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NOTE

from:	The Presidency
to:	The Working Party on Social Questions
on:	27 October 2011
No. Cion prop.:	11951/11 SOC 598 CODEC 1075
Subject:	Proposal for a Directive of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (XXth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

With a view to the meeting of the Social Questions Working Party on 10 November 2011 and following the comments and questions sent by delegations, delegations will find attached an enlarged exploratory note from the Presidency on the methodology applied in the drafting amendments to the Annex II to the Presidency compromise proposal.

Changes in relation to the previous version (doc. 15910/11) are indicated as follows: deletions are marked "**[…]**" and new text is in **bold**. The added footnotes contain Presidency's replies to detailed questions and comments sent by delegations in writing. Examples of realistic parameters of electromagnetic fields at the workplace which may be a subject of an application of the Directive, are to be found in the Addendum to this document.

The Presidency would like to thank the delegations for all received questions and suggestions which contributed substantially to the improvement of the draft Annex II. The Presidency would also like to apologize, if any question/comment was not - unintentionally - responded.

Explanation of the methodology applied in the drafting of amendments to Annex II to the Presidency compromise proposal for a Directive of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)
(XXth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
(doc. 15528/11, Oct. 20, 2011)

1. MOTIVATION

1. The results of the discussion examining the proposed EMF[1] Directive of June 22, 2011[2], conducted during the SQWP meetings (on: July 15, July 20, September 5, September 28, October 13 **and October 27**[3]), when the following main expectations were expressed by the Member States' representatives and experts:

   a) the proposed EMF directive needs improvements in the section laying down exposure limits;

   b) the directive should be directly linked to international science-based safety guidelines, preferably ICNIRP[4] ;

   c) EMF exposure limits should be measurable to allow them to be used when monitoring exposure at the workplace, especially in SMEs [5];

   d) EMF exposure limits may include proportionality and flexibility appropriate to the nature of exposure and related risks;

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1 EMF - electromagnetic fields.
2 doc. 11951/11.
3 for the outcomes of meetings see references in the doc.: 12754/11, 13797/11, 14313/11 and 14879/11.
4 ICNIRP - International Commission on Non-Ionizing Radiation Protection.
5 SMSs – small and medium -sized enterprises.

e) low- frequency EMF exposure limits should be expressed in *peak-in-time* values correlated with the electrical tissues stimulation phenomenon;

f) the directive should be more precise.

2. The clarifications regarding the principles applied by ICNIRP while deriving EMF exposure limits composed as a set of:

- Basic Restrictions (BRs) expressed in the internal measures of exposure (to be calculated only from complex numerical models);

- Reference Levels (RLs) expressed in the external measures of exposure (to be measured or calculated from simplified formulas or complex numerical models)

were received from Dr Rüdiger Matthes, ICNIRP Vice-Chairman, in his letter on September 2, where the following main explanations were expressed:

a) the relation between internal and external measures depends on many exposure scenario parameters;

b) the purpose of a RLs is to simplify compliance testing - as long as exposure is below the RLs, it is compliant with the BRs limit. Ideally, the RLs and the BRs limit would exactly match;

c) within the ICNIRP concept[6]:

- if exposure is only to EMF of a frequency below 100 kHz, the 2010 guidelines have to be applied;

[6] **This explanation refers to questions raised by <u>UK, NL, FR</u>: See Note 4 to Table 3. (ICNIRP 2010, page 827) - *In the frequency range above 100 kHz, RF specific reference levels need to be considered additionally* (to the RL of f < 10 MHz covered by the Table).**

- if exposure is only to EMF of a frequency above 10 MHz, the 1998 guidelines have to be applied;

- if exposure is to EMF of a frequency between 100 kHz and 10 MHz, both sets of guidelines apply; it means that the restrictions on heating effects from the 1998 guidelines and the restrictions on electrical stimulation of tissues from the 2010 guidelines apply;

- in the case of multiple frequency exposure, the summation formulas apply; for stimulation effects as set out in the 2010 guidelines with a summation interval of up to 10 MHz, and for heating effects as set in the 1998 guidelines with summation interval from 100 kHz to 300 GHz.

d) ICNIRP does not recommend deviating from this concept and does not support the idea of a single RL in the transition region - such an approach is liable to produce to incorrect results;

e) time averaging is only applicable to parameters that concern heating effects; below 100 kHz there are no such parameters in the ICNIRP guidelines (2010);

f) the concept of new RLs for special types of non-uniform exposure is generally in line with the ICNIRP guidelines and is already provided for in the ICNIRP 2010 guidelines.

2. METHODOLOGY APPLIED

1. In collaboration with Member States' experts, the following ICNIRP guidelines[7] were examined in detail:

a) ICNIRP 1998 - ICNIRP Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). Health Physics, 74, 4 (April), 1998, 494–522;

[7] http://www.icnirp.org/PubEMF.htm

b) ICNIRP 2010 - ICNIRP (International Commission on Non-Ionizing Radiation Protection), Guidelines for Limiting Exposure to Time-Varying Electric and Magnetic Fields (1 Hz to 100 kHz), Health Physics, vol. 99, No. 6 (December), 818-836, 2010;

c) ICNIRP 2009 - Guidelines on Limits of Exposure to Static Magnetic Fields. Health Physics 96(4):504-514; 2009;

d) ICNIRP 1994 - Guidelines on Limits of Exposure to Static Magnetic Fields. Health Physics 66 (1): 100-106; 1994;

e) ICNIRP 2003 - ICNIRP - International Commission on Non-Ionizing Radiation Protection. 2003. Guidance on determining compliance of exposure to pulsed and complex non-sinusoidal waveforms below 100 kHz with ICNIRP guidelines. Health Physics .84(3): 383-7.

2 Parameter of different exposure scenarios, which have to be considered during the implementation of the EMF Directive in enterprises, were analyzed on the basis of the published results of international European research projects, in particular:

a) European Cooperation in the Field of Scientific and Technical Research (COST) Action BM 0704 - Emerging EMF-Technologies: Health Risk Management[8];

b) EMF-NET co-ordination activity: Effects of the Exposure to Electromagnetic Fields: From Science to Public Health and Safer Workplace, Main Task-2 (MT2) WORKEN covered by the European 6th Framework Programme in 2004–2008 (Policy Support and Anticipating Scientific and Technological Needs, contract SSPE-CT-2004-502173);

[8] http://www.cost-bm0704.eu

c) Occupational exposure to electromagnetic fields: paving the way for a future EU initiative, 6-8 October 2009, Umea, Sweden – the conference held by the Swedish EU Presidency in association with the European Commission and was arranged by the Swedish Work Environment Authority and Umeå University[9];

d) Hansson Mild 2009 - Hansson Mild K., et al. (2009) Exposure of Workers to Electromagnetic Fields. A Review of Open Questions on Exposure Assessment Techniques, Int. J. Occup. Safety and Ergonomics (JOSE) 2009, Vol. 15, No. 1, 3–33[10];

e) Capstick 2008 - Capstick M, et al. (2008) An investigation into occupational exposure to electromagnetic fields for personnel working with and around medical magnetic resonance imaging equipment. Report on Project VT/2007/017 of the European Commission, DG Employment, Social Affairs and Equal Opportunities[11];

f) Wilén J 2010 - Wilén J, de Vocht F. 2010. Health complaints among nurses working near MRI scanners - A descriptive pilot study. Eur J Radiol. 2010 Oct 13. doi:10.1016/j.ejrad.2010.09.021.

3. THE CONCEPT OF EXPOSURE LIMIT VALUES AND ACTION LEVELS

1. Annex II as set out in the Presidency compromise proposal (doc. 14897/11), including Exposure Limit Values (ELVs) and Action Levels (ALs), was drafted on the basis of the discussions held during SQWP meetings and in close consultations with experts from the Member States. Based on the opinions expressed by representatives of many Member States, the exposure limit values were derived in line with the principles published in the ICNIRP guidelines and in consultation with the Chairman of ICNIRP, Prof. Paolo Vecchia, who confirmed that the present draft of Annex II was compatible with the guidelines.

[9] http://www.av.se/inenglish/about/international_cooperation/electromagnetic.aspx
[10] http://www.ciop.pl/jose
[11] http://www.myesr.org/html/img/pool/VT2007017FinalReportv04.pdf

2. The concept of ELVs and ALs should reflect both the concept of ICNIRP BRs and RLs derived from the EMF exposure effects in the human body, as well as the EMF exposure parameters related to workers' exposure, where: *The most realistic EMF exposure pattern for workers is multi-frequency exposure of a variable level, resulting from non-sinusoidal emission from single or multiple EMF sources, movements of EMF sources, movements of the worker or modulated output power of the EMF source (existing separately or all together)* [Hansson Mild, 2009, p. 4]. Consequently, it was assumed that the EMF to which ELVs and ALs are applicable may be characterized by various frequencies, non-uniform spatial distribution over workplace and non-sinusoidal time variability.[12]

3. The main principles followed by the Presidency when drafting Annex II, while paying attention to the practical usefulness of exposure limitations, were:

- following the ICNIRP concept, the ELVs and ALs are set in two parallel frequency bands: 0-10 MHz and 100 kHz – 300 GHz and both are applicable in the frequency band 100 kHz – 10 MHz;[13]

- ALs were set as a tool to simplify compliance testing - as long as exposure is below the ALs, it is compliant with the ELVs - and also to identify the levels of exposure related to other risks, e.g. ballistic risks in static magnetic field;

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12 **Taking into account realistic patterns of EMF existing at the workplace, on one hand, and the need to be precise (required for the transposition of the Directive at the national level), on the other, it was assumed that the parameters called ELVs and ALs need to be precisely defined in the „3D domain" - against: 1) frequency (related to different EMF exposure effects in the body: electrical excitation of tissues and tissues heating; 2) spatial distribution (related to the workspace): homogeneous field distribution or non-homogeneous field / localised exposure; 3) time distribution (related to the exposure pattern): sinusoidal CW field, non-sinusoidal CW field, pulsed fields or other which may exist at the workplace.**

13 **Taking account of the explanation by ICNIRP, mentioned on page 3 of this document.**

- measurable ELVs were defined as applicable to the ideal case of spatially homogeneous exposure over the worker's body and consequently derived as copies of RLs from ICNIRP Guidelines (1998, 2010) (such ELVs follow the ICNIRP concept and are useful for inspections in the workplace and for drawing up guidelines for assessment of the EMF at various workplace types);[14]

- non-measurable ICNIRP BRs expressed in parameters, which need to be numerically calculated, are referred to in the notes in Annex II, Point A, to make them useful if there is a special need to analyze the level of EMF risk, e.g. based on the results of numerical calculations performed in the process of product testing;

- measurable ALs were defined as a spatial maximum at a worker's position in order to create a link with more realistic exposure situations (spatially localized type), then situations covered by ELVs and consequently derived and named as Reference Levels from ICNIRP Guidelines (1998, 2010);[15]

- ALs defined as a spatial maximum also made it possible to set limits intended for limb-localized exposure (for magnetic B-field of f < 10 MHz) as provided for by ICNIRP Guidelines (2010) – conservative relaxation factor "x3" were used for limb exposure taking account anthropometric data on limbs and trunk dimensions;[16]

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[14] **Taking account of the ICNIRP comments and, in particular, of the note published by ICNIRP'2010 guidelines, page 827: "*The reference levels assume an exposure by a uniform (homogeneous)field with respect to the spatial extension of the human body*".**

[15] **Taking account of the function of ALs (to be used for testing compliance with ELV, but by using a simplified protocol), this definition refers to the comments made by ICNIRP and in particular ICNIRP 2010 guidelines [page 827: "*... that the distribution of the field in non-uniform or localised to a small part of the body. In these cases the measurement of the maximum field strength in the position of space occupied by the body always result in a safe, albeit very conservative exposure assessment*". And, consequently, for a relatively small number of workplaces with exposure exceeding ALs, compliance with ELVs is still probable and shall be tested by a more complex exposure assessment protocol.**

[16] **Explanation refers to a question raised by SE.**

- ALs defined as a spatial maximum also made it possible to establish the main rules of flexible exposure limits, applicable provided that the risks related to head exposure are managed by appropriate prevention measures (for EMF of f < 400 Hz) (relaxation factor was derived directly from ICNIRP 2010 guidelines: x1,6f - for frequency f of 1-10 Hz; x16 - for frequency 10-25 Hz; x400/f – for frequency f of 25-400 Hz; relaxation factor was applied for electric field of f > 100 Hz only, because of electric shock hazards which limits exposure for lower frequencies; for magnetic fields the frequency pattern of relaxed limits was simplified due to the use of uniform formula $4.2x10^5/f$ for the whole frequency band of f < 3 kHz);[17]

- following comments by numerous Member States, the ELVs and ALs for f<10 MHz (related to electrical excitation) were expressed as peak- in -time values and calculated directly from ICNIRP as 1.41 x RL and expressed with a low precision of 2 digits – what is based on scientific literature cited by ICNIRP 2010 and practical examples for assessment of non-sinusoidal field provided in Appendix to ICNIRP 2010;[18]

- the added values of the use of peak-in-time values for ELVs and ALs for f<10 MHz also avoid the problem of defining the time period in formula defining the RMS value and clear separation between limits related to nerve excitation effects (established as peak-in-time applicable for f < 10 MHz) from limits related to heating effects (established as 6-min averaging RMS values, applicable for f > 100 kHz);

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17 **The concept is based on comments made by ICNIRP [ICNIRP 2010, page 825] - Explanation refers to questions raised by UK and NL.**

18 **This explanation refers to questions by CZ, NL and FI: The concept of using the parameter of the field which is the easiest to be defined is based on rationale published by ICNIRP 2010 (page 820), where research results, related to the peak value correlation with nerve excitation, are discussed, and in Annex to that document (page 832), where examples of limits expressed in peak values were listed. Following the general rules, the use of other equivalent parameters, like frequency summation of harmonics, time derivative, weighted peak, which requires a precise technical definition (see examples in ICNIRP 2010, page 829 and 832), will be defined by guidelines or standards provided for practical assessment of exposure at various workplaces.**

- the term "Action Level" was suggested instead of "Action Value" to make it easier to interpret the Directive's provisions and to reduce problems with misinterpretation of two similar terms denoting very different functions (meaning ELV and AV); the term Action Level is also closer to the original ICNIRP term - Reference Level;

- taking account of the fact that dielectric properties of insulated and conductive materials are highly varying with the frequency, which makes it difficult to distinguish conductive and non-conductive objects in high- frequency fields, and the possibility of using the same measurement technique to assess contact currents and induced currents of a wide frequency range , and a roughly 2-fold bigger cross-section of ankle in comparison with wrist - it was suggested for practical purposes that criteria for contact current and induced current (from ICNIRP guidelines) be merged and this parameter expressed as Limb current;[19]

- ELV for static magnetic field were derived from ICNIRP 2009 with respect to spatially uniform exposure. ALs were derived as applicable to spatially non-uniform exposure (limbs localized exposure) or to other risks – ballistic, implants or movement- related hazards – limits were derived from ICNIRP 2009, ICNIRP 1994, Capstic 2008 and Wilen 2010;

[19] **This explanation refers to questions from NL, FI and UK: This concept takes into account the metrological practice, whereby it is often very difficult, when making measurements at the workplace, to distinguish between a component of the measurement results representing the induced current and the component representing the contact current (e.g. when a worker is in contact with a part of a device covered by plastic material and is exposed to electromagnetic field of low radiofrequency). It was also considered that thermal hazards related to the induced current are related to the dimension of a cross section of the part of a body exposed to the current flow. Following the general rules, a detailed protocol for the assessment of limb current of various frequencies, mentioned by e.g. FI in its comments, will be defined in the guidelines or standards provided for practical assessment of exposure at various workplaces.**

- ELV for static electric field [20]were calculated for the purpose of preventing the worker from being exposed to perceptible electrostatic discharges through the body (calculated for the minimum energy of the perceptible spark discharge – 50 mJ, the electric capacitance of the human body – C = 50 pF, effective surface of the human body exposed to an electrostatic field – S = 2 m^2 - this parameter can be easily measured)[21].

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[20] **Referring to the question raised by the UK, the suggested parameter related to the hazards caused by static electric fields is measurable. The Presidency is flexible on this point and welcomes any references to already existing legislation which set equivalent limits related to such hazards.**

[21] Strojny J., Safety of maintenance of the electric capacitors. (in Polish). Atest, 3, 2007, p. 13 - 15; Guderska H.. Doctoral thesis: Influence of electrostatic discharges on physiological responses of the human body. 22-th of June 1981, Wrocław University of Technology.

ANNEX II

EXPOSURE LIMIT VALUES AND ACTION LEVELS

(copied from doc. 15528/11, Oct. 20, 2011)

A. EXPOSURE LIMIT VALUES

The following physical quantities and values are used to specify the exposure limit values (compliance will all[22] ELVs shall be demonstrated under Article 5 of this Directive):

- ELV-E_1 and ELV-E_2 for electic field strength E of time varying electric field as specified in Table **A**1;

- ELV-B_1 and ELV-B_2 for magnetic flux density B of time varying magnetic field as specified in Table **A**1;

- ELV-S for power density S of radio- or microwave frequency electromagnetic fields as specified in Table **A**1;

- ELV-B_0 for magnetic flux density of static magnetic field as: ELV-B_0 = 2 T;

- ELV-Q for electric charge transfered from the source of static electric field as: ELV-Q = 70 nC.

[22] **This explanation refers to questions by <u>FR and UK</u>: An important aspect of the ELVs system is that all ELVs shall be taken into consideration in parallel.**

Exposure limit values are referred to a homogeneous in space exposure[23] condition of the worker. It means a field that is constant in amplitude, direction, and relative phase over the dimensions of the worker's body under consideration. **[...] It** applies to an environmental **electric and magnetic** field undisturbed by the presence of the body.[24]

In case of a non-homogeneous in-space-exposure to electromagnetic field, when exposure effects in the body are reduced, the compliance of workers' exposure with Exposure Limit Values, as specified in Table A1, may be demonstrated while using scientifically proven exposure assessment procedures or safety-related data which refer to spatial distribution of the field and to the principles specified in Note A1-5 and Note A1-6 (derived from international safety guidelines of International Commission on Non-Ionizing Radiation Protection (ICNIRP)).[25] [26]

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[23] **This explanation refers to questions from <u>BG, DK, FR, HU, NL, SI, AT and UK</u>: An important aspect of the ELVs system is that ELVs are related to the homogeneous in-space-exposure which justifies the use of measurable ELVs. It is very important for the practical implementation of the Directive by enterprises, especially by the SMS (ALs are related to a maximum in-space-exposure, therefore, when comparing ELVs and ALs, spatial distribution of exposure have to be considered) (see comments on pages 7 and 8of this document)**

[24] **Suggested by experts, because, in case of RF electromagnetic fields, a magnetic field can be disturbed by the human body presence.**

[25] **http://www.icnirp.org/PubEMF.htm**

[26] **Text compiled from Note 9, taking into account suggestions by <u>BG, DK, FR, HU, IT, NL, FI, AT, SI, SE, and UK</u> in order to clarify the relation among ELVs and SAR and Ein limits.**

Table A1.[27] Exposure limit values for exposure to **time-varying electromagnetic field**

Frequency range	Electric field strength ELV-E_1 [V/m]	Electric field strength ELV-E_2 [V/m]	Magnetic flux density ELV-B_1 [μT]	Magnetic flux density ELV-B_2 [μT]	Power density ELV-S [**W/m**][28]
1 – 8 Hz	2.8×10^4	*NA*	$2.8 \times 10^5 / f^2$	*NA*	*NA*
8 – 25 Hz	2.8×10^4	*NA*	$3.5 \times 10^4 / f$	*NA*	*NA*
25 – 300 Hz	$7.0 \times 10^5 / f$	*NA*	1.4×10^3	*NA*	*NA*
300 Hz – 3 kHz	$7.0 \times 10^5 / f$	*NA*	$4.2 \times 10^5 / f$	*NA*	*NA*
3 – 100 kHz	2.4×10^2	*NA*	1.4×10^2	*NA*	*NA*
100 kHz – 1 MHz[29]	2.4×10^2	6.1×10^2	1.4×10^2	$2.0 \times 10^6 / f$	*NA*
1 – 10 MHz	2.4×10^2	$6.1 \times 10^8 / f$	1.4×10^2	$2.0 \times 10^6 / f$	*NA*
10 – 400 MHz	*NA*	61	*NA*	0.2	*NA*
400 MHz – 2 GHz	*NA*	$3.0 \times 10^{-3} f^{1/2}$	*NA*	$1.0 \times 10^{-5} f^{1/2}$	*NA*
2 – 10 GHz	*NA*	1.4×10^2	*NA*	4.5×10^{-1}	*NA*
10 – 300 GHz	*NA*	*NA*	*NA*	*NA*	50[30]

Note A1-1: f is the frequency expressed in hertz (Hz).

Note A1-2: *NA* means not applicable.

Note A1-3: Magnetic field may be expressed by magnetic flux density B or alternatively by magnetic field strength H.

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27 **Based on a suggestion by experts, more precise indexing was applied.**

28 **Unintentional misprint, corrected following a comment by the UK.**

29 **With regard to suggestions and questions by FR, NL, SE and UK and in accordance with the ICNIRP's concept in the frequency range 100 kHz – 10 MHz, 2 set of limits shall be both applied in parallel (see also comments on pages 7 and 8 of this document).**

30 **This explanation is based on a comment by the UK: Copied from ICNIRP 1998, BRs, as it is a measurable parameter, E and B fields were mentioned among ALs**.

Note A1-4: ELV-E_1 and ELV-B_1 values correspond to the peak in time E-field or B-field values. Peak in time value may be derived from root-mean-squared (RMS) values of sinusoidal signal by multiplying by square root of 2 (it mean app. 1.41). In case of non-sinusoidal signal **equivalent parameters shall be considered following relevant metrological practice, in particular** the **summation of** frequency compo**nents** (harmonics), time derivative or weighted peak related to **[…]** time variability **of this signal**[31] **[…]**. In case of non-sinusoidal the signals equivalent frequency f is equal to $1/(2t_p)$, where t_p is the duration of the pulse **rise/fall time**[32].

Note A1-5: ELV-E_1 and ELV-B_1 are derived from both following **limits related to**[33] electrical stimulation of tissues, expressed in RMS values of electric fields E_i caused by electromagnetic exposure in the body in nervous tissue (in V/m):

(a) **limits related to** direct excitation effects on all peripheral and central nervous system tissues in the body including head; the compliance with such **limits** does not however prevents phosphenes and minor changes in brain activity for frequencies up to 400 Hz:

- from 1 Hz up to 3 kHz - 0.8 V/m;
- from 3 kHz up to 10 MHz - 2.7 f x10^{-4} V/m;

(b) **limits related to** effects of phosphenes and minor changes in some brain activity for frequencies up to 400 Hz on the central nervous system in the head:

- from 1 Hz up to 10 Hz - 0.5/f V/m;
- from 10 Hz up to 25 Hz - 0.05 V/m;
- from 25 Hz up to 400 Hz - 0.002 f V/m;

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31 **This explanation refers to questions raised by <u>CZ and FI</u>: Clarification suggested by experts, (see also comments at page 7 and 8 of this document).**

32 **More precise term suggested by experts.**

33 **This explanation refers to comments made by the <u>UK</u>: Suggested by experts in order to avoid a misinterpretation of the notion of "thresholds".**

Where justified by the practice or process, exposure limits specified **for frequencies up to 400 Hz** can be temporarily exceeded during the shift, provided that **direct excitation does not occur**[34] and protection and prevention measures and information to workers have been adopted. In this case the workers shall soon report the occurrence of transient symptoms related to effects in central nervous system of the head to the employer, who shall update, if necessary, risk assessment and protection and prevention measures.

Note A1-6: ELV-E_2 and ELV-B_2 are derived from the following **limits** related to internal thermal effects cause by exposure to electromagnetic field of frequencies from 100 kHz up to 10 GHz and are given as RMS values of SAR (in W/kg) and averaged over any 6-minutes:

(a) **limit related to** whole body heat stress expressed as averaged SAR in the body: 0.4 W/kg;

(b) **limit related to** head and trunk localised heat stress expressed as localised SAR in the body: 10 W/kg;

(c) **limit related to** limbs localised heat stress expressed as localised SAR in the limbs: 20 W/kg.

Where: localised SAR averaging mass is any 10 g of contiguous tissue; the maximum SAR so obtained should be the value used for estimating exposure. These 10 g of tissue are intended to be a mass of contiguous tissue with nearly homogeneous electrical properties. In specifying a contiguous mass of tissue, it is recognised that this concept can be used in computational dosimetry but may present difficulties for direct physical measurements. A simple geometry such as cubic tissue mass can be used provided that the calculated dosimetric quantities have conservative values relative to the exposure guidelines.

[34] **Following a suggestion by <u>IT</u>, the text has been made clearer to better match the concept of ICNIRP.**

For the pulsed exposure in the frequency range 10 MHz - 10 GHz the maximum peak in time should not exceed values of ELV-E_2 and ELV-B_2 multiplied by 32.[35]

For pulsed exposures in the frequency range 0.3 to 10 GHz and for localised exposure of the head in order to limit and avoid auditory effects caused by thermo elastic expansion, an additional exposure limit value is recommended. This is that the SA should not exceed 10 mJ/kg averaged over 10 g of tissue.

Note A1-7: In case of non-sinusoidal time variability of E-field or B-field the frequency composition (harmonics) of ELV-E_2 and ELV-B_2 shall be counted according to relevant international guidelines**, covering in particular summation of weighted components and time averaging of squared components**.[36]

Note A1-8: ELV-S for power density in the frequency range 10 GHz – 300 GHz are provided to prevent excessive tissue heating at or near the body surface. Power densities are to be averaged over any 20 cm^2 of exposed area and any 50/f-minute period (where f is in GHz) to compensate for progressively shorter penetration depth as the frequency increases. Spatial maximum power densities averaged over 1 cm^2 should not exceed 20 times the value of 50 W/m^2.

Note 9: […]

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[35] **For frequencies up to 10 MHz the peak value is already limited by ELV-E_1 and ELV-B_1.**

[36] **Following comments by experts and by NL, a text has been added to make the provision clearer.**

B. ACTION LEVELS

[…]

The following physical quantities and values are used to specify the Action Levels (ALs), the magnitude of which is established to ensure by simplified assessment the compliance with relevant exposure limit values or at which relevant protection or prevention measures specified in this Directive must be taken (compliance will all ALs shall be demonstrated under Article 5 of this Directive):

- AL-E_1 and AL-E_2 and AL-E_3 for electric field strength E of time varying electric field as specified in Table B1;

- AL-B_1 and AL-B_2 and AL-B_3 and AL-B_4 for magnetic flux density B of time varying magnetic field as specified in Table B2;

- AL-I_L for limb current as specified in Table B3;

- AL-B_0 for magnetic flux density of static magnetic field as specified in Table B4.

Action Levels correspond to estimated or measured field values at the workplace in absence of the worker, as maximum value at the worker position.

In case of exposure to electromagnetic field non-homogeneous in space when exposure effects in the body are reduced, when relevant ALs are exceeded it is still possible the compliance of workers' exposure with Exposure Limit Values as specified in Table A1. The compliance may be shown with the use of scientifically proven exposure assessment procedures or safety-related data, which refer to spatial distribution of the field and principles specified in corresponding Note A1-5 and Note A1-6, derived from international safety guidelines of International Commission on Non-Ionizing Radiation Protection (ICNIRP). [37] [38]

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[37] http://www.icnirp.org/PubEMF.htm

[38] **Text compiled from Note A1-9, while taking into account suggestions by <u>BG, DK, FR, IT, NL, HU, AT, SI, FI, SE and UK</u> to in order to clarify the relation among ELVs and SAR and Ein. limits.**

When applying, the assessment of the measurement results shall take into account the measurement uncertainties determined in accordance with metrological practice.

Table B1. Action Levels for exposure to **electric field**

Frequency range	Electric field strength $AL\text{-}E_1$ [V/m]	Electric field strength $AL\text{-}E_2$[39] [V/m]	Electric field strength $AL\text{-}E_3$ [V/m]
1 – 8 Hz	2.8×10^4	2.8×10^4	*NA*
8 – 25 Hz	2.8×10^4	2.8×10^4	*NA*
25 – 100 Hz	7.0×10^5 /f	2.8×10^4	*NA*
100 - **400** Hz	7.0×10^5 /f	2.8×10^8 / f^2	*NA*
[…]	**[…]**	**[…]**	**[…]**
400 Hz - 3 kHz	**7.0×10^5 /f**	[...] *NA*	*NA*
3 – 100 kHz	2.4×10^2	**[...] *NA***	*NA*
100 kHz – 1 MHz	2.4×10^2	**[...] *NA***	6.1×10^2
1 – 10 MHz	2.4×10^2	**[...] *NA***	6.1×10^8 /f
10 – 400 MHz	*NA*	*NA*	61
400 MHz – 2 GHz	*NA*	*NA*	3×10^{-3} $f^{1/2}$
2 – 300 GHz	*NA*	*NA*	1.4×10^2

Note B1-1: f is the frequency expressed in hertz (Hz).

Note B1-2: *NA* means not applicable.

Note B1-3: $AL\text{-}E_1$ and $EL\text{-}E_2$ values correspond to the peak in time E-field values (**[…] see** Note **A1**-4).

[39] **Taking into account comments related to the justification of these limits, Psv does not support the FR suggestion to delete it.**

Note B1-4: AL-E_1 correspond to ELV-E_1 derived from both **limits related to** electrical stimulation of tissues on all peripheral and central nervous system tissues in the body including head; the compliance with such thresholds prevents also phosphenes and minor changes in brain activity for frequencies up to 400 Hz.

Note B1-5: AL-E_2 are applicable where justified by the practice or process; **in the case of electromagnetic fields of frequency up to 400 Hz**, exposure limits ELV-E_1 can be temporarily exceeded during the shift, provided **[…] direct excitation does not occur** and protection and prevention measures and information to workers **have** been adopted. **Compliance with AL-E_2 ensures direct excitation does not occur, in particular when maximum exposure over worker body position is not related to the head exposure.** In this case the workers shall soon report the occurrence of transient symptoms related to effects in central nervous system of the head to the employer, who shall update, if necessary, risk assessment and protection and prevention measures.[40]

Note B1-6: The action levels for electric fields for the frequency range 1-100 Hz are set to limit the risk of indirect effects which are spark discharges which may occur when a worker comes into contact with a conducting object at a different electrical potential. Where the risk of spark discharges is managed using technical means and the training of workers, exposures in excess of action values can be accepted provided that the exposure limit values are not exceeded, in accordance with Article 5(5).

Note B1-7: AL-E_3 correspond **to** ELV-E_2 derived from the thresholds related to internal thermal effects cause by exposure to electromagnetic field **(see Note A1-6 and Note A1-7).**
[…]

[…][41]

[40] **Clarification based on suggestions by IT.**
[41] **Already covered by the modified Note B1-7.**

Note B2-9: ALs are to represent maximum estimated or measured values at workers body position, corresponding measurement results by isotropic E-field app. 5-**12** cm diameter according to relevant metrological practice[42].

Table B2. Action Levels for exposure to **magnetic field**

Frequency range	Magnetic flux density AL-B_1 [μT]	Magnetic flux density[43] AL-B_2 [μT]	Magnetic flux density (limbs only)[44] AL-B_3 [μT]	Magnetic flux density AL-B_4 [μT]
1 – 8 Hz	$2.8 \times 10^5 / f^2$	$4.2 \times 10^5 / f$[45]	$8.4 \times 10^5 / f^2$	*NA*
8 – 25 Hz	$3.5 \times 10^4 / f$	$4.2 \times 10^5 / f$	$1.0 \times 10^5 / f$	*NA*
25 – 300 Hz	1.4×10^3	$4.2 \times 10^5 / f$	4.2×10^3	*NA*
300 – 3 kHz	$4.2 \times 10^5 / f$	**[...]** ***NA***	$1.3 \times 10^6 / f$	*NA*
3 – 100 kHz	1.4×10^2	**[...]** ***NA***	4.2×10^2	*NA*
100 kHz – 1 MHz	1.4×10^2	**[...]** ***NA***	4.2×10^2	$2.0 \times 10^6 / f$
1 – 10 MHz	1.4×10^2	**[...]** ***NA***	4.2×10^2	$2.0 \times 10^6 / f$
10 – 400 MHz	*NA*	*NA*	*NA*	0.2
400 MHz – 2 GHz	*NA*	*NA*	*NA*	$1.0 \times 10^{-5} f^{1/2}$
2 – 300 GHz	*NA*	*NA*	*NA*	4.5×10^{-1}

Note B2-1: f is the frequency expressed in hertz (Hz).

Note B2-2: *NA* means not applicable.

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42 **Suggested by experts in order to ensure a better harmonization with metrological practice.**

43 **Taking account comments related to the justification of these limits, Psy does not support the FR suggestion to delete it.**

44 **The use of 3xAL-B_2 for limbs localised exposure, as suggested by the UK, instead of 3xAL-B_1 is acceptable provided that is already decided to keep AL-B_2 limits in the Directive (see com. No 44).**

45 **Following a suggestion by SE, the formula has been corrected.**

Note B2-3: AL-B_1 and AL-B_2 and AL-B_3 values correspond to the peak in time B-field values (**[…]** see Note A1-4).

Note B2-4: AL-B_1 correspond to ELV-B_1 derived from both **limits related to** electrical stimulation of tissues on all peripheral and central nervous system tissues in the body including head; the compliance with such thresholds prevents also phosphenes and minor changes in brain activity for frequencies up to 400 Hz.

Note B2-5: AL-B_2 are applicable where justified by the practice or process; **in case of electromagnetic fields of frequency up to 400 Hz**, exposure limits ELV-B_1 can be temporarily exceeded during the shift, provided **direct excitation does not occur […]** and protection and prevention measures and information to workers have been adopted. **Compliance with AL-B_2 ensures direct excitation does not occur, in particular when maximum exposure over worker body position is not related to the head exposure.**[46] In this case the workers shall soon report the occurrence of transient symptoms related to effects in central nervous system of the head to the employer, who shall update, if necessary, risk assessment and protection and prevention measures.

Note B2-6: AL-B_3 are applicable to localized limbs exposure significantly exceeding the torso and head exposure.

Note B2-7: AL-B_4 are corresponds ELV-B_2 derived from the thresholds related to internal thermal effects cause by exposure to electromagnetic field **(see Note A1-6 and A1-7) [...].**

[...][47]

Note B2-8: Magnetic field may be expressed by magnetic flux density B or alternatively by magnetic field strength H. ALs are to represent maximum values at workers body position, corresponding measurement results by isotropic B-field or H-field of app. 5-**12** cm diameter according to relevant metrological practice.

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46 **Clarification based on suggestions by IT.**

47 **Already covered in the modified Note B1-7.**

Table B3.[48] Action Level for **limb current I_L**

Frequency	Limb current action level, AL-I_L [mA]
up to 2.5 kHz	1.0
2.5-100 kHz	0.4 *f*
100 kHz – 110 MHz	40

Note B3-1: *f* is the frequency in kHz.

Note B3-2: AL-I_L specified in the table referred to root-mean-square (RMS) value of a current flowing through each hand of exposed worker.

Note B3-3: AL-I_L specified in the table referred to values averaged over 6-minutes period for the frequency range 100 kHz – 110 MHz.

Note B3-4: In case of assessing a current flowing through each foot of exposed worker AL-I_L specified in the table shall be multiply by 2.5.

Note B3-5: In case of assessing a current flowing through other than limb part of worker body be in contact with an exposed object, AL-I_L specified in the table shall apply.

[48] **An explanation concerning the comments by FI was already presented on page 9 of this document; nevertheless, a completed proposal by FI which could replace equivalently limits set in Table B3 and Notes B3-1 to B3-5 is also welcomed.**

Table B4. Action Levels for exposure to **static magnetic field**

Hazards	Action Level AL-B_0
Active implanted devices, e.g. cardiac peacemakers	0.5 mT
Ballistic hazards (so-called flying objects)[49]	3 mT
Movements related effects[50]	1**.3** T
Localised limbs exposure	8 T

Note B4-1: Where justified by the practice or process, exposure of head and trunk up to 8 T can be temporarily permitted during the shift, provided preventive measures and information to workers has been adopted. In this case the workers shall soon report the occurrence of transient symptoms such as nausea and vertigo, related to movement induced effects, to the employer, who shall update, if necessary, the risk assessment and the preventive measures".

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[49] **This explanation concerns comments by NL: In the literature all terms are used: ballistic, flying objects and projectile; taking into account that the term "projectile" creates linguistic problems in translations, it has been suggested to use the terms "ballistic and flying objects".**

[50] **This explanation concerns comments by NL: - There is no conflict between the proposed action level related to movement related effects and a mentioned publication by Prof. Kari Jokela [Health Physics 6, 2011]. The publication refers to modelling of movement related effects of exposure to static magnetic field in the case of "normal head and/or body movement" [see Health Physics 6, 2011,page 651]. As MRI worker's reports identified, in the case of rapid movements, even when using 1.5T scanners, effects may occur, there is a need to cover 1.5T scanners to avoid these hazards. To make clearer that in the case of 1T scanners such problems rather do not occur, it was suggested to modify AL to a bit higher level, but well below 1.5T.**