unspecified definition of 'appropriate' delimitation and access measures in the action plan, such as markings and access barriers, give the employer quite some freedom depending on how the local enterprise assessment was conducted. Member states often do not have EMF-specific measures for workers younger than 18 years. Some participants thought that the scientific basic for special treatment of young workers was small for age-specific anatomical vulnerabilities. Smaller body size is a factor, but this is not only related to age. A more important mediator of increased risk, and motivation for stricter measures, could be reduced experience, understanding or trustworthiness. With regard to health surveillance, in vivo studies are still lacking and there are currently no generally agreed examination guidelines. Although occupational physicians have the freedom of the medical profession, the employers would find such guidelines helpful. Health surveillance may also be important in the case of the higher exposures allowed for limbs and for the potential exposures above the limits in working environments falling under one of the derogations, where they might be overlooked.

## Breakout Session 4: Articles about Workers at Particular Risk, Health Surveillance

With regard to derogations, the authorities in one country had received an application for the ELV to be temporarily exceeded in duly justified circumstances for transcranial magnetic stimulation. Participants responded that a derogation for this application had not been granted in other countries, since exceeding the ELV could be adequately prevented with other measures (e. g. coil fixed to a stand, keeping distance). Better information and instruction of the relevant workers is needed to create more awareness of this.

## New and complex sources, future of occupational EMF research

Rapporteur: Carsten Alteköster

The aim of Workshop 2 "New and complex sources, future of occupational research" was to discuss the challenges of assessing exposure to electromagnetic fields from complex sources. In the context of this workshop, the term "complex source" primarily referred to sources emitting non-sinusoidal electromagnetic fields. The difficulty in assessing such fields is that a simple comparison with the action levels of the EMF Directive 2013/35/EU is not sufficient, as the action levels were derived on the basis of exposure to homogeneous sinusoidal fields. Of particular interest were not only such sources that are already frequently found in workplaces today, but also those that could possibly gain relevance in the future.

Three breakout sessions were initiated to approach the topic:

- 1. Types of complex sources
- 2. Measuring complex EMF
- 3. Assessment of complex EMF exposure

## **Breakout Session 1: Types of complex sources**

This breakout session dealt with the different types of complex sources. Well-known are systems for resistance welding or induction heating, which are frequently encountered. However, the participants also mentioned frequency converters and generally systems that produce short pulses with high intensity. The difficulty here is that not only the non-sinusoidal field pattern has to be considered, but the peak value of the field that is generated has to be limited. Another problem that was seen is that incorrect installation or poor maintenance makes the exposure situation even more complex. For example, the use of unshielded cables or the problem of insufficient earthing on plastic welding machines were mentioned.

One way to approach the assessment of emissions from complex sources is to use the relevant manufacturer information. However, the participants reported that it is often very difficult to obtain information at all, even on request, or that it is not provided at all. Here it would be desirable to find ways to raise awareness by manufacturers to the problem of exposure to electromagnetic fields and to encourage them to provide useful documentation for the operator.

Finally, the topic of 5G was also addressed. The participants saw this as the topic that will be most relevant in the near future with regard to exposure from complex sources. The difficulty with this topic is still seen in the description of a standardised measurement procedure, which also describes how beamforming is to be taken into account correctly. In general, the need for documentation on how to assess exposure from 5G was considered high.

## **Breakout Session 2: Measuring complex EMF**

The discussion about measurement focussed on two facets: procedures and equipment.

To choose appropriate measurement procedures and equipment, the properties of the EMF-source under assessment need to be considered regarding its size, field generation (coil, dipole, capacitator, line, ...), field characteristics (duty cycles, pulsation and power alternation, slope of signal, expected magnitude, ...) as well as exposure properties like working positions, exposure duration, distance to EMF-source (near field/ far field), protective equipment.

Regarding potential measurement procedures it was quickly agreed upon the necessity to record the signal with an oscilloscope to check the waveform and to validate the assessment of measurement devices. However, information about the actual field strength cannot be obtained by using an oscilloscope only. Measurement devices field are required to provide scaling factors, such as current or field strength values.

Depending on the recorded signal (waveform, slope, frequency components ...) appropriate frequency selective measurement equipment is chosen; if not, non-selective broadband devices are used to collect information. The following considerations were discussed to guide the selection process of appropriate measurement devices:

- dynamic range, sensitivity, overload, sampling rate
- RC constant of measuring device relates to averaging time
- lower sensitivity means good signal-noise-ratio but lower overload
- isotropic field probes may not be isotropic in 360° in all dimensions due to differing spatial centres
- anisotropic measurement for locating maximum field strength and information about polarisation of wave

## **Breakout Session 3: Assessment of complex EMF exposure**

Breakout session number three dealt with the assessment of complex EMF exposure. For the assessment of non-sinusoidal EMF, the European EMF Directive 2013/35/EU specifies the Weighted Peak Method (WPM) as the reference method. Participants stated that they, for example, use the WPM to assess EMF of welding machines in the automotive industry. Some use self-implemented versions of the WPM. It was reported that comparisons between different implementations showed slightly different results depending on the parameters used in the implementation. It was discussed if there is a need for a more specific definition of the WPM or for a reference implementation to achieve uniform results. Furthermore, it was reported that the WPM is typically used up to 400 kHz. Apart from assessing magnetic fields, the WPM has also been used to assess current measurements. Assessing electric fields with the WPM methodology might be difficult due to the strongly frequency dependent permittivity. None of the participants used other methods than the WPM to assess non-sinusoidal EMF.

# The Role of Standardisation to enhance the Implementation of the EMF-Directive 2013/35/EU

Rapporteur: Benjamin Vatovez

This workshop focuses on how ongoing and possible future standardisation could contribute to enhance the implementation of the Directive 2013/35/EU [1]. Its main objective is to lead an open discussion on what standardisation efforts could contribute to meet the needs of public and private organizations involved in the EMF exposure assessment on the workplace. The normative needs could be specific to certain sources and industries.

In order to optimise the discussions, the workshop is divided into three topics:

- How to implement "reasonably foreseeable use"?
- Use of harmonised standards and non-harmonised standards
- Are new standards needed in order to achieve the goals?

## Breakout session 1: How to implement "reasonably foreseeable use"?

As described in the CENELEC document "Basic elements for a common understanding of use conditions in standards intended purpose (edition 2021)" [2], "intended use" assumes that the product is properly stored, installed, maintained and used for its intended purpose. It includes only those uses for which the product is designed. "Other expected use" refers to additional use that cannot be regarded as misuse.

Certain Directives and regulations, like the Radio Equipment Directive (2014, RED) [3] use the term "reasonably foreseeable use" or a similar expression, which always includes intended use and the other expected uses, and sometimes, but not always the reasonably foreseeable misuse (use of a product which is not in accordance with the information for use provided by the manufacturer, but which could be known or anticipated). Other misuse (abuse) refers to an intentional misuse of the product and does not need to be taken into account by standardizers and manufacturers.

Amongst the panel of attendees, one of the risen questions was about the practical meaning of the term foreseeable use. How to implement it? Should it be assessed case by case, according to the exposure scenario or to the source? What are the foreseeable uses for workers at particular risks such as cardiac devices carriers?

Directives and product regulations implementation certainly benefits from clear definition and description of what a foreseeable use and misuse refers to.

An example is given by security gates because the exposure levels can be greater than the reference levels in the vicinity of these products, so that "foreseeable use/misuse" can be a critical topic which needs to be discussed.

Another asked question was how to properly assess the exposure from 5G equipment in the workplace. The EN62232 standard [4] explains how to assess exposure levels in the vicinity of antennas, however not specifically for occupational exposure from

indoor sources or other specific 5G equipment in the workplace. 5G products have to be tested under worst exposure conditions such as maximal radiated power, because the European Commission does not provide standards using statistical methods, although this equipment amongst others can generate EMF which strength substantially varies in time. Another topic to discuss is how the standards address the dosimetry related to foreseeable use: should we always assess the exposure at a distance of 5 mm between the source and the body or should we consider shorter distances for the dosimetry?

#### Breakout session 2: Use of harmonised standards and nonharmonised standards

This working session consists of sharing experience in the use of harmonised and non-harmonised standards.

A harmonised standard is a technical document that states how to comply with a European directive. These documents are created by recognised European Standards Organisations (CEN, CENELEC, or ETSI) and included in the Official Journal by the European Commission. Harmonised standards provide a presumption of conformity for products on the market, which means that products which fulfil the requirements stated in the standard automatically conform to the European Directive.

Non-harmonised standards are not included in the Official Journal and do not automatically comply with the essential requirements of a directive but still can be used to comply with directives.

The attendees shared their experience in the military as well as in companies.

Although the EMF Directive [1] grants derogations for the military, the measurement of exposure levels and a risk analysis must be carried out in certain situations, for which a significant number of harmonized standards and non-harmonized standards could exist. In particular, regulation for manufacturers often provides standards for one product at a time, while EMF Directive [1] and product standards are separate. For this reason, smaller organisations may find it difficult to implement the existing regulation correctly, the EMF Directive being no exception. For these organizations, guidelines definitely are useful.

The discussion eventually focused on the Optical Radiation (OR) Directive [5]. EMF Directive, ICNIRP guidelines [6] and technical standards related to optical radiation (e. g. laser safety [7]) are more recent than the OR Directive [5]. The OR limit values at 300 GHz, the frequency-domain boundary with radiofrequency radiation, need to be consistent with the EMF Directive. The optical industry could benefit from a coordination effort within the various dedicated standards.

#### Breakout session 3: Which standards are needed?

This breakout session is dedicated to the specific needs and opportunities for developing new standards for the workplace.

In general, a first debatable question is whether it is appropriate to establish new standards or whether updating an existing standard is not preferable.

The attendees of the session highlighted some areas where needs were identified, such as:

- working conditions in the vicinity of radar installations and measurements of exposure levels in the vicinity of such installations,
- developing/updating standards for applications in the band around 27 MHz,
- risk assessment of emerging implants.

The discussion finally focused on the constraints of establishing new standards in view of the cost and time required, noting that a limited number of experts have to be shared between the working groups of official standardisation bodies such as IEC, IEEE and CENELEC and ETSI.

#### References

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#### Workers at particular risk

Rapporteur: Klaus Schiessl

The workshop started with an introduction summing up the most prominent groups of workers at particular risk. Three of those groups have previously been introduced in the keynote contributions, first by Carsten Alteköster, on persons with active implanted medical devices (AIMD) and, in a second contribution on passive implants (PIMD) and pregnant workers, by Klaus Schiessl. A quick poll showed that the majority (2 out of 3) of the workshop participants was having a background in engineering, and about a third was having with a background in medicine, biology, or similar.

In order to best trigger detailed discussions in subgroups, four breakout sessions were implemented to tackle the following questions:

- 1. Which limits may ideally apply today to pregnant workers?
- 2. What regulations and experience with passive implants are there specifically for each European member state (if any)?
- 3. How to assess and make final decisions for the workplace persons with active implants such as pacemakers?
- 4. Concerning health surveillance & workers at particular risk: what kind of medical examinations need to be performed to quantify the particular risk?

Implementation status with respect to those topics and opinions collected in those breakout sessions may be summarised as follows:

- As the EMF-Directive does not specify by which rules workplaces for pregnant workers must be assessed, member states implementation differs considerably. In some countries, specific limit values are not available in the moment. In other countries, e. g. Austria, general population limits of the Council Recommendation are enforced for pregnant workers, which would also apply to MRI workers and thus prevent assignment of pregnant workers near MRI devices. Literature such as the ICNIRP guidelines clearly state that goal of protection is the fetus that must be considered as a person of the general public. Dosimetry shows that the application of the action levels of the Directive is thus not sufficient.
  - On the other hand, localised exposure of limbs exceeding the general public provision seems possible as long as the fetus is still sufficiently protected. However, corresponding exposure situations would be quite rare, and maybe encompass hand scanners in wireless article detection or similar EMF sources localised within the hand only.
- For passive implants, specifications (apart from scientific literature and some general recommendation in the Non-Binding Guide (NBG) to use the Council Recommendation) are rare within the European member states. Some national guidelines suggest, for practical reasons, a minimum size of a passive implant that leads 'automatically' to a positive assessment if not exceeded.
- Active implanted medical devices comprise a larger number of devices, from Cochlea implants, neurostimulators to pacemakers, the latter being the most critical class of devices. It seems quite clear and common in the member states that an occupational physician or occupational health practitioner need to take the final

decision for an assignment of workers with AIMD at an exposed workplace. Relevant workplaces are well known and listed in various publications such as the NBG. Among upcoming, soon highly abundant sources of possibly relevant EMF-fields, charging of electric cars (both wireless and rapid-charge technologies) has been identified.

 Health surveillance (HS) and, if necessary, provision of medical examination is needed under the regulative of article 8 of the Directive, i. e. for workers at particular risk. In contrast to HS for unwanted symptoms and possible overexposure, relevant topics for particular risks due to implants (as well as due to impaired thermoregulation) are largely straightforward. Information given to affected workers should focus on electromagnetic interference (EMI) of AIMD and enhanced interaction with EMF in the tissue in the vicinity of PIMD. Possible medical examinations should be performed accordingly.

Nevertheless, specific guidelines for the occupational physician are still lacking and it was largely agreed on that enterprises and employers would find such guidelines beneficial.

Also lacking is a good overview over number and type EMF-related incidents with implants on the workplace. Transparent reporting of such health incidents in a database, of course with respect to data privacy, would be beneficial as well.

However, HS also aims for the detection of previously too little-known effects and their symptoms – both below and above the exposure limits (which might be exceed in case of a derogation). It seemed to be critical to distinguish unspecific symptoms from idiopathic environmental intolerance attributed to electromagnetic fields (IEI-EMF). Such symptoms and fears in relation to EMF exposure should be properly addressed with accessible and neutral information.

Finally, provision for young workers have been discussed. In part, no specific measures exist here, too but. Not considering children, there is also no scientific basis for a particular EMF-related risk of young adults, that would only connected to age. It was acknowledged that EMF-related risk may be related primarily to body size, and also to some extend to development of tissue etc. On the other hand, it was also acknowledged that provisions for young workers are commonly set due to their status as e. g. being in training and not yet being as trustworthy to follow strict rules near dangerous EMF-sources as a fully trained, skilled worker of adult age would be.

#### Best practice in exposure assessment

Rapporteur: Kjell Hansson Mild; Mihaela Ivanova; Tsvetelina Shalamanova

The workshop on exposure assessment had two breakout sessions.

In the first we posed two questions:

- 1. How to provide a competent external service for enterprises obliged to manage electromagnetic hazards?
  - minimal requirements for competence
  - how the problem is solved at national level
  - how to access the competence accreditation
- 2. How far the experience form the laboratory EMF measurements may be applicable for the in-situ measurements aimed at workers exposure evaluation?
  - simplifying measurement procedure in real work environment limitations
  - measurement conditions
  - measurement protocol

The second session contain these questions:

- 3. What rules of managing the measurement uncertainty may be acceptable when evaluating the safety of workers exposed to EMF?
  - shared uncertainty
  - added uncertainty or combination of approaches
  - uncertainty in the case of time and spatial averaging
- 4. How to manage differences between "the reasonably foreseeable use" versus "the worst case exposure" of workers in the assessment procedures?
  - "worst case exposure" in practice
  - Spatial and time averaging and the "worst case exposure"
  - Including the time duration of exposure in exposure assessment

To start the discussion Dr. Jolanta Karpowicz, Central Institute for Occupational Protection (CIOP), Warsaw, Poland, introduced the workshop and gave her view on the posed questions.

#### **Breakout session 1: Competence and Experience**

The basic opinions of the participants in the discussion in breakout group 1 regarding "How to provide a competent external services for enterprises obliged to manage electromagnetic hazards?" are that companies has no additional requirements to hire external competent personnel to assess electromagnetic hazards. The personnel with basic education in physics or engineering has not enough knowledge and practice to make adequate measurements and exposure assessment. Even in the case of additional training, the specialist does not dare to make decisions due to the lack of specific practice. Requirements of the Directive for accreditation of laboratories for performing EMF measurements is not proof for granting competence. As a general breakout group 1 concluded that there is a need of international requirements for competence including experience in occupational EMF exposure assessment.

Regarding the second question "How far the experience form the laboratory EMF measurements may be applicable for the in-situ measurements aimed at workers exposure evaluation?" results of discussion show that the human is very different and need more complex approach and depends on many variables. During the in-situ (on site) measurements methods should be adjusted to the specific environment and complex EMF – near field/far field zone, additional factors influencing measurement procedure; environmental factors, etc. meanwhile ensuring adequate and reliable procedures for exposure assessment.

## **Breakout session 2: Measurement Uncertainty, Exposure Conditions**

The conclusions from the discussion in breakout group 2 regarding the uncertainty in measurement (question no 3) was that when workers EMF exposure is evaluated with respect to the Action Levels a shared uncertainty budget is not an option since the errors are quite large. First, one has to consider the errors occurring in the repeated measurement where variation can occur due to positioning of the probe, variations in the production, spatial averaging, etc., and to this all the instrumental errors should be added. When workers EMF exposure is evaluated with respect to the Action Levels based on the thermal or electro stimulation effects of exposure (direct hazards), developed applying small reduction factors – the implication is that the uncertainty of measurements should be added to the measurement results in compliance analysis.

Regarding the question on "foreseeable use" it was clear from the discussion that the manufacturer of devices emitting EMF should provide data on the exposure considering "the reasonably foreseeable use" (by measurements or numerical simulations regarding the functioning of a new device). However: still "the worst case exposure", which in real work situation may occur over the entire life of the EMF-emitting devices (during intentional use, maintenance, malfunctions, etc.) needs careful considerations.

**Posters** 

# Use of exposimeter during risk assessment for workers with cardiac implants

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#### Keywords

Magnetic field, ICD, exposimeter

#### **Topic**

Workers at particular risk (assessing active/passive implants, pregnant workers, ...)

#### Introduction

Working in an electrical company can expose workers to 50 Hz electric and magnetic field higher than reference levels for the public. A personal risk assessment is necessary for workers with cardiac implants. Measurements of field at the workplace of the worker with cardiac implant is often asked by the occupational physician, which will take the decision of aptitude to work.

We give here recent examples of such measurements for workers with implanted cardiac defibrillator (ICD). In particular we assessed the used of personal exposimeter with alarm function.

#### **Materials and Methods**

Risk assessment is performed according to EN 50527-2-2 [1].

#### **EMF** meters

Magnetic field is measured at the workplace with EFA-300 (Narda). In addition, a colleague of the ICD worker is equiped with 2 exposimeters:

- an EMDEX High Field (0,4–12 000 μT) (Enertech) set up to record maximum numbers of values of magnetic field: every 3 s if measurement of broadband (40– 800 Hz) and harmonics (100–800 Hz) or every 1 s if measurement of broadband only already known that the field is purely 50 Hz.
- a Wavemon LF-400 (Wavecontrol) set up to record maximum numbers of values of magnetic field: every second if magnetic field is higher than 25 % of the limit, and every 10 s if magnetic field is lower. Wavemon uses weighted peak method between 10 Hz and 400 kHz, so the result is expressed in percent of the limit. The limit is chosen for active implanted medical device (AIMD) bearer (reference level for the public in the 1999/519/EC recommendation [2]. Two alarms are set up

(always with light, possible with noise and vibration) in percentage of the limits (we chose 100  $\mu$ T and 1000  $\mu$ T).

#### **Measurement protocol**

Magnetic field (and electric field if relevant) is measured at the ICD worker workplace. If not possible because the worker is going on different places in a large area, a representative sample of the workplaces is chosen.



**Fig. 1** Colleague of the ICD worker wearing Wavemon exposimeter.

#### **Results and Discussion**

In the first example, the ICD worker was a technician in a company in charge of distribution of electricity. His job implies to go in a large number of substations in the area of Nantes, so a representative sample of substations was selected, including different types of 63 kV and 225 kV substations, but also MV/LV substations. Field measurement were coherent with measurement already performed on similar substations.

At the workplace, the Wavemon is very easy to use once it as been programmed with a PC. There is no annoyance for the worker. The comparison in real time with EFA-300 confirms that the alarms react instantaneously when the thresholds fixed are attained. The records fit well with the records of the EMDEX, which is an older exposimeter widely used.

The second example is an ICD worker in an hydroelectric power plant. The results will be presented if possible to organise the measurements before the conference.

#### Conclusion

The Wavemon is a good tool for alerting in real time the workers who wears it that a certain level of 50 Hz magnetic field is exceeded. It works well when the magnetic field exceed the reference level for the public. We intend to test it in workplaces with higher level of magnetic field, exceeding the low action level.

#### **Acknowledgements**

The authors thank Dr. Capitaine and Enedis colleagues in Nantes for their welcome and assistance in the measurements.

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# Working in MRI scan duty during pregnancy – international comparison of regulation and survey of work allocation in Japan

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#### **Keywords**

Pregnant worker, MRI, legislation

#### **Topic**

Workers at particular risk (assessing active/passive implants, pregnant workers, ...)

#### **Background**

Magnetic Resonance Imaging (MRI) is a powerful diagnostic tool which uses various types of non-ionising radiation (NIR) [1]. Especially, use of a static magnetic field (0.5–7 T) is a feature of MRI system. To date there have been no clear reports of MRI scans exerting a harmful effect on fetal development and growth, but fetal exposure can exceed the ICNIRP basic restrictions. Views on pregnant employees performing MRI scan procedures vary internationally. Since no legislation exists in Japan to protect employees from NIR, it is estimated that policies on allocating pregnant employees to perform MRI scans differ between facilities. In contrast, the legislations regarding this issue are already effective in several European countries although extensive surveys have not been done so far.

Therefore, the present study implemented two surveys independently to collect the work situation of MRI scan duty during pregnancy in the European Union (EU) and Japan. Firstly, we surveyed the existing legislation in the EU member states and 7 industrialised countries outside the EU regarding the protection for pregnant employees from NIR exposure to understand the current situation in Europe. Secondly, the questionnaire study was conducted among the managers and workers in MRI facilities in Japan to clarify actual allocation pattern for pregnant workers.

#### Methods

#### Survey of existing regulation (survey 1)

In February 2018, a standardised question was sent to electromagnetic fields and regulatory experts at ministries, inspectorates or government institutes in the 28 member

states of the EU and 7 other industrialised countries (Australia, China, India, Japan, Russia, USA, Switzerland). The question posed was: "Is there legislation or advice by government, hospital organisations or (para)medical professional associations that prohibits or aims to limit the exposure of pregnant (para)medical workers to MRI-related magnetic or electromagnetic fields? (if yes, please specify the policy)". Follow-up questions were sent if needed for clarification or non-response.

#### Survey of allocation pattern for pregnant workers in MRI facilities (survey 2)

In November 2018 and February 2019, the questionnaire was sent to 5763 facilities equipped with MRI devices in Japan twice in order to survey their policies on allocating MRI scan duties to pregnant employees [2, 3]. The number of valid data was n = 2072 (for managers, response rate: 36.6 %), n = 2422 (for male employees, response rate: 49.2 %), and n = 1193 (for female employees, response rate: 53.2 %).

Choices of allocation patterns were divided into three groups according to the frequency of allocation as follows:

- 1. a "less-promoted allocation pattern" that is considered as a precautionary measure for pregnant employees,
- 2. a "no change in allocation pattern", and
- 3. a "promoted-allocation pattern (increase opportunity to allocate to MRI scan duty instead of ionising radiation duties)" that increases opportunities in MRI scan duties.

Chi-square automatic interaction detection (CHAID) and logistic regression analysis were used to examine background factors in the selection of a "less-promoted allocation pattern".

#### Results and Discussion

Thirty-three out of 35 countries responded to the questionnaire or follow-up questions in the survey 1. The results showed that legislation regarding the protection for pregnant worker from EMF exposure has been implemented in 6 countries, one of them applying specifically to MRI workers and 5 to pregnant workers in general. Twenty-seven countries responded that they had no specific legal regulations. However, 7 of these countries had government recommendations or professional guidance, 5 specific for MRI workers and 2 for pregnant workers in general. The situation of the legislation is similar between most EU countries and Japan (no regulation or advice).

From results of survey 2, a "less-promoted allocation pattern" showed that precautionary measures were preferred among the majority of respondents (56.5 % in manager, 66.1 % in male employees, and 59.9 % in female employees). Even in the selection of 2) a "no change in allocation pattern" (35.3 % in manager, 28.1 % in male employees, and 35.1 % in female employees) and 3) a "promoted-allocation pattern" (8.2 % in manager, 5.8 % in male employees, and 4.9 % in female employees), work options which lead to refrain from entering MRI scan room, such as "prohibit to entering MRI scan room", were often selected. These results showed that precautionary measures were preferred among managers and employees in Japan. Classification tree modelling and binomial logistic regression analyses showed that concerns of adverse health effects caused by non-ionising radiation (NIR) exposure were strong motivations in deciding a pregnant employee's allocation.

#### Acknowledgements

This research was supported by research promotion in JNIOSH (N-P29-01).

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## Challenges in the Implementation of the Directive 2013/35/EU in the National Practice in Romania

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#### Keywords

Electromagnetic fields, regulations, exposure limits

#### **Topic**

Best practice in exposure assessment (qualification, equipment, uncertainty, numerical dosimetry ...)

#### Introduction

The EMF Directive 2013/35/EU was transposed into national legislation of Member States within three years after issuing. In Romania the transposition was accomplished in 2016 by the Government Decree (HG) 520/2016 on the exposure of workers to electromagnetic fields. The EMF Decree uses the same exposure limit values and action levels as the Directive. Therefore, the experience at national level in applying the decree HG 520/2016 can also be considered as experience with the EMF Directive.

The authors have been involved in various activities related to occupational EMF exposure including advising, supervising, habilitating and offering consultancy services on EMF exposure assessment and on compliance with national regulation. Practical experience with applying the new regulations and analysing activities of third parties is briefly described below.

## Ambiguities and deficiencies in the provisions of the Directive 2013/35/EU

A few ambiguities in the provisions of the Directive 2013/35/EU have been noticed. The most important ones are related to time-varying magnetic fields with frequencies below 1 Hz. No action levels (ALs) are provided for magnetic fields below 1 Hz. The Directive does not specify that, although ALs were not set, the ELVs for external magnetic flux density from 0 to 1 Hz could be used, in principle, as term of comparison for measured levels of magnetic flux density, as this quantity can be easily measured in the environment. On the other hand, the exposure limit values (ELVs) for magnetic flux density, specified in Table A1 from the Annex II, are: 2 T for normal working conditions and 8 T for controlled working conditions and for the exposure of limbs. At the frequency of 1 Hz, the ELV of 8 T is too large and does not provide adequate protection. Therefore, to compensate for inadequate protection related to missing ALs

and too large ELVs for time-varying magnetic fields with frequencies below 1 Hz, the basic restrictions and the reference levels from ICNIRP 2014 guidelines should be used instead of the ELVs, not in addition to them.

#### Implementation difficulties in the national practice

#### Inadequate measurements

Analysing EMF measurement reports received from measurement service providers and during the process of habilitation of laboratories involved in EMF measurement, we noticed several deficiencies. Some laboratories used inadequate procedures, wrong measurement methods and/or inappropriate equipment. In some cases, they used the measuring equipment in deficient ways or with improper settings. In other cases, places were investigated where measurements were not necessary or not relevant. It has become obvious that, in Romania, the number of measurement service providers capable to carry out good quality measurements in various EMF environments has been too low to cover the demand.

#### Analysis of measurement reports by other entities

At county level, measurement reports from service providers are analysed, usually, by the Public Health Directorate (PHD) of the county. Understanding the new provisions of the national regulations based on the EMF Directive proved to be challenging for their personnel involved in this task. Scientists from National Institute of Public Health (NIPH) provided advice to clarify the way the provisions of the EMF regulations should be applied. However, further difficulties occurred when measurement reports were not fully compliant with regulations or when EMF measurements were performed in complex EMF environments.

#### **Problem solving activities**

To help overcoming the difficulties of implementing the EMF regulations into national practice, the authors carried out several types of activities. Advice has been provided to territorial entities that analyse measurement reports and check compliance with EMF regulations. Some algorithms were developed and disseminated to help interpretation of EMF measurement results in various situations. Moreover, a system of habilitation of EMF laboratories was established by the Ministry of Health and NIPH to help measurement service providers to perform good quality environmental measurements that allow human exposure assessment and testing compliance with exposure regulations.

The EC guide for implementing EMF Directive was recommended as needed lecture to all parties involved. As the guide represents an extensive document and some parts of it are very technical and difficult to understand, a shorter and differently structured Practical Guide that also included the practical experience of the authors of this paper was elaborated.

#### Conclusion

Five years of experience with implementing national EMF regulations based on EMF Directive showed several ambiguities and deficiencies of provisions, as well as difficulties in applying the provisions into national practice. In Romania, the National Institute of Public Health got involved in helping different entities to overcome the difficulties encountered. A national qualification and habilitation system for EMF measurement service providers can help good practice. It would be useful for the next Directive to consider the experience from Member States with current Directive in order to not only achieve a good technical document, but to also facilitate good implementation of its provisions into national practice.



#### **Concluding Remarks of the Organising Committee**

The organising committee highly appreciated all oral and written contributions by keynote speakers, workshop moderators, poster presenters, and especially the participants. Thank you!

The organising committee would like to highlight the following observations and experiences with the EMF Directive 2013/35/EU [1] as discussed at the conference and draw some general inferences.

The presentation by Laura Vicente offered insights into the update process and current update status of the EMF Directive in the light of the ICNIRP Radiofrequency Guidelines published in 2020 [2]. Currently, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) is consulted to decide on the need to (technically) revise the annexes of both EMF Directive 2013/35/EU and EMF Council Recommendation 1999/519/EC [3] following ICNIRP's new guidelines. Considering the experiences since the publication of the EMF Directive in 2013, it seems important to consider the whole frequency range in the revision process and to keep in mind that the system of exposure limits should not be unduly complex for effective compliance in occupational safety and health practice and assessment by national labour authorities. This is strongly supported by findings of workshops about "Evolving EMF Directive" "New and Complex Sources" and "Best Practice in Exposure Assessment".

Due to the flexibility provided in the Directive, some member states have already made their own choices to implement more specific rules for e. g. workers at particular risk, or in the way (or not) they made use of the derogations. These may serve as an inspiration for the upcoming revision process and the implementation of any future revised Directive.

European standardisation already provides of several product related standards to provide safe products and machinery at the European single market. In the EU, safety at work results from safe products and machinery on the one hand and safe use/working conditions on the other. It is important to distinguish between foreseeable use in terms of safe products (conformity assessment) and foreseeable use in terms of usage at the workplace (risk assessment). Standards developers are encouraged to consider foreseeable use further and acknowledge afore mentioned differences by specifying standards for application at workplaces and take due account of the possible exposure to multiple EMF sources and frequencies. National implementations of the EMF Directive would benefit from affordable and standardised risk assessment procedures for more specific technologies based on EN 50413 [4], including e.g. exposure assessment or deriving preventive measures. Examples for such technologies are radar-applications, smart factory (5G), and dielectric machinery working around 27 MHz. To prevent standardisation from becoming too purpose driven by only a few contributors, we see the necessity to place the basis for standardisation on a plurality of opinions and attract contributors of various backgrounds, e. g. science or labour authorities.

Regarding the current state of research on and application of health surveillance of exposed workers it still requires further clarification of how to (medically) define an incident of overexposure, who is to examine and to judge, and what should be examined and reported to (what) authorities to comply with the requirements of Art. (8) and (10) of the EMF Directive. There has been little progress since these observations were made at the 2009 Umeå conference on "Occupational Exposure to EMF: paving the

way for a future EU initiative" [5]. An international incidence database would help to report incidences in a standard manner to gain visibility and comparability along with providing a transparent foundation to avoid similar incidents in future.

When considering workers at particular risk, the discussion mostly comprised pregnant workers, young workers, and workers with active or passive medical implants. Such established risk factors should be distinguished from the issue of workers with idiopathic environmental intolerance attributed to electromagnetic fields (IEI-EMF), which also plays a role outside working hours, and where efforts should be made, to provide neutral specific science-based information. We acknowledge, that the mechanism linking IEI to the exposure to EMF are yet to be verified.

EMF-exposure of all workplaces has to be considered. Some workplaces show no or little exposure, which is acknowledged by an abbreviated risk assessment without measurement, field simulation, or deriving protective measures. Other workplaces require a comprehensive risk assessment procedure. Some employers in the European member states may still be unaware of their obligations and how to fulfil them. Representatives of some national labour authorities report similar knowledge gaps related to monitoring and preventive counselling. Comprehensive and easy to use practical guidelines are important tools to increase awareness and assist implementation. Some of the practical experiences in the past five years suggest areas where the non-binding guide [6] and shorter (national) guides can be improved, such as spatial averaging, calibration of measurement equipment, and transparent and comparable specification of measurement uncertainty.

#### Outlook

We, the organising committee, are grateful of the positive feedback we received at and after the conference. We are encouraged to discuss ideas and ways to maintain the momentum the community gained by networking and discussions at the conference.

During the conference, it was suggested to establish a continuing communication channel to disseminate information. Further on we expect to draft a COST proposal as well as journal articles elaborating on selected conference results, to hold a workshop about "EMF-Exposure of Electronic Article Surveillance" supported by PEROSH in conjunction with EU-IRPA 2022 in Budapest, and perhaps to pursue other initiatives with interested colleagues. So, you are invited to further contacts with the network's members to nourish and develop the EEMFF according to your ideas.

We are looking forward to report to you about how all that will have evolved at the next EEMFF conference in 2023. Stay tuned!

#### References

[1] Parliament and Council of the European Union (2013) "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 L 179, 1–21.

- [2] ICNIRP "Guidelines on Limits of Exposure to Electromagnetic Fields (100 kHz to 300 GHz)", Health Physics 118(5), pages 483–524, 2020.
- [3] Council of the European Union, "Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) (1999/519/EC)," Official Journal of the European Communities L 199, 59–70, 1999.
- [4] EN 50413 "Basic standard on measurement and calculation procedures for human exposure to electric, magnetic and electromagnetic fields (0 Hz–300 GHz)", 2020.
- [5] Swedish Presidency of the European Union "Occupational Exposure to Electromagnetic Fields: paving the way for a future EU initiative", Conclusions and doctors' statement, Umeå University, Umeå, 2009.
- [6] European Commission "Non-binding guide to good practice in implementing Directive 2013/35/EU Electromagnetic Fields Volume 1 Practical Guide", 2015.