

ICNIRP GUIDELINES

ON LIMITS OF EXPOSURE TO STATIC MAGNETIC FIELDS

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GUIDELINES ON LIMITS OF EXPOSURE TO STATIC MAGNETIC FIELDS

International Commission on Non-Ionizing Radiation Protection*

INTRODUCTION

THE RAPID development of technologies in industry and medicine using static magnetic fields has resulted in an increase in human exposure to these fields and has led to a number of scientific studies of their possible health effects. The World Health Organization (WHO) recently developed a health criteria document on static electric and magnetic fields within the Environmental Health Criteria Program (WHO 2006). The document contains a review of biological effects reported from exposure to static fields and, together with other recent publications [mainly International Commission on Non-Ionizing Radiation Protection (ICNIRP) 2003, McKinlay et al. 2004, and Noble et al. 2005], serves as the scientific database for the development of the rationale for the guidelines described in the current document, which supersede those published by ICNIRP in 1994 (ICNIRP 1994).

SCOPE AND PURPOSE

These guidelines apply to occupational and general public exposure to static magnetic fields. The guidelines do not apply to the exposure of patients undergoing medical diagnosis or treatment. Detailed consideration of protection of patients is given in an ICNIRP statement on protection of patients undergoing a magnetic resonance imaging (MRI) examination (ICNIRP 2004; ICNIRP in preparation).

QUANTITIES AND UNITS

Whereas electric fields are associated with the presence of electric charge, magnetic fields result from the physical movement of electric charge (electric current). Similarly, magnetic fields can exert physical forces on

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electric charges, but only when such charges are in motion. A magnetic field can be represented as a vector and may be specified in one of two ways: as magnetic flux density \boldsymbol{B} or as magnetic field strength \boldsymbol{H} . \boldsymbol{B} and \boldsymbol{H} are expressed in teslas (T) and amperes per meter (A m⁻¹), respectively. In a vacuum and with good approximation in air, \boldsymbol{B} and \boldsymbol{H} are related by the expression

$$\mathbf{B} = \mu_0 \mathbf{H}. \tag{1}$$

The constant of proportionality μ_o in eqn (1) is termed the permeability of free space and has the numerical value $4\pi \times 10^{-7}$ expressed in henrys per meter (H m⁻¹). Thus, to describe a magnetic field in air or nonmagnetic materials (including biological materials) with an adequate approximation, only one of the B or H quantities needs to be specified.

The magnitude of the force F acting on an electric charge q moving with a velocity v in a direction perpendicular to a magnetic flux density B is given by the expression

$$F = q(\mathbf{v} \times \mathbf{B}). \tag{2}$$

The direction of the force (the Lorentz force) is determined from the vector product of the velocity of the charge and the magnetic flux density and is therefore always perpendicular to the direction of the flow of electric charge. As a result, the interaction of a magnetic field with electric charge will result in a change of direction of the flow of the charge, but never a change in velocity. Static magnetic fields do not deposit energy into tissues.

The magnetic flux density, measured in teslas, is accepted as the most relevant quantity for relating to magnetic field effects. The magnetic flux within a given area of surface is the product of the area and the component of the magnetic flux density normal to its surface.

A summary of magnetic field quantities and units is provided in Table 1.

Standard international (SI) units are the internationally accepted units for expressing quantities in the

^{*} ICNIRP, c/o BfS – G. Ziegelberger, Ingolstaedter Landstr. 1, 85764 Oberschleissheim, Germany.

For correspondence contact G. Ziegelberger at the above address, or email at info@icnirp.org.

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Table 1. Static magnetic field quantities and corresponding SI units.

Quantity	Symbol	Unit
Current	I	Amperes (A)
Current density	J	Amperes per square meter (A m ⁻²)
Magnetic field strength	H	Amperes per meter (A m ⁻¹)
Magnetic flux	Φ	Weber (Wb or T m ²)
Magnetic flux density	\boldsymbol{B}	Tesla (T)
Permeability	μ	Henrys per meter (H m ⁻¹)
Permeability of free space	$\mu_{ m o}$	$4\pi \times 10^{-7} \text{ H m}^{-1}$

scientific literature. For a more complete list and discussion of concepts, quantities, units, and terminology for non-ionizing radiation protection, the reader is referred to the relevant ICNIRP publication (ICNIRP 2003).

SOURCES OF EXPOSURE

The natural static magnetic field of the Earth is \sim 50 μT and, depending on the geographic location, varies from ~ 30 to 70 μ T. Magnetic flux densities of the order of 20 µT are produced under high direct current transmission lines. In the future there is a potential for exposure to greater magnetic flux densities due to the development of new transport technologies. Fast passenger trains based on magnetic levitation produce relatively high magnetic flux densities close to the motor. However, for both magnetically-levitated trains and conventional electric trains, the fields inside the passenger cabin are relatively low, below 100 μ T, but localized magnetic fields of up to several mT at floor level can result from the presence of inductors beneath the floor of passenger coaches (WHO 2006; ICNIRP 2008). Other sources of static magnetic fields in residential and occupational environments include small permanent magnets in magnet clips and magnetic attachments (such as bags, buttons, magnetic necklaces and bracelets, magnetic belts, magnetic toys, etc), which generate local static fields in excess of 0.5 mT.

The highest non-occupational exposure occurs in patients undergoing a diagnostic examination by magnetic resonance (MR), a technique that is used to obtain diagnostic information about the body and increasingly to guide surgical interventions within the body. MR is based on the phenomenon of nuclear magnetic resonance and underlies MRI and magnetic resonance spectroscopy (MRS). In MR procedures, magnetic flux densities typically range from 0.15 to 3 T and the exposure is usually limited to less than 1 h, but can be a few hours in duration (Gowland 2005). Interventional medical procedures under direct real-time control by MRI are becoming increasingly common. These procedures also lead to increased occupational exposure, especially for medical professionals (surgeons, radiologists, nurses, and technicians). During such

procedures the medical staff may be within the main magnetic field region for a long period of time, up to a few hours. Increased staff exposure can also occur in emergency situations, when the medical professionals have to intervene very close to the patient. In addition, brief staff exposures occur during movement of patients in and out of MR systems. Finally, staff involved with the manufacture or maintenance of these MR systems are also occupationally exposed to high static magnetic fields.

Functional MRI is now widely used in academic and medical research on human brain function. MR systems using higher magnetic fields, up to about 10 T, are currently used for research in several institutions worldwide, and operate with special approval from a local institutional review board or equivalent entity. Exposures can also occur during other medical applications of static magnetic fields, such as the use of magnets to hold various prostheses in place or for magnetic navigation, where moveable permanent magnets are used to guide the tip of cardiac catheters; however, these devices produce only localized fields.

Strong fields are also produced in high-energy technologies such as thermonuclear reactors, magneto-hydrodynamic systems and superconducting generators. Research facilities that use bubble chambers, particle accelerators, superconducting spectrometers, and isotope separation units also have areas with high magnetic flux density around these devices. Other industries where exposure to strong magnetic fields occur are those involving electrolytic processes such as chlorine or aluminum production, where typical exposures for most of the working day are a few mT, with peak exposures up to several tens of mT, and in the manufacture of permanent magnets and magnetic materials.

REVIEW OF THE SCIENTIFIC EVIDENCE

Interaction mechanisms

The three established physical mechanisms through which static magnetic fields interact with living matter are magnetic induction, magneto-mechanical, and electronic interactions.

Magnetic induction. This mechanism originates through the following types of interaction:

• Electrodynamic interactions with moving electrolytes: Static fields exert Lorentz forces on moving ionic charge carriers and thereby give rise to induced electric fields and currents. This interaction is the basis of magnetically-induced potentials associated with flowing blood which have been theoretically analyzed (Kinouchi et al. 1996). These authors suggested that the sinoatrial node of the heart that controls cardiac

pacing may be the region most sensitive to current and calculate that, for a field of 5 T, the current density in this region is around 100 mA m⁻², which is around 10% of the maximum endogenous current from cardiac electrical activity, rising to around 20% for 10 T. A detailed assessment of the effects of the electric fields on cardiac function using computational models of cardiac electrophysiology indicated that, while fields up to 8 T are unlikely to affect the heart rate and rhythm, this would not necessarily be true for higher fields (Holden 2005).

• Induced electric fields and currents: Time-varying magnetic fields induce electric currents in living tissues in accordance with Faraday's law of induction. Currents may also be induced by movement in a static magnetic field. In particular, motion along a field gradient or rotational motion, either in a uniform field or in a field gradient, produces a change in flux linkage which induces an electric current, in contrast to linear motion of the body within a uniform static field. With regard to linear movement in a gradient field, the magnitude of the induced currents and associated electric fields increases with velocity of the movement and amplitude of the gradient. Calculations suggest that such induced electric fields will be substantial during normal movement around or within fields >2-3 T (Crozier and Liu 2005), and may account for the numerous reports of vertigo and nausea and magnetic phosphenes experienced by patients, volunteers, and workers moving in such fields (Schenck et al. 1992; Chakeres and de Vocht 2005; de Vocht et al. 2006b). Measurements of in situ surface electric fields induced by typical human body movements such as walking or turning in the fringe magnetic fields of a whole-body 3 T MRI scanner gave 0.15, 0.077, and 0.015 V m⁻¹ for the upper abdomen, head, and across the tongue, respectively (Glover and Bowtell 2008). A peak electric field of 0.30 V m⁻¹ was measured on the chest. Note that the speed of movements was not specified in this study. For a body moving at a constant speed of 0.5 m s⁻¹ into a 4 T magnet, Crozier and Liu (2005) estimate the maximum induced electric field strength in the body to be approximately 2 V m⁻¹, approximately equal to the apparent threshold for peripheral nerve stimulation in the frequency range 10 Hz-1 kHz (ICNIRP 1998). It should be noted, however, that frequencies associated with body movement are likely to be less than 10 Hz, the frequency below which accommodation decreases the electrical excitability of nerve tissue due to the slow inactivation of the voltage-gated sodium ion channels (Bezanilla 2000). Head translational and rotational frequencies during walking, for example, vary between 0.4–4 Hz (Grossman et al. 1988; Pozzo et al. 1990; MacDougall and Moore 2005).

Magneto-mechanical effects

The two types of mechanical effects that a static magnetic field can exert on biological objects are as follows:

- Magneto-orientation: In a static field, paramagnetic molecules experience a torque that orients them in a configuration that minimizes their free energy within the field. This effect has also been well studied for assemblies of diamagnetic macromolecules with differing magnetic susceptibilities along the principal axes of symmetry. Generally, these forces are considered too small to affect biological material in vivo because of the very small ($\sim 10^{-5}$) values of magnetic susceptibility (Schenck 2000). However, geomagnetic field has been implicated in the detection of directional cues during the orientation and migration of some animal species (Kirschvink et al. 2001; WHO 2006). Moreover, strong static magnetic fields (>17 T) have been shown to induce mitotic apparatus reorientation, i.e., changes to the orientation of the cleavage planes of frog embryos during the first to third cycle (Valles et al. 2002); and
- Magneto-mechanical translation: In the presence of gradients, static magnetic fields produce a net translational force on both diamagnetic and paramagnetic materials. The direction of the force is the same as or opposite to the gradient of the field for paramagnetic and diamagnetic materials, respectively. The force is proportional to the product of magnetic flux density (B) and its gradient (dB/dx). The force exerted on ferromagnetic objects such as metal of high magnetic susceptibility (>1 for iron or certain types of steel) tools poses danger due to their acceleration in strong magnetic field gradients. For biological material, the force is as large as the force of gravity when BdB/dx $>1,000 \,\mathrm{T^2\,m^{-1}}$ (WHO 2006). It has been demonstrated that an 8 T magnet with a gradient of 50 T m⁻¹ can decrease the depth of water in a horizontal trough running through the magnet, parting the water by pushing it to either end of the trough lying outside the magnet (Ueno and Iwasaka 1994). The effect at 10 T amounts to a change in pressure from the inside of the magnet to the outside of less than 40 mm of H₂O, which is thought to be insufficient to affect systemic blood flow in humans (Schenck 2005). However, Ichioka et al. (2000) observed a reduction in skin blood flow when a static magnetic field of 8 T was applied to the whole body of rats; the product of magnetic flux density and field gradient varied from 200 to 400 T² m⁻¹ along the rat's longitudinal body axis.

Electron spin interactions

Certain metabolic reactions involve an intermediate state comprising a radical pair, usually in a singlet state with the spin of one unpaired electron anti-parallel to the spin of the other (Schulten 1982; McLauchlan and Steiner 1991; Grissom 1995; Nagakura et al. 1998; Hore 2005; WHO 2006). These spin-correlated radical pairs recombine to form reaction products; an applied magnetic field affects the rate and the extent to which the radical pair converts to the triplet state (parallel spins) in which recombination is no longer possible. Although experimental evidence for such effects in biochemical systems has been reported (Eveson et al. 2000; Liu et al. 2005), their biological significance is not clear at present. The "radical pair mechanism" has been suggested (Ritz et al. 2000) as a mechanism by which animals, particularly birds, may use the Earth's magnetic field as a source of navigational information during migration, and there is some experimental support for this view (Ritz et al. 2004).

IN VIVO AND IN VITRO STUDIES

A large number of studies have been conducted in an effort to detect biological responses to static magnetic fields ranging in flux densities from the millitesla range to several teslas. These have been reviewed comprehensively in ICNIRP (2003), McKinlay et al. (2004), Miyakoshi (2005), Noble et al. (2005), and WHO (2006). The following is a brief summary of the main conclusions.

Laboratory studies with in vitro systems

Different levels of biological organization at a cellular level have been investigated, including cell-free systems (employing isolated membranes, enzymes or biochemical reactions) and various cell models (using both bacteria and mammalian cells). Endpoints studied included cell orientation, cell growth, cell metabolic activity, cell membrane physiology, and gene expression.

Positive and negative findings have been reported for all these endpoints. The observed effects are rather diverse and were found after exposure to a wide range of magnetic flux densities of up to 8 T. Thresholds for some of the effects were reported, but other studies indicated non-linear responses without clear threshold values. However, these responses are not well established. The aforementioned effect on the mitotic apparatus (Valles et al. 2002) represents a more consistent set of evidence; it confirmed earlier observations made by the same group (Denegre et al. 1998).

With regard to effects on radical-mediated metabolic reactions, the results of studies conducted so far suggest that there is no strong likelihood of major effects of physiological consequence or of long-term mutagenic effects arising from magnetic-field-induced changes in free radical concentrations or fluxes (Hore 2005).

Only a few studies on genotoxicity have been performed (Miyakoshi 2005). No genotoxic or epigenetic effects of exposure to static magnetic fields of up to 9 T have been shown, except for one study with repair deficient bacterial strains (Zhang et al. 2003). The studies with combined exposure to mutagens and static magnetic fields indicated modification of the effects of some of the tested mutagens, but there were no indications of field-dependence.

Overall there is little convincing evidence from cellular and cell-free models of biologically harmful effects of exposure to magnetic fields with flux densities up to several teslas.

Laboratory studies with animals

A large number of animal studies on the effects of static magnetic fields have been conducted (Saunders 2005). The most consistent responses seen in behavioral studies suggest that the movement of laboratory rodents in fields of about 4 T and higher may lead to aversive responses and conditioned avoidance (Weiss et al. 1992; Nolte et al. 1998; Houpt et al. 2003). Such effects are thought to result from interactions with the vestibular apparatus (Snyder et al. 2000). At field levels of the order of 2 T and lower, however, there is little convincing evidence from laboratory studies for effects of exposure on learning or on conditioned and unconditioned behavioral responses to a variety of stimuli (Trzeciak et al. 1993). Consistent with this finding, experimental studies on the electrical excitability of nerve tissues exposed to static magnetic fields have not demonstrated any robust effect at field levels up to 2 T (Gaffey and Tenforde 1983; Hong et al. 1986).

A well-established effect of exposure of animals to static magnetic fields greater than about 0.1 T is the induction of blood flow potentials in and around the heart and other major vessels of the central circulatory system (Gaffey and Tenforde 1981; Tenforde et al. 1983). These are also well documented in humans (see below) but have not been associated with any adverse effect in volunteer studies. The presence of these induced voltages has been demonstrated by electrocardiogram (ECG) studies in rodents, dogs, baboons, and monkeys performed during exposures of several hours to several days duration involving exposures up to 2 T (Tenforde 2005). However, their significance for health remains unclear. Extensive measurements in dogs and monkeys exposed to 1.5 T fields provided no evidence for changes in blood flow rate, blood pressure, or cardiovascular dynamics (Tenforde et al. 1983). Exposures of several hours duration to an 8 T field had no effect on cardiovascular function in pigs (Kangarlu et al. 1999). Several other studies with rodents exposed to field levels ranging from milliteslas to 10 T have led to reports of minor changes in cardiovascular parameters such as blood pressure and flow rate (Ichioka et al. 2000; Okano et al. 2005; Okano and Ohkubo 2006). However, the experimental endpoints in these studies have generally been rather labile and sensitive to confounding factors such as anesthesia, and firm conclusions cannot be drawn without independent replication of the reported effects.

Exposure to static fields of up to 1 T has not been demonstrated to have an effect on fetal growth or postnatal development in mice (Sikov et al. 1979; Konermann and Monig 1986). Other studies report a lack of effect on mouse fetal development following brief (2–7 d) exposure during organogenesis to fields of 4.7 T (Okazaki et al. 2001) and 6.3 T (Murakami et al. 1992).

There are few studies on possible genotoxic or carcinogenic effects of static magnetic fields in laboratory animals (Bellossi 1984, 1986; Mevissen et al. 1993). To date no lifetime exposure studies have been conducted to evaluate cancer induction or promotion by static magnetic fields. It is not possible to draw any conclusions from animal studies regarding these particular endpoints and long-term health consequences in general.

Several other endpoints that have been studied, including haematopoietic, endocrine system and blood chemistry, have not provided convincing evidence of any adverse effects (WHO 2006).

Laboratory studies in humans

Since the publication of the 1994 ICNIRP guidance (ICNIRP 1994), there have been a number of human studies evaluating the physiological and neurobehavioral influence in humans exposed while stationary to static magnetic fields of up to 8 T.

Detailed physiological studies evaluating various physiological parameters including body (sublingual) temperature, respiratory rate, pulse rate, blood pressure, and finger oxygenation levels have not shown any pronounced effects of exposure to magnetic fields up to 8 T (Chakeres et al. 2003a). Distortion of the electrocardiogram (ECG) signal was observed, which was caused by the induced flow potentials around the heart (see above). At 8 T, their magnitude was sufficient to render the ECG uninterpretable; however, the heart rate was unaffected. The only physiological parameter that demonstrated a statistically significant change was a small increase of less than 4% in systolic blood pressure, which lies within the range of a predicted increase in blood flow resistance due to magneto-hydrodynamic effects. Based

on modeling of such effects, a clinically significant blood flow reduction of >10% is predicted only at field levels in excess of 15 T (Kinouchi et al. 1996). The recorded blood pressure change did not represent a clinically significant or symptomatic alteration for healthy human subjects and is well within normal physiological variation. There is no evidence in humans of effects of static magnetic fields on other aspects of cardiovascular functions. It has also been reported that exposure of human volunteers to static magnetic fields up to 8 T does not induce body temperature changes (Shellock and Crues 1987; Chakeres et al. 2003a). These findings have been confirmed in a recent MRI study in which the static field component was 9.4 T (Atkinson et al. 2007), but there was no change in heart rate or systolic blood pressure. It should be noted, however, that switched gradient and radiofrequency (RF) magnetic fields were also present in this study.

Recent neurobehavioral studies on humans exposed while stationary at field levels up to 8 T have demonstrated no significant changes in many different parameters, including short term memory, working memory, speech, and auditory-motor reaction time (Kangarlu et al. 1999; Chakeres et al. 2003b; Chakeres and de Vocht 2005).

Behavioral studies carried out on subjects situated in the proximity of MR systems of up to 7 T have suggested that there may be a transient negative influence of exposure on eye-hand coordination and visual contrast sensitivity associated with head movement in the field (de Vocht et al. 2003, 2006a, 2007a, 2007b). De Vocht and colleagues describe decrements in the performance of a visual tracking and an eye-hand coordination task, both specific measures of the vestibular-ocular reflex, immediately following a standardized series of head movements conducted in static fields of between 0.5 T and 1.6 T, generating rates of change of field of up to 0.3 T s⁻¹ (at 1.6 T). The magnitude of the effect seemed to depend on the time-varying flux of the field due to head movement.

Several studies have reported that individuals exposed to static magnetic fields above 2–3 T experience transient sensory effects associated with motion in a static field gradient such as vertigo, nausea, a metallic taste, and magnetic phosphenes when moving the eyes or head (Schenck et al. 1992; de Vocht et al. 2006a, 2006b; Atkinson et al. 2007). However, the incidence and severity of these symptoms can be decreased by slowing the rate of motion of an individual through the magnetic field gradient (Chakeres and de Vocht 2005).

The theoretical and experimental basis for magnetic-field-induced vertigo experienced by people working in and around strong static magnetic fields has been investigated in some detail by Glover et al. (2007). Movement

of volunteers into the bore of a 7 T whole-body magnet at a speed of 0.1 m s⁻¹ resulted in a sensation of rotation (pitch forwards or backwards) in some but not all of the subjects. This direction of apparent rotation was reversed when the orientation of the subject was reversed in relation to the field, e.g., by moving from a supine to a prone position, suggesting an effect of induced current on the neural output of the vestibular system. Head movement within the homogeneous (zero gradient) field at the center of the magnet resulted in mild to severe vertigolike effects, with two subjects experiencing severe nausea. These feelings persisted for up to 30 min.

In contrast to movement-induced effects, postural sway was significantly increased in some (less than 50%) of the subjects standing stationary adjacent to the MRI scanner in a field of \sim 0.8 T. The effect is thought to be consistent with differences in magnetic susceptibility between the calcite crystals that comprise the otoconia (otoliths) of the vestibular organ and the surrounding fluid (Glover et al. 2007).

It is clear that sensitivity to these effects varies considerably between individuals. Thresholds for motion-induced vertigo in sensitive people were estimated to be of the order of 1 T s⁻¹ for greater than 1 s, and of a field-gradient product of 1 T² m⁻¹ for postural sway. The long integration times required for these effects to become apparent are indicative of the relatively low frequency response of the vestibular system (0.4–4 Hz).

A study of workers engaged in the manufacture of 1.0 T and 1.5 T MRI equipment (de Vocht et al. 2006b) investigated the incidence of sensory symptoms, assessed by questionnaire at the end of each working shift, and the performance of cognitive tasks, tested before and directly after a working shift. The results indicated that, during the work shift, the occasional reports of vertigo, a metallic taste in the mouth, and concentration problems occurred more frequently in those involved in MRI manufacture compared with controls. In general, these symptoms occurred more often in workers who moved quickly compared with those moving more slowly, although there was considerable inter-individual variability in sensitivity. However, there were no significant decrements in cognitive performance following each work shift compared with values assessed before work. The results support the view that magnetic-field-induced effects on cognitive performance reported in other studies are transient.

In conclusion, current information does not indicate any serious health effects resulting from the acute exposure of stationary humans to static magnetic fields up to 8 T. It should be noted, however, that such exposures can lead to potentially unpleasant sensory effects such as

vertigo and transient decrements in the performance of some behavioral tasks during head or body movement.

Epidemiological studies

The few available epidemiological studies have mostly been conducted on workers exposed to moderate static magnetic fields of up to several tens of mT either working in aluminum smelters or chloralkali plants or as welders. However, such work is also likely to involve exposure to a variety of potentially hazardous substances, such as coal tar pitch and polycyclic aryl hydrocarbons, which may confound the results. In addition, the static fields used in industrial processes such as electrolysis are produced by rectified power supplies with imperfect smoothing, so extremely low frequency (ELF) fields are also present. Assessment of static magnetic field exposure has been poor or nonexistent, and in some of the studies the number of participants has been very small. Health endpoints studied include cancer incidence, hematological changes and related outcomes, chromosome aberrations, reproductive outcomes, and musculoskeletal disorders.

Rockette and Arena (1983) studied a large cohort of male aluminum workers comparing the mortality among aluminum workers with that of the general United States male population. They reported a slightly higher than expected mortality from pancreatic, genitourinary and lympho-hematopoietic cancers, although not statistically significant. Static magnetic fields were not measured, and could not be separated from other exposures present in the work environment. Spinelli et al. (1991) reported a significantly increased risk of brain tumor mortality [standardized mortality ratio (SMR) was 2.2; 90% confidence interval (CI): 1.2-3.7] and non-significantly increased leukemia mortality (but not incidence), which did not appear to be explicable by coal tar pitch volatile (CTPV) exposure, in a cohort of aluminum workers. (There were also increases in other cancers related to CTPV exposure.) The authors found no increased risks associated with cumulative exposure to static magnetic fields. Two small Norwegian studies of aluminum workers reported no increased cancer risk associated with estimates of static magnetic field exposure (Rønneberg and Andersen 1995; Rønneberg et al. 1999). In a study of French aluminum workers conducted by Mur et al. (1987), cancer mortality and mortality from all causes were found not to differ significantly from the levels observed for the general male population of France.

Studies of chloralkali workers in Sweden and Norway (Ellingsen et al. 1993) reported increased risks of lung cancer of borderline statistical significance, but did not attempt to estimate magnetic field exposure. These workers were also exposed to other agents such as mercury vapour. No control of potential confounding

from smoking was made. Bårregard et al. (1985) conducted a study on a cohort of workers at a chloroalkali plant where the 100 kA direct currents used for the electrolytic production of chlorine gave rise to static magnetic flux densities at worker locations ranging from 4 to 29 mT. The observed incidence of cancer among these workers over a 25-y period was not significantly different from that expected.

Non-cancer health effects have been considered even less frequently. Most of these studies were based on very small numbers and had numerous methodological limitations. One of the larger studies examined fertility and pregnancy outcome in 1,915 female MRI operators (Kanal et al. 1993), possibly involving exposures to fields up to ~1 T. The risk of miscarriage for pregnancies during MRI work was slightly increased (not statistically significant) compared with work in other jobs and considerably higher than the risk in housewives. Minor differences were found for early delivery and low birth weight when compared with housewives, but not when compared with other workers. Age was not controlled in the analysis. The MRI workers were markedly older than the other groups, and selection bias may have affected this cross-sectional study.

Overall, the few available epidemiological studies have methodological limitations and leave a number of issues unresolved concerning the possibility of risk of cancer or other outcomes from long-term exposure to static magnetic fields. These studies do not indicate strong effects of static magnetic field exposure of the level of tens of mT on the various health outcomes studied, but they would not be able to detect small to moderate effects. Other occupations with a potential for higher magnetic field exposures have not been adequately evaluated, e.g., MRI operators.

EXPOSURE LIMITS

Separate guidance is given for occupational exposures and exposure of the general public. It is recommended that the limits for occupational exposure in these guidelines be applied to those individuals who are exposed to static magnetic fields as a result of performing their regular or assigned job activities. The term "general public" refers to the entire population.

Occupational exposures

Exposure limits. It is recommended that occupational exposure of the head and trunk should not exceed a spatial peak magnetic flux density of 2 T except for the following circumstance: for work applications for which exposures above 2 T are deemed necessary, exposure up to 8 T can be permitted if the environment is controlled

and appropriate work practices are implemented to control movement-induced effects. Sensory effects due to the movement in the field can be avoided by complying with basic restrictions set in the ELF guidelines. When restricted to the limbs, maximum exposures of up to 8 T are acceptable.

Explanation. Development of guidelines for static fields raises two difficult issues. First is the extent, if any, to which guidelines should allow potential occurrence, in some exposed workers, of temporary sensory effects with no known long term or serious consequences. Second is the extent to which restrictions should prevent levels of exposure higher than those for which there is human experience hence for which there is no known adverse effect but a concern about lack of knowledge. With regard to the first issue, ICNIRP considers that there are occupational circumstances where, with appropriate advice and training, it is reasonable for workers voluntarily and knowingly to experience possible transient sensory effects such as nausea, since they are not believed to lead to long term or pathological health effects. With regard to the second issue, ICNIRP considers that the exposures permitted under the guidelines should be based on levels for which there is appreciable evidence, and should not go higher than this merely because of lack of evidence of adverse effects.

Note: It is recognized that, for research purposes, there might be a wish to investigate the effects of these higher levels; such experimental exposures, however, are a matter for ethics committees (institutional review boards).

Since publication of the 1994 guidelines there have been several studies on humans exposed to static magnetic fields up to 8 T (Kangarlu et al. 1999; Chakeres et al. 2003a, 2003b; Glover et al. 2007). Above 2 T, transient effects such as vertigo, nausea and phosphenes have been occasionally observed in some people, but no evidence has been found for any irreversible or serious adverse health effects. Because the vestibular system is optimally stimulated by low frequency (around 1 Hz), induced electric fields or currents (Stephen et al. 2005) at levels below nerve stimulation thresholds (Glover et al. 2007), it is considered that protection against vertigo and nausea will provide adequate protection against other effects of induced currents in the head and trunk such as peripheral nerve stimulation.

In animal studies aversion responses, which may have resulted from similar effects, have been observed between 4 T and 14 T. However, there is no evidence up to 8 T of clinically significant cardiovascular or neurological effects, which are the major potential concerns with respect to limiting exposure to static magnetic

fields. Therefore, for general workplaces, the limit on exposure is set at 2 T, to prevent vertigo, nausea and other sensations, but for specific work applications, when the environment is controlled and appropriate work practices are implemented, then exposure up to 8 T is acceptable. The extent of these sensations is highly dependent on individual factors such as personal propensity to motion sickness and the speed of movement in the field; therefore, if an individual experiences such effects, they can be avoided or minimized by moving as slowly as possible. Guidance is not based on time-averaged exposure because, in addition to the experience gained with the use of MR and other static field sources world-wide over the last 20 y, mechanistic considerations indicate that any effects are likely to be acute.

Adverse effects on the limbs from exposures up to 8 T are not expected based on modeling of blood flow in smaller vessels compared with those of the head and trunk, and experience from existing sources. There is no evidence on which a higher limit of exposure for the limbs can be based.

General public exposures

Exposure limits. Based on scientific knowledge on the direct effects of static fields on humans, acute exposure of the general public should not exceed 400 mT (any part of the body). However, because of potential indirect adverse effects, ICNIRP recognizes that practical policies need to be implemented to prevent inadvertent harmful exposure of people with implanted electronic medical devices and implants containing ferromagnetic materials, and injuries due to flying ferromagnetic objects, and these considerations can lead to much lower restriction levels, such as 0.5 mT (IEC 2002). The exposure limits to be set with regard to these non-biological effects are not, however, the duty of ICNIRP.

Explanation. These ICNIRP guidelines are based on direct biological effects of static magnetic field exposure. There are, however, other hazards of static fields that are not directly biological and therefore not the purview of ICNIRP, but are nevertheless important to health protection (see section on protective measures).

Based on the available scientific data above 2 T, the exposure limit for the general public (any part of the body) is derived by applying a reduction factor of 5 with respect to the occupational limit for the head and trunk. This reduction factor accounts for all members of the population.

The limits recommended for occupational and general public exposures to static magnetic fields are summarized in Table 2.

Table 2. Limits of exposure^a to static magnetic fields.

Exposure characteristics	Magnetic flux density
Occupational ^b	
Exposure of head and of trunk	2 T
Exposure of limbs ^c	8 T
General public ^d	
Exposure of any part of the body	400 mT

^a ICNIRP recommends that these limits should be viewed operationally as spatial peak exposure limits.

PROTECTIVE MEASURES

ICNIRP recommends that the use of these guidelines should be accompanied by appropriate protective measures. These measures need to be considered separately for public places where exposures to static magnetic fields are likely to be very low and infrequent, and workplaces where, in some work situations, strong static fields may be regularly encountered.

There are three main areas of concern: for members of the public, there is a need to protect people with implanted medical devices against possible interference and against forces on implants containing ferromagnetic material. In addition, in some specific situations, there is a risk from flying ferromagnetic objects such as tools. Thirdly, in work situations involving exposure to very high fields, there is a need for a set of site-specific work procedures intended to minimize the impact of transient symptoms such as vertigo and nausea.

Effects on implanted medical devices

Safety authorities need to ensure that there are restrictions to protect individuals who are wearing implanted ferromagnetic or electronic medical devices sensitive to magnetic fields. There are many individuals wearing such devices, in some cases without being aware that they have them (e.g., surgical clips).

Electromagnetic interference from low-intensity static magnetic fields has been observed to affect the operation of pacemakers, particularly those with magnetic switches, and other types of medical electronic devices, including cardiac defibrillators, hormone infusion pumps (e.g., for insulin), neuromuscular stimulation devices (e.g., for the sphincter muscle of the bladder), neurostimulators, and electronically operated prosthetic devices (e.g., for the limbs and inner ear). In general, the

^b For specific work applications, exposure up to 8 T can be justified, if the environment is controlled and appropriate work practices are implemented to control movement-induced effects.

^c Not enough information is available on which to base exposure limits beyond 8 T.

^d Because of potential indirect adverse effects, ICNIRP recognizes that practical policies need to be implemented to prevent inadvertent harmful exposure of persons with implanted electronic medical devices and implants containing ferromagnetic material, and dangers from flying objects, which can lead to much lower restriction levels such as 0.5 mT.

operation of these devices is not adversely affected by static magnetic fields below 0.5 mT.

In addition to potential problems arising from electromagnetic interference, many implanted medical devices contain ferromagnetic materials that make them susceptible to forces and torques in static magnetic fields. These mechanical effects can lead to the movement and potential dislodging of implanted ferromagnetic devices, especially those of large size such as hip prostheses. Other ferromagnetic devices that might be affected include aneurysm clips, metal surgical clips and stents, heart valve prostheses and annuloplasty rings, contraception implants, cases of implanted electronic devices, and metallic dental implants, although most modern implants are not ferromagnetic. The safety of exposing these devices to the fields used in MRI has been extensively studied (New et al. 1983; Kanal et al. 1990; Shellock and Crues 2004). From studies performed to date, there is no evidence that static magnetic fields at or below the level of 0.5 mT would exert sufficient forces or torques on these devices to create a health hazard.

Accordingly, warning signs or lines are drawn around locations with magnetic flux densities >0.5 mT to mark public exclusion zones, for instance around MRI systems.

Movement of metallic objects

Protection needs to be given against danger from flying metallic objects moved by magnetic field forces. Such risks occur in fields of the order of several milliteslas. The 400 mT limit recommended by ICNIRP is based solely on grounds of direct biological effects of the field and is greatly above the level at which accidents can occur from mechanical forces on metallic objects; hence, the appropriate safety authorities need to guard the public against such mechanical hazards.

A 0.5 mT limit for protection of medical devices is consistent with protection against flying metal objects that experience substantial mechanical forces in static magnetic fields. The amount of force imparted on such objects depends on their size and content of ferromagnetic materials, but fields with flux densities in excess of a few milliteslas can cause significant rapid movement of many tools and other common metal objects.

Transient symptoms

For certain occupations, e.g., surgeons operating within an open MRI device, acute exposure symptoms such as nausea could affect performance and hence the safety of the patients on whom they are operating. Similarly, these acute symptoms could affect the accident-proneness of a worker. Each such workplace should have a set of work procedures and practices

specific to the work situations that will minimize any adverse consequences of exposure.

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