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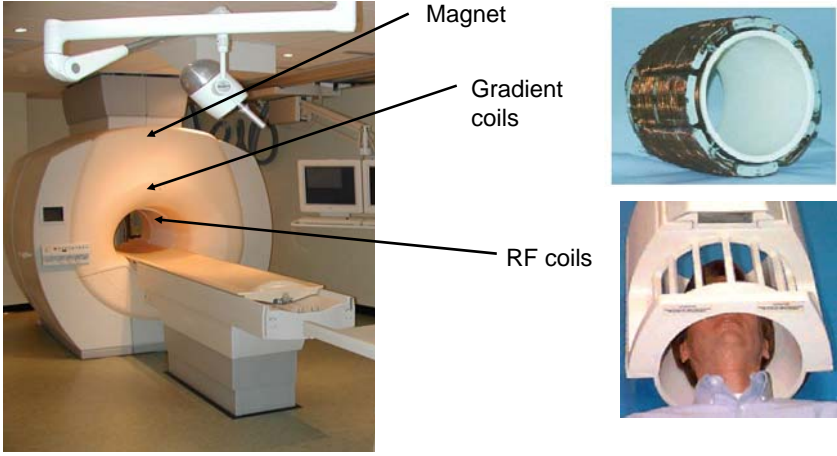
Project EMF-IMPACT Workshop, Ljubljana, 18th-19th February 2009

Policy options for amendment of Directive 2004/40/EC: assessment of impact on magnetic resonance imaging (MRI)

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on behalf of the Alliance for MRI

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Magnet

Gradient coils

RF coils


The diagram illustrates the components of an MRI machine. On the left, a photograph of an MRI scanner is shown with arrows pointing to the Magnet, Gradient coils, and RF coils. On the right, two inset images provide close-up views: the top one shows the Magnet, a large cylindrical structure, and the bottom one shows the RF coils, which are part of the patient's head and neck support structure.

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	Frequency	Exposure limit value (ELV)	Estimated maximum occupational exposure in MRI
Static magnetic field	0 Hz	None	3 T (clinical) 9.4 T (research)
	<1 Hz (typical) (due to movement)	Current density 40 mA ² head and trunk	200 – 400 mA ² (CNS) ¹ ELV exceeded 0.5 - 1 m from magnet if moving at 1 ms ⁻¹
Switched gradients	1 kHz (typical)	Current density 10 mA ² head and trunk	> 200 mA ² (CNS) ² ELV exceeded ≈ 1 m from end of gradient coils
RF	10s – 100s MHz	SAR 0.4 W kg ⁻¹ whole body 10 W kg ⁻¹ head and trunk 20 W kg ⁻¹ limbs All SAR values averaged over 6 mins, localised SAR averaged over 10g of tissue	Not expected to exceed ELV because of spatial and temporal averaging.

¹ Crozier S et al. J. Magn. Reson. Imaging 2007;26:1261-1277.
² Crozier S et al. J. Magn. Reson. Imaging 2007;26:1236-1254.

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In what situations are ELVs exceeded?			
<ul style="list-style-type: none"> ▪ Probably c. 300,000 patient examinations in the EU per year <ul style="list-style-type: none"> ▪ Imaging of vulnerable patients requiring monitoring, help or comfort during scan – children, elderly, anaesthetised... ▪ Some forms of functional MRI , e.g. deaf-blind subjects ▪ Interventional MR, performing clinical procedures during imaging ▪ Research work, adjusting apparatus during imaging ▪ Some servicing activities, performed with scanner operating ▪ Movement in static field: much wider impact on scanner construction, installation, patient set-up, servicing, cleaning... 			


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Groups of workers affected

- MRI radiographers / technologists – c. 10,000 in EU
- Radiologists, particularly interventionalists
- Anaesthetists
- Nurses , particularly anaesthetic nurses
- Research scientists
- Manufacturers' service personnel
- Other medical specialists?


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Residual risks not considered in the impact assessment

- Indirect effects of static magnetic field
 - Projectile effect
 - Risk to workers with active implanted medical devices (e.g. cardiac pacemakers)
 - Managed by means of safety rules, access controls, training...
- Acoustic noise
 - Generated by operation of switched gradients
 - Managed under Noise Directive (2003/10/EC)


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Safety record of MRI

- c. 500 million MRI examinations have been performed over 25 year
- There have been **very few** reports of adverse incidents or health effects (0.004% of scans in the UK in 2005)
 - RF burns to patients due to faults / operator error (40%)
 - Indirect static magnetic field effects (26%)
 - **Direct EMF effect:** peripheral nerve stimulation in patients (1%)
- Transient sensory effects sometimes reported by workers moving in static field, controlled by guidance on safe working practices
- IEC standard (60601-2-33), adopted as an EN standard harmonised to the Medical Devices Directive, addresses both patient and worker safety
- Local and national safety guidelines also exist

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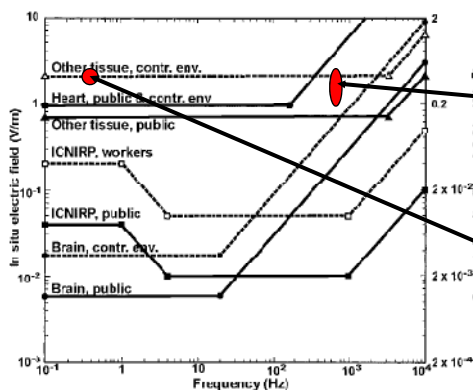


Option A: no new legislative action

- Health and social impact: a range of clinical procedures and practices will be prohibited
 - Some patient examinations not possible by other means
 - Others transferred to x-ray imaging: less effective and involves ionising radiation
 - **Movement in static field:** Servicing of equipment impractical
- Health and safety **detriment** to workers due to increased ionising radiation dose
- No perceivable health and safety benefit to workers
- Impact on medical research and innovation in EU
- Economic impact on MRI development and manufacturing base

Option B: binding legislation using latest international recommendations

- Assume MRI represents a 'controlled environment' in terms of the forthcoming ICNIRP static field guidelines, so limit of 8T applies
- Effects related to movement in the static field addressed through working practices, so **assume these effects are explicitly excluded from low frequency limits**
 - This aspect makes this option potentially less restrictive than option A
- Problem is what limits to use in the low frequency range?
- Have been asked to assume IEEE C95.6 limits




Reilly JP (2005) *Health Physics* **89** 71-80

Maximum occupational exposure due to switched gradients at 1 kHz

Maximum occupational exposure due to movement in static field up to ≈ 1 Hz


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Option B: binding legislation using latest international recommendations

- Addressing movement in static field would solve many of the servicing and manufacturing problems
- The IEEE limits are somewhat less restrictive in the frequency range relevant to switched gradients
- But the problems for clinical practice remain: impact similar to Option A
- Of course this conclusion depends on which international recommendations are used and what those recommendations say


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Option C: binding legislation using the latest international recommendations, with exemptions

- **Complete exemption** of MRI from all the requirements of the Directive
- This would satisfy the Alliance's request for a derogation for MRI
- It would **not** mean that MRI safety would be unregulated, which is not the intention of the Alliance
 - The risk assessment requirement would remain in place because of Directive 89/391/EEC
 - IEC 60601-2-33 and existing guidance on safe working practices would remain in place


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Option C: binding legislation using the latest international recommendations, with exemptions

- **Conditional exemption** of MRI, subject to risk assessment demonstrating that workers are protected without the need to meet the ELVs
- This could be demonstrated on the basis of IEC 60601-2-33 and existing/new guidance on safe working practices
- Could show that workers have the same level of protection as the Directive envisages from known short-term adverse effects
- Exemption of **specific MRI practices only** would not be future-proof and would give the false impression that some MRI workers were better protected than others


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Option C: binding legislation using latest international recommendations, with exemptions

- This option, in either form, would eliminate the negative impact of the Directive on MRI
 - As long as the exemption applies to MRI as a whole
- No impact on healthcare, society, economy or research and innovation relative to current situation
- No detriment to worker health and safety


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Option D: non-binding legislation using the latest international recommendations

- This resembles the current situation in many countries, where ICNIRP recommendations inform risk assessment but balanced, sector-specific solutions can be reached
- The possibility of a social partner agreement covering MRI has been discussed
- This could be based on IEC 60601-2-33 and existing /new guidance on safe working practices
- In this case, impact on MRI could be similar to Option C

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Option E: Directive withdrawn

- IEC 60601-2-33, Directive 89/391/EEC, and existing guidance on safe working practices would remain
- So this would **not** leave occupational EMF exposures unregulated in the case of MRI
- In countries without existing regulatory provision, the impact on MRI would be similar to Option C
- In countries with existing regulatory provision (including those that have already transposed the Directive), the impact on MRI would be similar to Option A
- Thus there would be a lack of harmonisation and inconsistency for the MRI community across Europe with associated health, social and economic costs

Conclusions

- In terms of their impact on MRI, the options collapse to two possibilities
- Imposition of limits based on current ICNIRP or IEEE recommendations (Options A, B and in some countries E). This would have detrimental impacts for healthcare, society, the economy and research without any demonstrable health and safety benefit
- Exemption of MRI from the ELVs, whether through repeal of the Directive, derogation, a social partner agreement, or a requirement to demonstrate worker protection in other ways (Options C, D and in some countries E). This would have no detrimental impact in the context of MRI