

***Who are the groups with special needs?  
Should minor or under aged workers be treated as  
general public? Different rules in different countries.  
How to deal with pregnant workers?***

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***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)***

***Introduces minimum requirements, for the protection of workers from the established health effects of EMFs including exposure limits and action values***

***Compliance with limit values “will ensure that workers exposed to electromagnetic fields are protected against all known adverse health effects” (Art. 2 b).***

***In any event, workers shall not be exposed above the exposure limit values (Art. 5, comma 4).***



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**Article 3. Exposure limit values and action values**

***The Directive introduce exposure limits values are introduced to protect workers from the established health effects of EMFs***

***But, the compliance of exposure limits and action values, may not protect specific groups of “workers at particular risk”***

***The 2004/40/EC does not give specific limits or action values for these workers “with special needs”***

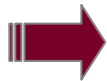


# Article 4. Determination of exposure and assessment of risks

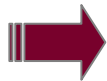
## Comma 5.

Pursuant to Article 6(3) of Directive 89/391/EEC, (General obligations on employers), **the employer shall give particular attention**, when carrying out the risk assessment, to the following:

.....



(c) any effects concerning the health and safety of **workers at particular risk**;



(d) any **indirect effects**, such as:

(i) **interference** with medical electronic equipment and devices (including cardiac pacemakers and other implanted devices);

.....



(f) appropriate information obtained from health surveillance, including published information, as far as possible;



## Article 5. Provisions aimed at avoiding or reducing risks

1. Taking account of technical progress and of the availability of measures to control the risk at source, **the risks arising from exposure to electromagnetic fields shall be eliminated or reduced to a minimum.**

.....

5. Pursuant to Article 15 of Directive 89/391/EEC, **the employer shall adapt the measures referred to in this Article to the requirements of workers at particular risk.**



# **“Workers at particular risk”**

***not defined in the Directive 2004/40/EC!***



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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

.....

Whereas:

.....

- .....
- (8) Employers should make adjustments in the light of technical progress and scientific knowledge regarding risks related to exposure to electromagnetic fields, with a view to improving the safety and health protection of workers.**



## Article 4. Determination of exposure and assessment of risks

### Comma 5.

Pursuant to Article 6(3) of Directive 89/391/EEC (General obligations on employers), the employer **shall give particular attention**, when carrying out the risk assessment, to the following:

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➡ (c) any effects concerning the health and safety of workers at particular risk;

➡ (d) any indirect effects, such as:

(i) **interference** with medical electronic equipment and devices (including cardiac pacemakers and other implanted devices);

.....

➡ (f) **appropriate information obtained from health surveillance, including published information, as far as possible**;



# **“Workers at particular risk”**

***Workers at “particular risk” not defined in the Directive 2004/40/EC***

***Currently, a shared comprehensive definition of the workers that can be considered at “particular risk” is lacking***



## PARTICULAR (HIGHER) RISK:

definition based on **knowledge**  
**on mechanisms** for adverse health effects induction

- *To date, the main **assessed mechanisms underlying adverse effects**, which have been considered in the definition of safety guidelines, are **magnetic induction** and **magnetomechanical effect** for static fields, the **ion motion** under the action of the electric field for low frequencies and the **energy transfer**, leading to a temperature increase, for radiofrequency fields (EMF-NET,2008, ICNIRP, 2009; R. Matthes, 2009)*
- *These mechanisms can induce acute effects*



## PARTICULAR RISK:

definition based on **knowledge on mechanisms** for adverse health effects induction

- *In spite of the great number of proposed models, except ion motion and thermal interaction, there **is not yet a specific mechanism able to link the action of the EM field** at different complexity levels, from the first interaction step, at molecular level, up to some **adverse effects on organism health***
- *In this context, further research work, including both theoretical and experimental activities, seems to be necessary (EMF-NET, 2008)*



## **PARTICULAR RISK:**

definition based on **knowledge**  
**on mechanisms** for adverse health effects induction

## **INDIRECT EFFECTS**

*The employer shall give particular attention to the **indirect effects** such as:*

- *interference with medical electronic equipment and devices (including cardiac pacemakers and other implanted devices)*
- *the projectile risk from ferromagnetic objects (static magnetic fields with magnetic flux density greater than some mT)*

*(art. 4, comma 5d)*



# MECHANISMS FOR ADVERSE HEALTH EFFECTS INDUCTION

## DIRECT EFFECTS

- *some scientific results suggest that some 5-10/100.000 people is particularly susceptible to re-entrant arrhythmia (van Rongen et al, 2007; Matthes, UMEA 2009) or that ELF may influence convulsion susceptibility in animals (Sung et al, 2003; Jeong et al, 2005) but scant data available in this field*
- *no adequate scientific data in groups of workers are available showing that specific physiological or pathological conditions can induce a significant increase in susceptibility of subjects to **magnetic induction** and **magnetomechanical effect** for static fields, **ion motion** and **thermal interaction***
- ***These aspects deserve further scientific development***



# MECHANISMS FOR ADVERSE HEALTH EFFECTS INDUCTION

## Interference

***Another established mechanisms of EMF-related adverse effects***

***The risk related to possible interference of EMF with active implantable medical devices, as pacemakers, is well known***

***Nevertheless, other implanted medical devices and, in principle, most medical metal implant or fragment, may pose a risk***

***Different mechanisms can be involved in the induction of such adverse effects, e.g. interference plays a role in the case of active electronic devices, but other, as thermal effect or magnetomechanical effect (e.g. see van Rongen et al, 2007), can be involved in the case e.g. of metal implants, or metallic fragments***



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***(12)***

***Adherence to the exposure limit and action values should provide a high level of protection as regards the established health effects that may result from exposure to electromagnetic fields but such adherence **may not necessarily avoid interference problems with, or effects on the functioning of, medical devices such as metallic prostheses, cardiac pacemakers and defibrillators, cochlear implants and other implants; interference problems especially with pacemakers may occur at levels below the action values and should therefore be the object of appropriate precautions and protective measures*****



**Implants, devices, or objects that may be hazardous and/or interfere with MRI**  
**(NB: not a list of higher risk conditions)** **(from MRIsafety.com, modified)**

<p><b>Cardiac pacemaker</b>  <b>Implanted cardioverter</b>  <b>defibrillator (ICD)</b>          Electronic implant/device          Magnetically-activated          implant/device          Neurostimulation system          Spinal cord stimulator          Internal electrodes or wires          Bone growth/bone fusion          stimulator  <b>Cochlear, otologic, or other</b>  <b>ear implant</b>          Insulin or other infusion pump          Implanted drug infusion          device</p>	<p>Any type of prosthesis (eye,  penile, etc.)  Heart valve prosthesis  Eyelid spring or wire  Artificial or prosthetic limb  Metallic stent, filter, or coil  Shunt (spinal or  intraventricular)  Vascular access port and/or  catheter  Radiation seeds or implants  Swan-Ganz or thermodilution  catheter  Medication patch (Nicotine,  Nitroglycerine)</p>	<p>Any metallic fragment or  foreign body  Wire mesh implant  Tissue expander (e.g.,  breast)  Surgical staples, clips, or  metallic sutures  Joint replacement (hip, knee,  etc.)  Bone/joint pin, screw, nail,  wire, plate, etc.  IUD, diaphragm, or pessary  Dentures or partial plates  Tattoo or permanent makeup  Body piercing jewelry  Hearing aid</p>
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# MECHANISMS FOR ADVERSE HEALTH EFFECTS INDUCTION

*The risk related to possible interference of EMF with active implantable medical devices, as pacemakers, is well known*

*Nevertheless, other implanted medical devices and, in principle, most medical metal implant or metallic fragment, may pose a risk*

*Different mechanisms can be involved in the induction of such adverse effects, e.g. interference plays a role in the case of active electronic devices, but other, as thermal effect (Hocking, Umea 2009) or magnetomechanical effect (van Rongen et al, 2007, Matthes, UMEA 2009), can be involved in the case e.g. of metal implants, or metallic fragments*



***Thresholds are variable, depending on the specific type of device or fragment, type of field, etc.***

***An adequate protection of these workers deserves an evaluation on an individual basis of the specific device or implant, and of the specific EMF exposure***

***Competence from different scientific background may be needed for an adequate management***





**Workers at particular risk:  
Pregnant workers**

***Pregnant workers are currently considered as  
“workers at particular risk”***

***The EMF Directive does not give any specific limit  
values or action values for pregnant workers***





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## **Workers at particular risk: Pregnant workers**

*In the **ELF** range, the overall evidence for developmental effects and for reproductive effects is inadequate (WHO, 2007), even if it is recognized the need of further research on induced electric fields in pregnant women and in the fetus, in order to assess possible enhanced induction of electric fields during fetal life (COST281; 2006)*

*In the case of **RF** no adverse effects on reproductive outcomes have been substantiated (ICNIRP 2009), but further development of dosimetric models of children of different ages and of pregnant women is considered opportune (COST281 seminar on EMF, 2006);*

*NB: below thermal levels!*



**LETTER FROM THE HEAD OF UNIT DG EMPL/D/4  
TO THE TECHNICAL DIRECTOR OF CENELEC**

Reference: Empl/D/4/TM/adg/D(2004)22661 –12.10.2004

***“CEN, CENELEC and ETSI shall take into account the limit values and action values laid down in Directive 2004/40/EC. This directive does not foresee **specific limit values or action values for pregnant workers.** Therefore, the only binding occupational limit and action values are those laid down in Directive 2004/40/EC***



Reference: Empl/D/4/TM/adg/D(2004)22661 –12.10.2004

*Of course, under Directive 92/85/EEC on the introduction of measures to encourage **improvements in the safety and health** at work of **pregnant workers** and workers who have recently given birth or are breastfeeding (tenth individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC), **the employer is obliged to assess in detail any specific risk of exposure of pregnant workers, in particular the exposure to non-ionizing radiation in order to decide what measures should be taken, including the moving of the worker concerned or the granting of a leave** (Articles 4, 5 and 6 and Annexes I and II of Directive 92/85/EEC).*



***According to the Directive 92/85/EEC, the employer must assess any specific risk of exposure of pregnant workers, including exposure to non-ionizing radiation (annex I, A, 1)***

***Based on this risk assessment, the employer shall decide adequate measures, including***

- moving of the worker to other job***
- granting of a leave***



## **Annex I A:**

**1. Physical agents where these are regarded as agents causing foetal lesions and/or likely to disrupt placental attachment, and in particular:**

**(a) shocks, vibration or movement**

**(b) handling of loads entailing risks**

**(c) noise**

**(d) ionizing radiation**

**(e) *non-ionizing radiation***

**(f) extremes of cold or heat**

**(g) movements and postures, travelling, mental and physical fatigue and other physical burden**



## ***Minor or under aged workers***

- ***Scant scientific data available on susceptibility to EMF of minor workers***
- ***longer cumulative exposure and, possibly, an higher susceptibility of nervous system?***
- ***the EMF Directive does not give any specific limit values or action values or indications***
- ***There is specific Directive: 94/33/EC of 22 June 1994 on the protection of young people at work; in this Directive, at least “Work involving high-voltage electrical hazards” is specifically cited (Annex II)***
- ***rules in different countries?***
- ***Problem probably limited from the practical point of view: in most high exposure activities few under age (if any)***



# A problem in definition of workers at particular risk: Have we to account of (suspected) **CHRONIC EFFECTS?**

(Schüz, Umea, 2009)



**ELF**

**Possible carcinogen (IARC 2B) childhood leukemia;**  
**Lower evidence leukemia in workers, brain cancer;**  
**Amyotrophic Lateral Sclerosis; Alzheimer's disease**



**RF**

**some data supporting the need of further research on**  
**some slow-growing tumors (meningioma, acoustic**  
**neuroma) and also of glioma use of among long-term**  
**users of mobile phones (> 10 y)**



## Have we to account for (suspected) *CHRONIC EFFECTS*?



**ELF**

*Should workers with diagnosed myelodysplastic syndrome, leukemia, brain cancer, neurodegenerative diseases, as Amyotrophic Lateral Sclerosis, Alzheimer's disease considered "at special risk"?*



**RF**

*Should workers with diagnosed brain tumors considered "at special risk"?*



# CONCLUSIONS (1)

- *Even if an agreement exists for some cases (e.g. pacemakers or implanted metal devices), a shared comprehensive definition of the workers that can be considered at “particular risk” is lacking*
- *An adequate protection of these workers deserves an evaluation on an individual basis; sometimes not simple*



# CONCLUSIONS (1)

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- *An adequate protection of these workers deserves an evaluation on an individual basis; sometimes not simple*
- *Pregnant workers: no specific limits, scant scientific data; Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding*



# CONCLUSIONS (1)

- *Even if an agreement exists for some cases (e.g. pacemakers or implanted metal devices), a shared comprehensive definition of the workers that can be considered at “particular risk” is lacking*
- *An adequate protection of these workers deserves an evaluation on an individual basis; sometimes not simple*
- *Pregnant workers: scant scientific data; no specific limits; Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding*
- *Minors/underaged workers: scant scientific data; no specific limits; Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work*



## CONCLUSIONS (2a)

**Employer:** central, formal role in the management of “groups at particular risk”: evaluation of exposure and risk assessment, elimination, or reduction, of EMF risk

**A pivotal role is played by the occupational physician:**

- conditions inducing “special needs” are **mostly medical**
- risk assessment must consider “appropriate information obtained from **health surveillance**” and a reassessment shall be carried out if an **health damage resulting from EMF exposure is detected**



## CONCLUSIONS (2b)

- *sound scientific data on groups at higher risk are insufficient to date, and do not give enough support to the occupational physician to adequately face the problem of the definition of groups with special needs, and of the protection*
- *large effort is on going to adopt shared and harmonized procedures for EMF risk evaluation and protection measures, but less effort, if any, for harmonization of “medical management”*



## CONCLUSIONS (2b)

- *sound scientific data on groups at higher risk are insufficient to date, and do not give enough support to the occupational physician to adequately face the problem of the definition of groups with special needs, and of the protection*
- *large effort is on going to adopt shared and harmonized measures for EMF risk evaluation and protection measures, but less effort, if any, for harmonization of “medical management”*
- *there is an evident and urgent need for the development of a shared medical approach and management of the problem of “particularly susceptible workers” (ethical reasons)*
- *ad hoc working group on this topic?*



# APPROPRIATE EXPOSURE METRIC?

***ELF-MF exposure in two workers engaged in different tasks (sewing machine worker and substation electrician): in both TWA is 0.38  $\mu$ T***

