The Advisory Committee on Safety and Health at Work

Opinion

DIRECTIVE 2013/35/EU – minimum health and safety requirements regarding the exposure of workers arising from electromagnetic fields (EMF)

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INSERTION of the ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz

Doc. 2045-14-EN

Adopted on 27/11/2014
This Opinion presents the view of the Advisory Committee on Safety and Health at Work (ACSH) regarding the insertion into Annex II of the Directive 2013/35/EU (hereinafter referred to as the Directive) of the ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz (hereinafter referred to as the ICNIRP guidelines). It was prepared by the ACSH Working Party on Electromagnetic Fields (WP EMF) during its meetings of 29-30 April 2014; 1-2 July 2014 and 1 October 2014.

The opinion reflects the shared view of the ACSH on the two specific questions asked by the Commission, and additional questions that were considered in developing an opinion. It includes detailed comments and reflections raised by the different members of the WP EMF.

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Introduction

Article 11(2) of the Directive states that “the Commission shall adopt a delegated act, in accordance with Article 12, to insert into Annex II the ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz as soon as they are available”. The ICNIRP guidelines were published in March 2014.

Article 11(1) stipulates that “the Commission shall be empowered to adopt delegated act in accordance with Article 12 amending in a purely technical way the Annexes, so as to: (...) c) make adjustments to the action levels (ALs) where there is a new scientific evidence, provided that employers continue to be bound by the existing exposure limit values (ELVs) set out in Annexes II and III”.

When adopting the delegated act the “Commission shall carry out appropriate consultations during its preparatory work, including at expert level” (Recital 16), and “should work in close cooperation with the Advisory Committee on Safety and Health at Work” (Recital 17).

In this regard, the remit of the WP EMF is:

- To work in close cooperation with the Commission in the preparation and adoption of a delegated act in accordance with Articles 11 and 12 of Directive 2013/35/EU and providing a draft opinion for adoption by the ACSH.

Commission’s questions to the ACSH

1) Are the values proposed by the ICNIRP guidelines "essential" or "non-essential", ("purely technical" or "not purely technical")?

2) Is there an "evident new scientific basis" for amending the Directive?

ACSH opinion

1) Answering these apparently simple questions needs a precise and argumented analysis with nuances.

2) The way forward:

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1 ICNIRP – International Commission on Non-Ionizing Radiation Protection; mentioned guidelines were published by Health Physics, March 2014, Volume 106, Number 3, pp 418-425.

2 A mandate of the WP EMF was extended on 23 April 2014 by written procedure to meet requirements of the Directive concerning adoption of delegated act.

3 Within the meaning of Article 290 of the Treaty on Functioning of the European Union (TFEU).

4 Within the meaning of Article 11(1) of the Directive 2013/35/EU.
• The ACSH recommends that the Commission ensures that advice on how to prevent the risks from movement in static and time-varying magnetic fields with a frequency of less than 1 Hz, taking into account the ICNIRP guidelines, is included in its non-binding Practical Guide on EMF;
• The ACSH considers that after 10 years of discussion, all stakeholders should allow the Directive to be applied and to learn by experience;
• The ACSH considers that the process of integrating scientific input should be better defined; as one can see, 10 years after its first adoption and 5 years after its postponement, the integration of scientific data into the Directive remains a difficult exercise.

Development of opinion

1) Are the values proposed by the ICNIRP guidelines "essential" or "non-essential", ("purely technical" or "not purely technical")?

Background

The Annex II of the Directive 2013/35/EU, mentioned in Article 11(2), includes ELVs and ALs in the frequency range from 0 Hz to 10 MHz, developed in the process of negotiations between the Council, European Parliament and Commission.

The Directive defines the ELVs as “values established on the basis of biophysical and biological considerations, in particular on the basis of scientifically well-established short-term and acute direct effects, i.e. thermal effects and electrical stimulation of tissues” (Article 2(d)); and the ALs as “operational levels established for the purpose of simplifying the process of demonstrating the compliance with relevant ELVs or, where appropriate, to take relevant protection or prevention measures specified in this Directive” (Article 2(g)).

The Directive also indicates that “the physical quantities, ELVs and ALs, laid down in this Directive are based on the recommendations of ICNIRP and should be considered in accordance with ICNIRP concepts, save where this Directive specifies otherwise” (Recital 15).

The concepts, ELVs and ALs, used in the Directive do not exist in the ICNIRP guidelines. ELVs were derived from “basic restrictions” provided by ICNIRP, and ALs from “reference levels”.

Discussions

The WP EMF considers the ELVs (basic restrictions) within the Directive as "essential", therefore not "purely technical".

The WP EMF considers that ALs (reference levels) are probably more "technical" values than ELVs (basic restrictions) even though most of them are strictly derived from the limit value. Before any changes can be made, consideration of the following points is necessary:

• To change ELVs there needs to be discussion and agreement between the co-legislators, so clarification is needed on how much of the ICNIRP guidelines can be introduced by means of a delegated act;
• The consequence of Article 11(1)(c) which explicitly states that a delegated act can be adopted by the Commission to “make adjustments to the ALs where there is a new scientific evidence, provided that employers continue to be bound by the existing ELVs set out in Annexes II and III”;

5 During the process of the Directive 2013/35/EU negotiations, the following ICNIRP guidelines were considered: ICNIRP 1998, ICNIRP 2009, and ICNIRP 2010. The "movement-related" guidelines, recently published as ICNIRP 2014, were available in the draft version since 2012.
Recital 16 of the Directive says very clearly that a delegated act can be adopted by the Commission in respect of purely technical amendments of the Annexes as well as to adjust the ALs (the Committee understands this as the modification of existing ALs, but not the creation of new ones which may be the case when inserting the ICNIRP guidelines);

The fact that the reference levels in the ICNIRP guidelines refer back to the basic restrictions (that cannot be inserted in the Directive by a delegated act when applying Article 11(1)), would imply the need to introduce the reference levels together with the associated basic restrictions and consequently the reference levels in question would be considered as "essential" elements.

Some members expressed the view that Article 11(2) of the directive gives a specific mandate to the Commission to integrate the ICNIRP guidelines (by amending ALs or ELVs and ALs) without consideration of the provisions of Article 11(1) and Recital 16. However, it needs to be highlighted that Article 11(2) does not specify if the ICNIRP guidelines should be inserted in Annex II of the Directive by adjusting ALs only, or ELVs and ALs. It also does not specify if such ALs/ELVs should be new or modified only.

Regardless of what is specified in Article 11, Article 12 applies when a change is made using a delegated act. This means that the Council and Parliament can challenge any delegated act within 2 months after their notification by the Commission.

Summary

- "Basic restrictions" of the ICNIRP guidelines (corresponding to ELVs within the Directive) are "essential", therefore not "purely technical";
- "Reference levels" of the ICNIRP guidelines (corresponding ALs within the Directive) are probably more "technical" values than "basic restrictions" (ELVs) even though most of them are strictly derived from "basic restrictions"; before any change can be made, consideration of other issues is needed.

2) Is there a “new scientific evidence” for amending the Directive?

Background

In order to ensure that this Directive remains up-to-date, Article 11(1)(c) foresees the possibility of purely technical amendments by “adjustments to the ALs” through a delegated act where there is a “new scientific evidence.”

Discussions

The WP EMF does have some concerns about scientific validity of the ICNIRP guidelines, based upon discussions between Professor Jokela, who represented ICNIRP’s working group which developed ICNIRP guidelines, and Dr Glover. Their discussions were on ICNIRP’s interpretation of Dr Glover’s research findings published in 2007 and the alternative mechanism postulated in more recent publications.

The WP EMF noted ICNIRP’s response explaining that to date the available scientific data do not provide sufficient reason for fundamental changes in the ICNIRP guidelines. However, the ICNIRP acknowledges that more studies are needed to clarify this important safety issue and that appropriate adjustments and clarifications will be provided, if necessary.

Summary

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6 Dr Gowland / Dr Glover’s letter to Health Physics http://journals.lww.com/health-physics/Citation/2014/09000/Comment_on_ICNIRP_Guidelines_for_Limiting_Exposure.9.aspx
7 The minutes of the WG EMF meeting of the 29 and 30 April give further details of the discussions between Dr Glover and Professor Jokela (Annex 2)
8 http://journals.lww.com/health-physics/Citation/2014/09000/Response_by_ICNIRP_to_the_Comments_of_Gowland_and.10.aspx
The ACSH does have some concerns about scientific validity of the ICNIRP guidelines, based upon the discussions between the expert representing ICNIRP’s working group which developed the ICNIRP guidelines, and the expert on whose study these guidelines are largely based.

3) **What was wanted by the Council and European Parliament from the European Commission?**

**Background**

Article 11(2) of the Directive states that “the Commission shall adopt a delegated act to insert into Annex II the ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz as soon as they are available”.

**Discussions**

The WP EMF recalls that during the legislative process the Commission, Council and Parliament expected that the ICNIRP guidelines regarding movement-related effects of exposure to static magnetic fields would be officially available before the Directive was adopted, and therefore accepted as a compromise the ELVs in the frequencies lower than 1 Hz in annex II table A1.

The WP EMF recalls that during the discussions on the Directive in the Council Working Group the provision to insert the future ICNIRP guidelines was included as a footnote to table A1 (regarding ELVs for external magnetic flux density ($B_0$) from 0 to 1 Hz) of the Annex II. The footnote specified that "when ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz will have been finalised, they will be inserted here at a later stage". However, the above provision did not specify by which procedure the ICNIRP guidelines will be inserted into Annex II of the Directive, i.e. it did not mention a delegated act application.

Considering the uncertainties of the dates of publication of the ICNIRP guidelines and the agenda of work of the Council, the footnote was addressed to the Council that was in charge to implement its insertion.

The WP EMF notes that publication of the ICNIRP guidelines happened after the Directive was adopted. At the final stages of the legislative process the footnote was moved by "lawyers-linguists" into Article 11(2) in the Directive stating that the ICNIRP guidelines will be inserted by the Commission in the Directive by a delegated act as soon as they are available.

The WP EMF notes that the ICNIRP guidelines that were published in March 2014 differ from the draft that was available when the Directive was under discussion in 2012 and 2013. These differences should be qualified in order to estimate if they are significant regarding the objectives and the values of the basic restrictions and reference levels.

**Summary**

The ACSH notes that the ICNIRP guidelines that were published in March 2014 differ from the draft that was available when the Directive was under discussion in 2012 and 2013.

4) **Are there any gaps in the directive?**

**Background**

The ICNIRP guidelines, referred to in Article 11(2) of the Directive, recommend that hazards related to exposure to magnetic fields in the frequency range from 0 to 1 Hz needs evaluation of magnetic fields at the workplace (by means of maximum change of magnetic flux density $\Delta B$ movements over any 3 second period and by means of peak-to-peak value of time varying magnetic field) and also evaluation of internal electric field induced in the body by movements using the limits of such electric field from the frequency range from 0 to
25 Hz. Together with the ICNIRP 2010 guidelines it provide “basic restrictions” for these parameters. “Reference levels” in the ICNIRP guidelines are provided by means of time derivative of magnetic flux density (dB/dt).

ELVs (derived from ICNIRP’s “basic restrictions”) already exist in the Directive for static magnetic fields and those varying with time at a frequency up to 1 Hz. Annex IIA states:

- "ELVs below 1 Hz (Table A1) are limits for static magnetic field which is not affected by the tissue of the body;
- ELVs for frequencies from 1 Hz to 10 MHz (Table A2) are limits for electric fields induced in the body from exposure to time-varying electric and magnetic fields;
- ELVs for external magnetic flux density from 0 to 1 Hz;
- The sensory effects ELV is the ELV for normal working conditions (Table A1) and is related to vertigo and other physiological effects related to disturbance of the human balance organ resulting mainly from moving in a static magnetic field;
- The health effects ELV for controlled working conditions (Table A1) is applicable on a temporary basis during the shift when justified by the practice or process, provided that preventive measures, such as controlling movements and providing information to workers have been adopted.

ELVs for internal electric field induced in the body because of EMF exposure exist in the directive only in the frequency range from 1 Hz to 10 MHz (Table A2). Consequently, the gap is the ELVs for internal electric field in the frequency range from 0 to 1 Hz.

The Directive also does not include the ALs (derived from ICNIRP’s “reference levels”) for the frequency range 0 to 1 Hz.

Discussions

Most members consider that there is no legal gap, but imprecision remains. The main remarks and elements of debate on Table A1 of Annex II are the following:

- In Table A1 of Annex II the ELVs relate to the external directly measurable quantity of the “magnetic flux density B_0”. So, they are directly measurable because they are relating to environmental magnetic fields. As these exposure levels are directly measurable, a second set of ALs is not necessary. They can also be seen as the ALs. One must remember that the reason for the introduction of ALs in the Directive is that the physiological quantities in the body from which the ELVs for frequencies greater than 1 Hz are derived, are not directly measurable. Given that the ELVs in table A1 are directly measurable, the introduction of ALs does not add value.

- However, some members do consider that the gap in the Directive, created by an unexpected lack of ALs in the frequency range 0 to 1 Hz (being the result of delayed publication of the ICNIRP guidelines), created a lack of objective limits for evaluation of the manner and speed of movements in static magnetic fields.

- Table A1 of Annex II mentions general measures of prevention but without detailed measures on the restriction or the control of the movements. However, the ICNIRP recommendation of 2009 raised the problem of the movement of the workers in a static field, depending of the speed of the movement etc. and some recommendations were given.

- Table A1 of Annex II applies to both "normal" and "controlled" conditions of work. "Normal" conditions of work could be understood as when the behaviour of the worker is "normal" but the directive does not define the exact meaning of "normal" and "controlled". In these conditions, the ELV of 2 tesla (T) is applicable. For higher fields (up to 8 T), "controlled working conditions" are applicable, based on ICNIRP 2009 guidelines on the limitation of exposure to static magnetic fields. It may be derived that some protection
measures are necessary such as controlling movements and providing information to workers. Among uncertainties created by provisions of the Directive is the lack of parameters to make a clear distinction between "normal" and "controlled" conditions of work and defining these concepts.

- The Directive does not provide objective criteria to help employers to decide when and where, at which workplace, measures should be taken regarding the manner and speed of movements in magnetic fields. The Directive cannot detail all the necessary provisions to manage this risk, but a general obligation of the employer to protect against adverse sensory effects related to movements in strong static magnetic fields, and maybe some global criteria would be useful. Some unexpected results of movement-related effects of static magnetic field interaction with workers’ body may cause accidents and health hazards to workers or other persons present near magnets, such as patients.

- Table A1 gives no information on the speed of movements to which the ELVs are applicable, so there is no relation between the field and the movement. These values cannot be used, strictly speaking, as total ALs because they don’t cover the risk raised by a “rapid” movement in a static magnetic field. An ELV of 2 T is sufficient to protect the worker moving “slowly”, during the work process, but for a more “rapid” movement, knowledge of some additional parameters, like ELVs provided in the ICNIRP guidelines are necessary. In these guidelines, three parallel parameters are used for evaluation of hazards caused by movements in static magnetic field reflecting such complex environmental hazard at the workplace.

- Although workers in the environment near MRI for patients in the health sector may be excluded from compliance with the ELVs (Article 10(1)(a)), when a set of conditions is met, the ICNIRP guidelines are useful to identify where such conditions needs to be applied and to evaluate if they are efficient.

- The workers’ interest group considers that additional ELVs and ALs are essential for the implementation of the employers’ obligations mentioned in Article 10(1)(a). The absence of parameters regarding movement will not facilitate the implementation of the derogation provisions regarding workers exposed to MRI-equipment for patients in the health sector (Article 10(1)(a)).

- On the other hand, the adoption of the ELVs and ALs for the various aforementioned reasons is not possible, especially it should be noted that only changes of the ALs would be possible, "provided that employers continue to be bound by the existing ELVs" (article 11(1)(c))."

- There are also other workplaces with exposures to static fields which need attention, for example the use of MRI (1.5 T) for veterinary diagnosis. The new limits and reference levels provided by ICNIRP could be useful to employers in managing the risks to workers moving around these devices.

- It seems there is a need for more scientific debate to achieve a consensus on a limit value for movements in static magnetic field (see point 2 above), but it needs to be pointed out that also limits for exposure to EMF of other frequencies are under permanent scientific discussion and periodic revision.

- Table A1 of Annex II on static fields is general. It mentions general conditions of exposure but without any detailed measures on restriction or control of movements. The ICNIRP recommendation of 2009 raised the problem of movement of the workers in static magnetic fields, depending of the speed of movement etc. some practical recommendations were given, but nothing about the speed of movements or time variation of the magnetic flux density (0-1 Hz).

Notes
When analysing the Directive’s content, the WP EMF observed that in the French/English versions article 5(7) refers to article 3(4)(a) which refers to annex II table A1, but the German version refers to article 3(3)(a). The translation must be checked in all the languages.

5 The way forward

Discussions

The workers’ interest group is in favour of creating the AL by delegated act for the time variation of magnetic flux density (0 to 1 Hz), but not by simply annexing the ICNIRP guidelines, and considering the existing controversy the workers’ interest group invites the Commission to consider some modifications of the ICNIRP guidelines.

The employers’ interest group and most Member States consider that it is more prudent not to reopen the directive. Some practical advice to prevent the risks from movement in static fields could be given in the MRI appendix of the good practice guide. Article 14(f) of the Directive already requests that the guide should deal with documented working procedures, as well as specific information and training measures for workers exposed to EMF during MRI-related activities falling under article 10(a) – derogation.

This choice is also motivated by the expected institutional and legal difficulties regarding the possibility of a delegated act. The specific historical context of this Directive obliged also to be particularly cautious with ICNIRP recommendation because the obligation to postpone the original 2004 directive was partly due to it including an ICNIRP recommendation. As underlined above, the fact that there is no organised process to discuss and validate the data communicated by ICNIRP remains problematic. However, a legislative procedure to revise the directive would be very long and probably not meet the implementation deadline of 1 July 2016.

The WP EMF

Recommends that the Commission ensures that advice on how to prevent the risks from movement in static and time-varying magnetic fields with a frequency of less than 1 Hz is included in its non-binding Practical Guide. Article 14(f) of the Directive requests that the guide should deal with documented working procedures, as well as specific information and training measures for workers exposed to electromagnetic fields during MRI-related activities falling under the derogation in Article 10(a)).

Considers that after 10 years of discussion, all stakeholders should allow the directive to be applied and to learn by experience.

Considers that the process to integrate scientific input should be better defined. As one can see, 10 years after its first adoption and 5 years after its postponement, the integration of scientific data remains a difficult exercise.

Thanks the Commission for this well-organised consultation. This is undoubtedly an indication of a better management of the legislative process.

Poland’s remarks:

Member States government needs more certainty in the process of the directive transposition.

The worst case for doing national legislation is the case, when now nothing will be done, our legislation will be prepared or published in 2015 or 2016, and because of re-interpretation of the Directive provisions it will be amended by new ICNIRP limits later (before 2018, e.g. in May 2016).

It needs to be counted also that the expectation that limits from a new ICNIRP will be included in the Directive was a formal part of the consensus achieved in the Council.
Annex 1: The minutes of the WG EMF meeting of the 29 and 30 April 2014
Doc. 1008-14-EN

Present:

**Members of the Working Group:**
Mr Franck Gambelli (EMPLOYERS FR/Chair)
M. Frank Bodemann (EMPLOYERS/DE)
Mrs Jolanta Karpowicz (GOV/PL, secretary)
Mrs Hannelore Neuschulz (GOV/DE)
Mrs Clare McNicholas (GOV/UK)
Mr Paul Schuurmann (GOV/NL)
Mr Marc Saphir (WORKERS/BE)
Mr Helder Pires (WORKERS/PT)
Mrs Peggy Matthieu (GOV/FR deputy)

**Experts:**
Mr Georg Hilpert (DE)
Mr Paul Glover (UK)
Mr Kari Jokela (FI)
Mr J. Arwel Barrett (UK)

**Commission:**
Mr Mathew Heppleston
Mrs Zinta Podnieczie

1. **Mandate of the working party and timetable**

Commission (Matthew/Zinta)

The working party was meeting on the basis of the extension of the mandate relating to the inclusion of new ICNIRP recommendations in the Directive. Accordingly, the usual experts and invited guests associated with the opinion concerning the guides had not been invited. Experts in static fields were in attendance to provide the working party with clarifications.

Another meeting of the working party would take place on 13 June or 1 July. The working party's opinion would be presented at the Advisory Committee plenary session in December.

As the Member States considered that there were not enough government representatives in the working party, they called for the establishment of a specific group within the framework of the council.

2. **Legal and institutional framework surrounding the issue of static fields**

The framework for this issue is provided by Article 11 of the Directive, which reads as follows:

**Technical amendments of the Annexes**

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 12 amending, in a purely technical way, the Annexes, so as to:

   a) take into account the adoption of regulations and directives in the field of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment or workplaces;

   b) take into account technical progress, changes in the most relevant standards or specifications, and new scientific findings concerning electromagnetic fields;
c) make adjustments to the ALs where there is new scientific evidence, provided that employers continue to be bound by the existing ELVs set out in Annexes II and III.

2. The Commission shall adopt a delegated act, in accordance with Article 12, to insert into Annex II the ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz as soon as they are available.

3. Where, in the case of the amendments referred to in paragraphs 1 and 2, imperative grounds of urgency so require, the procedure provided for in Article 13 shall apply to delegated acts adopted pursuant to this Article."

This meant that there were two possible scenarios:

1. It was essential for the recommendation to be taken up, which raised the question of whether the Directive needed to be amended or whether a delegated act would suffice.

2. In the light of the Directive as it stood, the ICNIRP recommendation did not need to be taken up and the Directive would enter into force with no amendments.

The working group's opinion would have to be delivered at the plenary meeting in December, with a meeting scheduled for the end of June.

3 The ICNIRP recommendation and scientific discussion

Professor Jokela presented the ICNIRP recommendation, which concerned the electric fields induced by movement of the human body in a static magnetic field. The frequency of this field was below 1 Hz.

The recommendation was primarily aimed at electromagnetic resonance imaging equipment used in hospitals or research laboratories. It concerned employees and other persons working in the immediate environs of MRI equipment, but not patients.

The electrical current generated by movement within a static field stimulated the nervous system and could trigger visual sensations (magnetophosphenes), peripheral nerve stimulation and vertigo. The recommendation proposed limit values.

Dr Paul Grover from Nottingham University presented the working group with a draft comment on the ICNIRP recommendations. Mr Glover explained that the ICNIRP recommendations were based on a study that he himself had conducted in 2007 and which was the first of its kind. No study had been conducted since then. The data available were insufficient to provide a basis for an international recommendation. Professor Glover stressed the importance of the physical mechanism known as the "Lorentz force", which was affected by the amplitude and direction of the fields and which has not been sufficiently taken into account by the recommendation.

After a scientific discussion between Professor Jokela and Professor Glover, Professor Jokela informed the working group that the ICNIRP's 2014 recommendation was already being revised.

Speaking on behalf of the CES, Mr Sapir wondered about the capacity of the working group to adopt a position in the scientific debate. He noted that the Euratom directives provided for a specialised committee responsible for liaising with international scientific authorities, which was not the case where EMFs were concerned.

The British Government stressed that while the Directive required a solid and "robust" scientific foundation, the doubts raised by the new ICNIRP recommendation meant that such certainty would be unattainable.

4 Institutional discussion of limit values

The Commission asked Professor Jokela whether he considered that the limit values appearing in the recommendation constituted "purely technical" data. Article 11(2) of the
Directive provided that only "purely technical" aspects could be the subject of delegated Commission acts. Professor Jokela responded that the limit values were not "purely technical" data, and this opinion was confirmed by Professor Glover and other members of the working group. A limit value was not only the result of a scientific observation but also incorporated, to a certain extent, voluntary decisions of a political nature.

The German Government explained that under Article 290 TFEU, the definition of a limit value was an essential act of a Directive that could only be adopted by embarking on a legislative process. Embarking on a long legislative process would mean amending the Directive again before it had even entered into force. The Directive should be allowed the possibility of entering into force in its existing form.

The Chair noted that the 2004 Directive had been suspended and revised because an ICNIRP recommendation had been taken up without sufficient consideration beforehand. In the light of the discussion between Professor Jokela and Professor Glover, and given that the 2014 recommendation was already being revised, he felt that it would be imprudent to embark on such a review.

The French government called for an impact assessment of the ICNIRP limit values.

The German Government stressed that there was no legal vacuum in the Directive, since Annex 2 provided for limit values for frequencies from 0 to 1 Hz. Furthermore, the Member States were free to implement the Directive on the basis of national texts. There was a recommendation from the BG on medical imaging. The Directive was sufficient to protect workers. It would be prudent to wait and see what experience, in the wake of the entry into force of the Directive, might bring before considering making amendments to it.

The Commission asked the Government representatives who had been present when the 2013 Directive had been negotiated how Article 11 had come about.

Several representatives of the States (D, UK, PL) explained that during the tripartite discussions the negotiators had been waiting for the ICNIRP to produce its recommendation. At that time, only an informal document existed. As the recommendation had not been issued in time, limit values had been established in the Annex. The Commission's lawyer-linguists had transferred a footnote that had originally appeared in Annex 2 to the main body of the Directive. That note became Article 11(2).

5 Medical aspects of the issue of static fields

EMF penetrate the head and fluctuate. They are easier to measure under the head. Inside the head, the current induced varies depending on the blood pressure. Sudden movements result in stronger currents.

Prevention

Static fields are found in medical imaging activities in hospitals and universities, as well as in veterinary activities, nuclear research (CERN cyclotron) and pharmaceutical research.

There are an estimated 10 000 MRI scanners in service in the EU, with some 50 000 workers exposed to static fields.

Staff employed to maintain MRI equipment must work on the equipment while it is operating but do not enter the machines. As a rule, they are trained.

Radiology staff are not only involved in MRI radiology. They also work in traditional radiology, where there is a constant stream of patients. There is therefore considerable variation in the pace of activity, and thus movement, from one activity to the other. Radiologists have to be trained to change pace, which is not always easy.

In practice, maintenance staff or staff who calibrate the equipment are not under any time constraints when carrying out their work. They are able to perform their tasks slowly, with no sudden movements, which almost completely eliminates the risk.
The group at greatest risk of exposure is made up of employees working close to MRI equipment on non-medical tasks and who are completely unaware of the risks associated with MRI: specifically, ambulance staff, accident and emergency staff, fire service personnel, external physicians accompanying patients, cleaners, weekend staff and security guards. Restrictions on access to the premises are essential.

New equipment placed on the market must meet the requirements of the Low Voltage Directive. It should normally be accompanied by instructions explaining the steps to be taken when working within static fields.

Mr Bodemann (EMPLOYERS) informed the group that manufacturers could provide maps of the static fields for medical imaging equipment.

However, it was clear that providing a user with a thick instruction manual would never be enough to persuade users to make changes to the organisation of their work. It was important to stress that the medical world and its specific organisation constituted a particular working environment.

It was important to take account of the fact that there were numerous old scanners in operation and that there was a significant trade in second-hand equipment. Such equipment did not, as a rule, come with instructions appropriate to preventing risks associated with static fields.

In practice, it was not easy to stop an MRI because the liquid helium would need to be dissipated, which could take a week.

Workers: the workers' group considered that it was not possible to be satisfied with the general provisions of the framework directive to ensure the protection of workers against static risks. Specific procedures would have to be defined.

Commission: The guide produced pursuant to the Directive would have to precisely define the procedures to be implemented for MRI equipment.

### Article 14

**Practical guides**

_In order to facilitate the implementation of this Directive the Commission shall make available non-binding practical guides at the latest six months before 1 July 2016. Those practical guides shall, in particular relate to the following issues: (…)_

_f) the establishment of documented working procedures, as well as specific information and training measures for workers exposed to electromagnetic fields during MRI-related activities falling under Article 10(1)(a); (…)_

As far as the exceeding of the values laid down in the Directive is concerned – with justification under certain circumstances – provision is made for this in the Directive.

### Article 10

**Derogations**

1. By way of derogation from Article 3 but without prejudice to Article 5(1), the following shall apply:

_a) exposure may exceed the ELVs if the exposure is related to the installation, testing, use, development, maintenance of or research related to magnetic resonance imaging (MRI) equipment for patients in the health sector, provided that all the following conditions are met:_

_i) the risk assessment carried out in accordance with Article 4 has demonstrated that the ELVs are exceeded;_

_ii) given the state of the art, all technical and/or organisational measures have been applied;_
iii) the circumstances duly justify exceeding the ELVs;

iv) the characteristics of the workplace, work equipment, or work practices have been taken into account; and

v) the employer demonstrates that workers are still protected against adverse health effects and against safety risks, including by ensuring that the instructions for safe use provided by the manufacturer in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices are followed.