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Protection of MRI workers within the Directive: possible solutions

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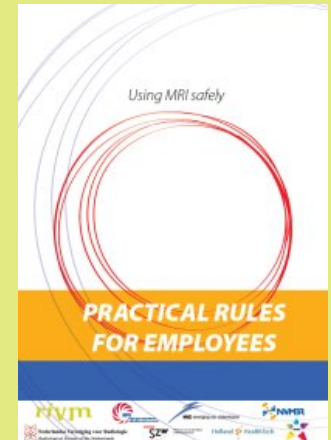
Background:

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)

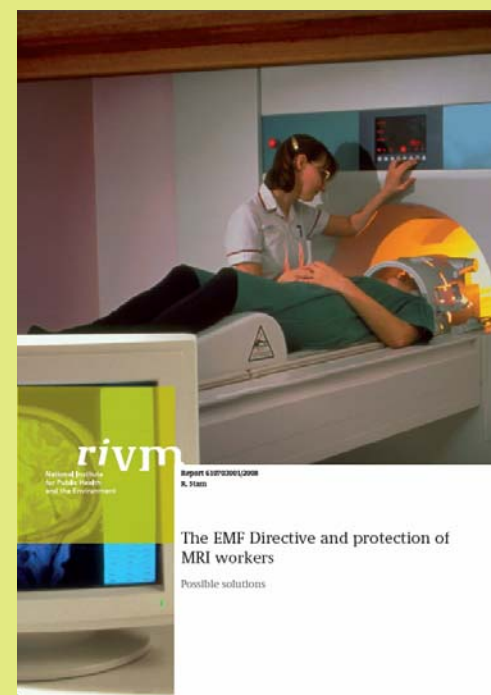
Autumn 2007: Dutch Ministry of Social Affairs and employment (SZW) asks RIVM to

- a) facilitate development of a national MRI safety protocol
- b) provide a scientific report on published exposure measurements, the MRI situation in the Netherlands and possibilities for new Directive [*this presentation*]



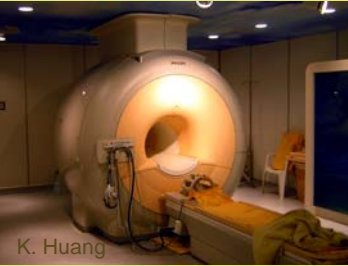
Methods

- analysis of peer-reviewed publications, official reports on exposure assessments and effects of MRI-related EMF
- national interviews and site visits to MRI departments
- international interviews with MRI and EMF exposure experts
- scientific peer review of draft report
- internal review and quality check of corrected draft
- publication as RIVM report (December 2008)



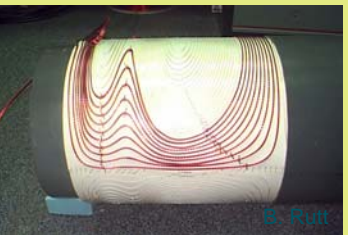
download report:
<http://www.rivm.nl/bibliotheek/rapporten/610703001.html>

MRI: biological effects and health risks



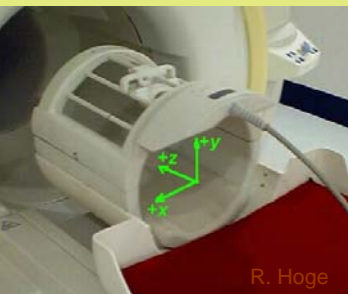
- *static field:*

movement-induced currents, subjective symptoms (vertigo, nausea, phosphenes), cardiovascular effects (above 8 T), altered nervous system functions?



- *gradient fields:*

induced currents, peripheral nerve stimulation (unpleasant to painful), altered electrical function of the heart, altered nervous system functions?



- *RF field:*

deposition of energy as heat: discomfort, altered physiological functions (general heat stress, local tissue overheating)

Exposure limit values in Directive 2004/40/EC

Exposure limit values (Article 3(1)). All conditions to be satisfied

Frequency range	Current density for head and trunk J (mA/m ²) (rms)	Whole body average SAR (W/kg)	Localised SAR (head and trunk) (W/kg)	Localised SAR (limbs) (W/kg)	Power density S (W/m ²)
Up to 1 Hz	40	—	—	—	—
1 — 4 Hz	40/f	—	—	—	—
4 — 1 000 Hz	10	—	—	—	—
1 000 Hz — 100 kHz	f/100	—	—	—	—
100 kHz — 10 MHz	f/100	0,4	10	20	—
10 MHz — 10 GHz	—	0,4	10	20	—
10 — 300 GHz	—	—	—	—	50

movement in static field

gradient fields

RF field

Action values in Directive 2004/40/EC

Action values (Article 3(2)) (unperturbed rms values)

Frequency range	Electric field strength, E (V/m)	Magnetic field strength, H (A/m)	Magnetic flux density, B (μT)	Equivalent plane wave power density, S_{eq} (W/m ²)	Contact current, I_c (mA)	Limb induced current, I_l (mA)
0 — 1Hz	—	$1,63 \times 10^5$	2×10^5	—	1,0	—
1 — 8 Hz	20 000	$1,63 \times 10^5 / f^2$	$2 \times 10^5 / f^2$	—	1,0	—
8 — 25 Hz	20 000	$2 \times 10^4 / f$	$2,5 \times 10^4 / f$	—	1,0	—
0,025 — 0,82kHz	$500 / f$	$20 / f$	$25 / f$	—	1,0	—
0,82 — 2,5 kHz	610	24,4	30,7	—	1,0	—
2,5 — 65 kHz	610	24,4	30,7	—	$0,4 f$	—
65 — 100 kHz	610	$1\ 600 / f$	$2\ 000 / f$	—	$0,4 f$	—
0,1 — 1 MHz	610	$1,6 / f$	$2 / f$	—	40	—
1 — 10 MHz	$610 / f$	$1,6 / f$	$2 / f$	—	40	—
10 — 110 MHz	61	0,16	0,2	—	40	100
110 — 400 MHz	61	0,16	0,2	10	—	—
400 — 2 000 MHz	$3 f^2$	$0,008 f^2$	$0,01 f^2$	$f / 40$	—	—
2 — 300 GHz	137	0,36	0,45	50	—	—

static field

movement in static field

gradient fields

RF field

Exposure measurements 1: human

static field:

- 0.2 T action value exceeded near bore end
- 0.2 T working day average not exceeded
- new ICNIRP 2 T limit not exceeded for systems ≤ 4 T
- new ICNIRP 8 T limit for controlled conditions not exceeded
- exposure limit value for induced current in central nervous system exceeded when moving near or into bore end



Exposure measurements 1: human

gradient fields:

- exposure limit value for induced current in central nervous system exceeded inside bore or close to bore end

RF field:

- RF exposure outside magnet bore, bending into bore end remains under exposure limit value (up to few minutes)
- exposure limit value whole body, local head SAR likely exceeded lying inside magnet bore in patient position
- at higher frequencies (ultra-high static field): hot spots?

Exposure measurements 2: non-human

veterinary MRI:

Netherlands: mostly small animal whole body scans or large animal leg scans; low static field (< 0.3 T) and worker procedures make exceeding limits unlikely

small laboratory animal MRI:

small diameter of magnet bore (≤ 30 cm), small stray fields; based on available data: static field $>$ action value, but < 2 T; gradient fields $<$ action value; RF field $<$ action value; calculations for movement-induced current are needed

dedicated MR spectroscopy ("NMR") systems

closed system, usually no gradients, RF outside negligible; static field $<$ action value due to active shielding

Possible solutions 1

optimisation of current MRI practice

- A. limitation of static field active shielding (movement) - unlikely to solve problem, increased projectile risk
- B. limitation of gradient field strength for close proximity - unlikely to solve problem, not possible for interventions
- C. improved scanner environment and working routines - will reduce number of workers with exposure above limits, but limits will still be exceeded in some situations

Possible solutions 2

alternative values for exposure limit/action values

A. *Static field:*

A1 Omit from Directive or provide voluntary guidelines, pending further research on health risks

A2 Provide static field exposure limits according to 2009 ICNIRP guidelines, but allow for future evaluation and rapid adjustment (2 T, 8 T controlled conditions)

Will not create problems for systems < 8 T

Future developments?

Possible solutions 2

alternative values for exposure limit/action values

B. EMF induced by movement in static field

B1 Provide clarification that limits in Directive do not apply to movement-induced EMF; instead these are covered by limits for static field flux density

B2 Provide clarification that limits apply to movement-induced EMF, and consider these effects in setting limits

B1: problem: current determined not by B, but product of dB/dx and movement speed (dx/dt)

B2: problem: subjective symptoms, widely varying sensitivity

Possible solutions 2

alternative values for exposure limit/action values

C. Low frequency EMF (gradient fields):

C1 Increase current density limits according to Health Council NL (rise to 100 mA/m² from 20-200 Hz)

C2 Increase current density limits according to nerve stimulation thresholds (appr. 1000 mA/m² from 0-10 kHz)

Will substantially reduce number of situations where limits are exceeded, but under C1 these will still occur (bending into bore)

Possible solutions 3

alternative parameters for exposure limit/action values

A. Low frequency EMF limits for induced electric (E) field

A1 Set E-field limits according to IEEE (or draft ICNIRP) guidelines, includes low-threshold effects on brain

A2 Set E-field limits according to risk for stimulation of nerve fibres

A1: limits likely to be exceeded, though less frequently than induced current limits

A2: limits unlikely to be exceeded for current systems and practice

Intermezzo: occupational exposure of MRI workers and 2009 draft ICNIRP low frequency guidelines

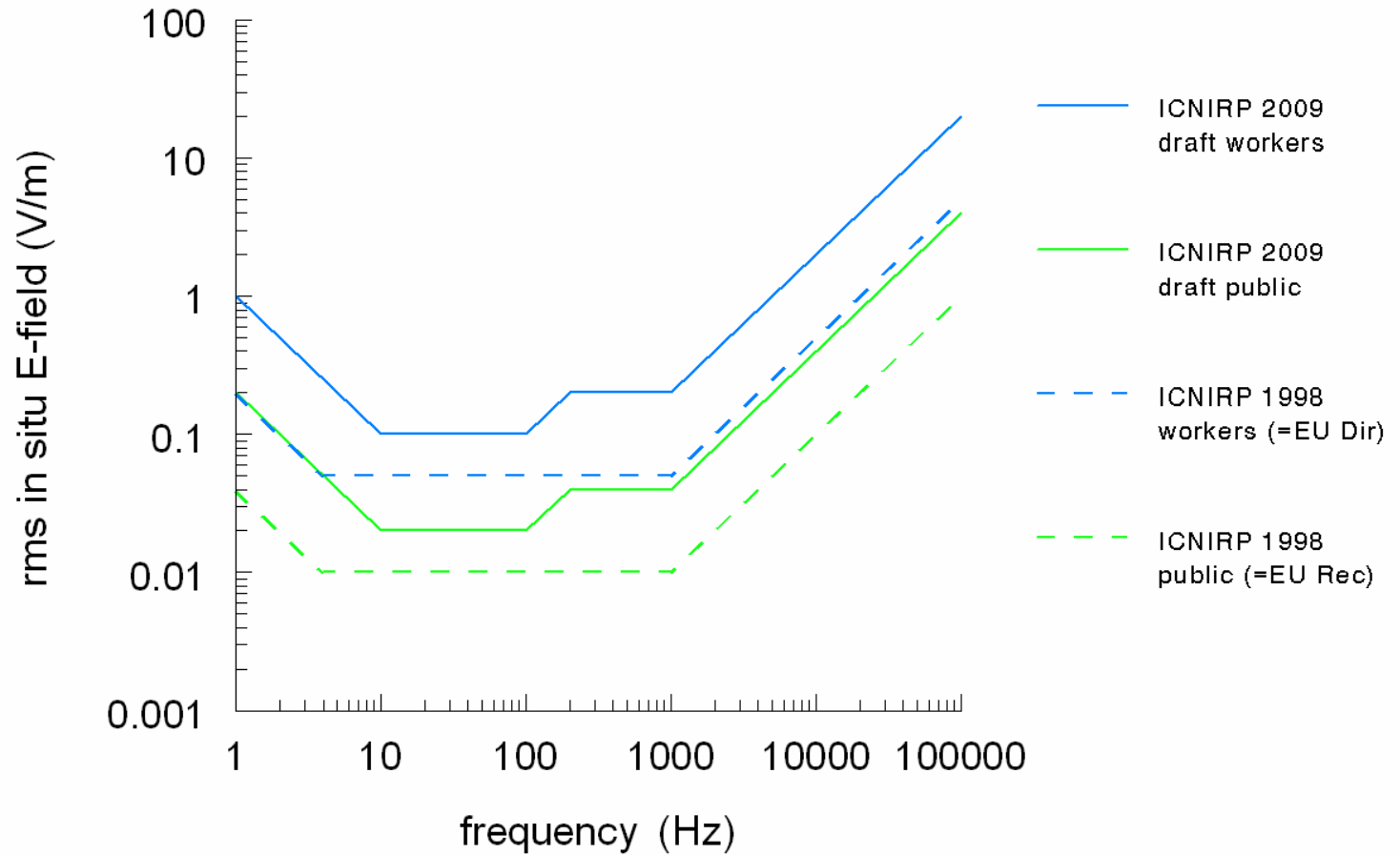
movement in static field: *basic restriction 1 V/m*

- "2009 ICNIRP *static field guidelines* should be applied to movement-induced electric fields"
- If not, exposure limit value for induced E-field (1 Hz) rarely exceeded inside or close to bore end

gradient fields: *basic restriction 0.2 V/m*

- exposure limit value for induced E-field in CNS exceeded inside bore or very close to bore end

ICNIRP basic restrictions



Possible solutions 4

two-level exposure limits

A. Higher level for certain categories of workers

B. Higher level for certain categories of tasks

- Basis: wide safety margins between high, potentially harmful and low, intrinsically harmless EMF strengths
- Upper limit could be set on basis of known risk of peripheral nerve stimulation
- Lower limit could be set on basis of low-threshold effects on brain with unknown significance for health
- Exposure between limits based on situation-dependent risk-benefit analysis, with additional control measures

Possible solutions 5

social sector agreements

- Solutions so far: inflexible with regard to developing technology and knowledge about health risks
- Basis: Directive will contain only general considerations for protection of workers against risks of EMF
- Specific exposure limits and behavioural rules will be set by social partners in a particular employment sector (e.g. hospitals & research facilities), assisted by experts
- Flexible procedures to adjust specific exposure limits, control measures or behavioural rules according to new scientific insights

Summary of possibilities:

1. accept present exposure limits, with 'minor' adjustments (ICNIRP, IEEE)
 - limitation of close proximity during scanning, and possibly of moving quickly in static field
2. create system with category of workers (or tasks) for which higher exposure limits and controlled working conditions are
 - defined at level of directive (*indicative* limits provide more flexibility for change than *legally binding* limits)
 - defined in social sector agreements at European level



Position Dutch Government

Exemption from the exposure limits most probably can be accepted for MRI, but only when social partners at European level have agreed about binding safety rules for that application.