Customer Name	Magnetic Building Solutions LLC
Customer Address	855 Abutment Rd, Ste 1 Dalton, Georgia
Contact	Scott Humphrey
Project Description	Phase 2: Review of possible adverse health effects of a magnetic flooring system
Sample Description	LVT Flooring (Film Color 7404-1) Flooring underlayment
Date of Receipt	11th Jan 2017: LVT Flooring (Film Color 7404-1) 10th Feb 2017: Flooring underlayment
ASC Code	ASC003385: LVT Flooring (Film Color 7404-1) ASC003391: Flooring underlayment
Report Number	ASCR092199
Report Date	6th March 2017

airmid healthgroup ltd Unit 5, Trinity Enterprise Campus, Grand Canal Quay, Dublin 2, Ireland.
T: +353 1 6336820 F: +353 1 6729846 E:info@airmidhealthgroup.com w: www.airmidhealthgroup.com
Directors: Dr. Bruce Mitchell (Chairman and CEO), Dr John Mc Keon, Richard Thomas, Robert Jenkins, Hubert Lippe, Serge Rolle. Co Reg: No: 444684 VAT Registration: IE9669332M

Contents

airmid healthgroup ltd Unit 5, Trinity Enterprise Campus, Grand Canal Quay, Dublin 2, Ireland.
T: +353 1 6336820 F: +353 1 6729846 E:info@airmidhealthgroup.com w: www.airmidhealthgroup.com
Directors: Dr. Bruce Mitchell (Chairman and CEO), Dr John Mc Keon, Richard Thomas, Robert Jenkins, Hubert Lippe, Serge Rolle. Co Reg: No: 444684 VAT Registration: IE9669332M

1. Purpose

This report seeks to summarize the current status of non-ionizing radiation protection in relation to static magnetic fields at international level. It focuses on the recommendations and guidelines of the key organizations involved and attempts to give an overview on presently understood safe exposure limits for both occupational engaged workers and the general public, and the scientific basis underpinning them.

2. Background

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 several scientific studies of their possible health effects. The International Commission on Non-Ionizing Radiation Protection (ICNIRP) is the internationally recognized body that sets guidelines for protection against adverse health effects of non-ionizing radiation (see Appendix I for a summary of the functions and activities of the ICNIRP).

In 2009 ICNIRP published guidelines on limits of both occupational and general public exposure to Static Magnetic Fields (SMF). Below, we outline the substance of these guidelines (ICNIRP, 2009a; 2009b) and the background to same.

The magnetic flux density, measured in teslas (T), is accepted as the most relevant quantity for assessing magnetic field effects. The natural static magnetic field of the Earth, the so-called geomagnetic field, is about 50 μT, varying geographically from about 30 to 70 μT and is perceived by certain animals that use it for orientation. In the case of the USA, the field generally speaking lies in the range 46–55 μT.

Magnetic flux densities of the order of 20 μT are produced under high direct current transmission lines. Other sources of static magnetic fields in residential and occupational environments include small permanent magnets in magnetic attachments and magnetic clips (e.g., handbags and magnetic toys), which generate local static fields in excess of 0.5 mT.

The highest non-occupational exposure to magnetic fields occurs in patients undergoing diagnostic examination by magnetic resonance imaging (MRI). In MRI procedures, magnetic flux densities typically range from 0.15 to 3 T. Staff involved with the manufacture or maintenance of these MRI systems are also exposed to high fields. Moreover, so-called functional MRI using magnetic fields of up to about 10 T are now widely used in research on human brain function.

Strong fields are also produced in high-energy technologies such as superconducting generators, thermonuclear research reactors, particle accelerators, and industry involving electrolytic processes such as aluminium or chlorine production, with peak exposures up to several 10's of mT, and in the manufacture of permanent magnets and magnetic materials.

In aluminium production, the current used can reach hundreds of kA with static fields of the order of some mT close to the conductors, and general levels in the factory of up to 1 mT. The current is rather smooth and the Extremely Low Frequency (ELF) component from the ripple is of the order of some μT only.

In other electrolytic processes, the static magnetic field levels at the operator's locations can be approximately 8-15 mT, but here the ELF component from the ripple from the AC rectification is perhaps the interesting part. The ELF magnetic field can reach some hundreds of μT at basic frequencies of 50 - 300 Hz.

It is understood that there are three main physical mechanisms by which static magnetic fields interact with living matter namely, magnetic induction, magneto-mechanical interactions, and electronic interactions.

Numerous in-vitro studies of potential biological effects of static magnetic fields have been conducted in recent decades, analyzing endpoints including cell orientation, cell growth, metabolic activity and gene expression. Overall, these studies do not yield convincing evidence of harmful effects of exposure to magnetic fields with flux densities up to several teslas. Laboratory studies of animals show adverse responses and conditional avoidance of fields of about 4 T or higher, believed to be vestibular in origin.

Fields greater than about 0.1 T induce flow potentials particularly in and around the heart and other major blood vessels, but their significance for health is unclear and no clinically significant neurological effect or effects on cardiovascular function, fetal development, carcinogenesis, or other endpoints have been found from exposures up to 8 T.

In laboratory studies of humans, no pronounced effects on physiological parameters have been reported from exposures up to 8 T, except for a small increase in systolic blood pressure. Based on modeling, a clinically significant blood flow reduction is predicted only at field levels in excess of 15 T. There is no evidence of effects of exposures up to 8 T on other aspects of cardiovascular function, or on body temperature, memory, speech or auditory-motor reaction time, or of any serious health effects in human volunteers. There is some evidence for effects on eye-hand co-ordination and visual contrast sensitivity. Fields of 2–3 T can cause transient sensory effects including nausea, vertigo, metallic taste, and phosphenes (i.e., visual sensations caused by non-photic stimuli) when moving the eye or head; sensitivity varies between individuals, and the effects can be minimized or eliminated by moving more slowly through the field.

There are few epidemiological data on long-term health in persons exposed to static fields, and even less on potentially high exposure groups such as MRI operators. Available studies on workers exposed up to several tens of mT in aluminium smelters, chloralkali plants, or as welders have had methodological limitations according to the ICNIRP, but do not indicate strong effects from exposure at the above levels on cancer incidence, reproductive outcomes, or other outcomes studied.

3. Recommendations and Guidelines of Key Organizations

3.1. International Commission on Non-Ionizing Radiation Protection (ICNIRP) Limits

Following a thorough review of the available scientific evidence, ICNIRP, in 2009, recommended the following limits (subsequently referred to as reference levels) for exposure based on the rationale detailed in an article in the international journal Health Physics (Vol. 96(4), 504–514, 2009) published by the US Health Physics Society (ICNIRP, 2009a; 2009b):

3.1.1. General public exposures

ICNIRP states that acute exposure of the general public to SMF should not exceed 400 mT (any part of the body), reflecting a reduction factor of 5 with respect to the occupational limit discussed below. The Commission further recommends that this limit be viewed operationally as a spatial peak exposure limit. In relation to continuous exposure of the general public, the more conservative limit of 40 mT is recommended by ICNIRP.

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 stresses that these considerations can lead to much lower restriction levels, such as the Institute of Electrical and Electronic Engineers (IEEE) recommended limit of < 0.5 mT (IEC, 2002). Perhaps surprisingly, the ICNIRP do not consider that it is part of their remit to recommend exposure limits for these non-biological effects.

3.1.2. Occupational exposures

ICNIRP recommends that occupational exposure of the head and trunk should not exceed a spatial **peak** magnetic flux density of 2 T. However, for specific work applications, **peak** exposures 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 movement in the field can be avoided by complying with basic restrictions as set out in ICNIRP's extremely low frequency (ELF) guidelines (ICNIRP, 1998). When restricted to the limbs, **maximum** exposures of up to 8 T are deemed acceptable. In relation to on-going occupational exposure in the workplace, a **time-weighted average** (working day) exposure limit of 200 mT is recommended by ICNIRP.

3.1.3. Effects on implanted medical devices

ICNIRP emphasizes that 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), neuro-stimulators, and electronically operated prosthetic devices (e.g., for the limbs and inner ear). In general, the 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, it has become the practice to install warning signs or draw lines around locations with magnetic flux densities exceeding 0.5 mT to mark public exclusion zones, for instance around MRI systems.

It is worthy of note that because of considerable design advances, several magnetic resonance imaging **conditional** cardiac pacing systems and implantable cardioverter defibrillators (ICDs), as well as cardiac monitors, are now available in the market place for patients referred for MRI examinations (Mavrogeni et al., 2017). Whether such developments will have a significant impact on the potential for adverse indirect effects arising from exposure to very low magnetic fields is difficult to gauge at this stage.

3.1.4. Movement of metallic objects in magnetic fields

Protection is also recommended against danger from flying metallic objects moved by magnetic field forces. Such risks occur in fields of the order of several mTs. The 400 mT acute or peak limit (for the general public) 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 considered to be 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 mTs can cause significant rapid movement of many tools and other common metal objects.

It is worth stressing that the ICNIRP, in its latest statement (ICNIRP, 2017), has again concluded that although MRI has been in clinical use for about three decades, few serious side effects have been reported aside from well-documented acute injuries resulting from effects on implanted electronic devices or acceleration of ferromagnetic materials towards the scanner by the magnetic field, or from RF-induced burns due to poor positioning of the patient in the scanner.

ICNIRP also reiterate that previous reviews of the health effects of fields of MRI equipment do not suggest long-term adverse health effects (HPA, 2008a; ICNIRP, 2009a), and point out that this is particularly so for static fields (WHO, 2006; HPA, 2008b; ICNIRP, 2009b), for which there is no substantiated evidence for any health effect that could inform the design of an epidemiological study.

3.2. Institute of Electrical and Electronic Engineers (IEEE) International Committee on Electromagnetic Safety on Non-Ionizing Radiation

In October 2002, the IEEE Standards Coordinating Committee (No. 28) of the above-mentioned body published a standard for safety levels with respect to human exposure to electromagnetic fields in the 0–3 kHz frequency range (IEEE, 2002). The relevant magnetic maximum permissible exposure (MPE) levels for the general public and the controlled environment are summarized in Table 3.1 below:

Table 3.1. Magnetic maximum permissible exposure (MPE) levels as recommended by the IEEE Standards Coordinating Committee (IEEE, 2002).

Region of the body	Frequency range (Hz)	General Public B – rms (mT)	Controlled Environment B – rms (mT)
Head and torso	< 0.153 [a]	118	353
Arms and legs	< 10.7 [a]	353	353

[a]Including static or quasi-static magnetic fields

The degree of precision (three significant digits) given in Table 3.1 is potentially misleading and should not be taken to imply that the numerical quantities are known to that precision. They are not; rather they are provided to enable the reader of this detailed and rather complex IEEE standard to follow the various derivations and relationships presented therein.

The IEEE Coordinating Committee also drew attention to the reported observation that in static magnetic fields, reactions under laboratory conditions include a 17% increase in human cardiac cycle length at 2 T (Jehesen et al., 1988). The authors gave the opinion that the observed effect is probably harmless in healthy subjects, but that its safety in dysrhythmic patients was not certain. Other observations included a 0.2–3% change in blood velocity between 1–10 T (Dorfman et al., 1971; Keltner et al., 1990). A host of adverse effects were noted at 1.5 T, including: vertigo, difficulty with balance, nausea, headaches, numbness and tingling, phosphenes, and unusual taste sensations. Much more marked reactions were noted at 4 T (Schenck et al., 1992). Other effects include benign enhancement of the cardiac T-wave in rats at 4 T (Gaffey and Tenforde, 1981; Tenforde et al., 1983).

The studies of Schenck and colleagues report adverse effects in a significant number of subjects at 1.5 T, which the committee adopts as a median threshold for adverse effects. A peak value of 1.5 T is associated with a slowly varying sinusoidal field of 1.06 T root-mean-square (rms). A statistical model has been assumed for the distribution of thresholds that follows the same lognormal distribution found in other electrical thresholds. Consequently, at a factor of 3 below the median, namely, 353 mT (the value listed in Table 3.1 for the lowest frequencies, including static magnetic fields), the affected population of sensitive individuals is estimated to be less than 1% of exposed individuals. For the general public the committee applies an additional safety factor of 3, which leads to the value of 118 mT (see Table 3.1).

3.3. International Electromagnetic Field Project of the World Health Organization

The International Electromagnetic Field (EMF) Project of the World Health Organization (WHO) also reviewed the health implications of high static electromagnetic field exposure and highlighted the importance of public health protection for medical staff and patients (particularly children and pregnant women), and workers in industries producing high-field magnets (WHO, 2006a; 2006b).

In the case of static magnetic fields, they were similarly of the opinion that acute effects are only likely to occur when there is movement in the field, such as motion of a person or internal body movement (e.g. blood flow or heartbeat). A person moving within a field above 2 T can experience sensations of vertigo and nausea, and sometimes a metallic taste in the mouth and perceptions of light flashes. Although only temporary, they took the view that such effects may have a safety impact for workers executing delicate procedures (such as surgeons performing operations within MRI units).

It is a given that static magnetic fields exert forces on moving charges in the blood, such as ions, generating electrical fields and currents around the heart and major blood vessels, which, in WHO's opinion, can slightly impede the flow of blood. Possible effects noted in their review range from minor changes in heartbeat to an increase in the risk of abnormal heart rhythms (arrhythmia) that might be life threatening (such as ventricular fibrillation). However, they stress that these types of acute effects are only likely within fields in excess of 8 T.

WHO acknowledge the work of the ICNIRP in addressing the issue of exposure limits and agree with the latter's recommendations. WHO recommend a time-weighted average (TWA) of 200 mT during the working day for occupational exposure, with a ceiling value of 2 T, and a continuous exposure limit of 40 mT for the general public. In addition, they agree that wearers of cardiac pacemakers, ferromagnetic implants and implanted electronic devices should avoid locations where the field exceeds 0.5 mT and advise that care be taken to prevent hazards from metal objects being suddenly attracted to magnets in fields that exceed 3 mT.

Finally, they concluded it was not possible to determine whether there are any long-term health consequences, even from exposure in the mT range because, prior to their review and, in their opinion, no well-conducted epidemiological or long-term animal studies had been undertaken. Thus, the carcinogenicity of static magnetic fields (as well as static and extremely low frequency electric fields) to humans was not considered to be classifiable (IARC, 2002).

3.4. UK Health Protection Agency Advisory Group on Non-ionizing Radiation

In the UK, the Health Protection Agency's Advisory Group on Non-ionizing Radiation published a report on static magnetic fields in May 2008 (AGNIR, 2008). The group concluded the fields used in medical MRI are high enough to produce symptoms in some people, but the symptoms tend to disappear soon after exposure. The available evidence did not indicate any long-term health effects of such exposures, but the data were sparse and the group considered more studies were required. A pressing need was identified for a well-conducted cohort study of mortality and cancer incidence in workers with high occupational exposures to static magnetic fields from MRI.

Note that the guideline levels recommended by the ICNIRP are adopted in the UK; for the general public a continuous exposure limit of 40 mT, and for occupational exposure a time-weighted average (working day) exposure limit of 200 mT (AGNIR, 2008; 2012).

3.5. University of California, Berkeley Campus, Office of Environment, Health and Safety, Non-ionizing Radiation Safety Manual

In the matter of continuous exposure to static magnetic fields, UC Berkeley's safety manual states that they comply with the guidelines of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the American Conference of Governmental Industrial Hygienists (ACGIH), as reproduced below (Table 3.2).

Table 3.2. UC Berkeley adopted standards for exposure to static magnetic fields (UC EH&S, 2017; ACGIH, 2001; ACGIH, 2016; ICNIRP, 2009a)

Category	mT
Highest allowed field for implanted cardiac pacemakers	0.5
Watches, credit cards, magnetic tape, computer disks damaged	1
Small ferrous objects present a kinetic energy hazard	3
Allowed TWA for routine exposure (whole body)	60
Allowed TWA for routine exposure (extremities)	600
Whole body ceiling limit (no exposure allowed above this limit)	2,000
Extremity ceiling limit (no exposure allowed above this limit)	(8,000)

Note: a time weighted average (TWA) is the average exposure within the workplace to any hazardous contaminant or agent using the baseline of an 8 hours per day or 40 hours per week work schedule. The TWA reflects the maximum average exposure to such hazardous contaminant or agent to which workers may be exposed without experiencing significant adverse health effects over the standardized work period.

The Berkeley safety manual stresses that all access points to rooms containing magnets fields in excess of 0.5 mT shall be marked with magnetic field hazard signs and that the 0.5 mT threshold line be clearly identified with floor tape or equivalent markings.

3.5.1. Bio-effects of exposure to static magnetic fields

The safety manual reiterates that there are no known adverse bio-effects for flux densities within the ICNIRP/ACGIH exposure limits. However, in accord with all others, the manual points out that implanted medical devices present a potential hazard to individuals exposed to fields above the ICNIRP/ ACGIH limits.

3.5.2. Kinetic energy hazards

The manual further warns that due to the large fields associated with NMR magnets, ferrous objects can be accelerated toward the magnet with sufficient energy to seriously injure persons and/or damage the magnet. As a precaution, even small metal objects (screws, tools, razor blades, paper clips, etc.) should be kept at least 1.5 meters from the magnet or anywhere the field exceed 3 mT. Large ferrous objects (equipment racks, tool dollies, compressed gas cylinders, etc.) should be moved with care whenever the field approaches 30 mT.

3.6. Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the Minimum Health and Safety Requirements regarding the Exposure of Workers to the Risks arising from Physical Agents (Electromagnetic Fields)

The physical quantities, i.e., Action Levels (ALs) and Exposure Limit Values (ELVs), laid down in this Directive on occupational exposure are based on the recommendations of the ICNIRP and are to be considered in accordance with ICNIRP concepts, save where the Directive specifies otherwise.

The Directive covers all known direct biophysical effects and indirect effects caused by electromagnetic fields. However, it does not address suggested long-term effects of exposure to electromagnetic fields, since the European Commission (EC) and its advisors believe that there is currently no well-established scientific evidence of a causal relationship. However, were such evidence to emerge in the future, the EC foresees the need to take account of the latest available research and emerging scientific knowledge.

The Directive acknowledges that undesired effects on the human body depend on the frequency of the electromagnetic field or radiation to which it is exposed. Therefore, exposure limitation systems need to be exposure-pattern and frequency-dependent to adequately protect workers exposed to electromagnetic fields.

In the Directive, Exposure Limit Values (ELVs) for external magnetic flux density of fields from 0 to 1 Hz are taken to be limits for static magnetic field and are set out in Table 3.3 below. The sensory effects ELV is the ELV for normal working conditions and is related to vertigo and other physiological effects associated with disturbance of the human balance organ resulting mainly from moving in a static magnetic field. The health effects ELV for controlled working conditions is applicable on a temporary basis during the working shift when justified by the practice or process, provided that preventative measures, such as controlling movements and providing (adequate) information to workers, have been adopted.

The Directive stresses that a system ensuring a high level of protection as regards the adverse health effects and safety risks that may result from exposure to electromagnetic fields should also take due account of specific groups of workers at particular risk and 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 or medical devices worn on the body. It acknowledges that interference problems, especially with pacemakers, may occur at relatively low field levels (even below the ALs) and should therefore be the object of appropriate precautions and protective measures.

Table 3.3. Exposure Limit Values (ELVs) for external magnetic flux density (B) from 0 to 1 Hz (EC Directive, 2013)	
Effects/ Conditions	**Exposure Limit Value (ELV) in mT**
Sensory effects:	
Normal working conditions	2,000
Localized limbs exposure	8,000
Health effects:	
Controlled working conditions	8,000

The Directive also specifies Action Levels (ALs), which correspond to calculated or measured electric and magnetic field values at the workplace in the absence of the worker. Action Levels relevant to static magnetic fields are given in Table 3.4.

Table 3.4. Action levels (ALs) for magnetic flux density of static magnetic fields (EC Directive, 2013)	
Hazards	**Action Level (AL) in mT**
Interference with active implanted devices, e.g., cardiac pacemakers	0.5
Attraction and projectile risk in the fringe field of high field strength sources (>100 mT)	3

3.7. Recommendation 1999/519/EC of the Council of the European Union of 12 July 1999 on the Limitation of Exposure of the General Public to Electromagnetic Fields (0 Hz to 300 GHz)

Regarding the general public, as far back as 1999, the Council of the European Union published a recommendation on the limitation of exposure to electromagnetic fields (0 Hz to 300 GHz), which specified a basic restriction of 40 mT (magnetic flux density) for static magnetic fields (EC Recommendation, 1999). However, the Council recognized that interference problems with pacemakers may occur at levels below the recommended reference levels and should therefore be the object of appropriate precautions which, however, were not deemed to be within the scope of this recommendation, being dealt with in the context of legislation on electromagnetic compatibility and medical devices.

The reader may find it helpful if we clarify the distinction between basic restrictions and reference levels, as set out in the recommendation:

3.7.1. Basic restrictions

Restrictions on exposure to time-varying electric, magnetic, and electromagnetic fields, which are based directly on established health effects and biological considerations, are termed 'basic restrictions'. Depending upon the frequency of the field, the physical quantities used to specify these restrictions are magnetic flux density (B), current density (J), specific energy absorption rate (SAR), and power density (S). Magnetic flux density and power density can be readily measured in exposed individuals. Of course, for static fields, the frequency is zero.

3.7.2. Reference levels

These levels are provided for practical exposure-assessment purposes to determine whether the basic restrictions are likely to be exceeded. Some reference levels are derived from relevant basic restrictions using measurements and/or computational techniques and some reference levels address perception and adverse indirect effects of exposure to EMFs. The derived quantities are electric field strength (E), magnetic field strength (H), magnetic flux density (B), power density (S) and limb current (IL).

Note that for static fields and the general public, the recommended basic restriction and the recommended reference level are identical at 40 mT magnetic flux density.

3.8. European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIH) Opinion on Potential Health Effects of Exposure to Electro-magnetic Fields

In January 2015, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR – see Appendix II) published an updated and detailed opinion of the effects of electromagnetic fields, including Static Magnetic Fields (SMF), on humans (SCENIHR, 2015).

In regard to SMF, they stated that in most of the available in vitro studies reviewed, SMF above 30 μT induced effects in the cellular endpoints investigated, although in some cases the effects were transient. Gene expression was affected in all studies, with predominantly up-regulated outcomes. They concluded that the latest studies are consistent with the results of previous studies.

They also pointed out that a number of studies report that effects of SMF exposures occur in animals, at levels ranging from mT to T. However, since many of the findings are limited to single studies, they concluded that they do not provide a firm foundation for risk assessment.

They further noted that observational studies have shown that movement in strong SMF may cause effects such as vertigo and nausea. These can be explained by established interaction mechanisms and are more likely to occur in fields above 2 T. They added that the relevance of these effects for the health of personnel remains unclear.

3.8.1. Cautionary Note

It is evident from a perusal of the literature that potential health effects of static magnetic fields have received far less attention than, for example, power frequency or radio-frequency fields. There are only a few epidemiological studies available, and the majority of these have focused on cancer risks. There are some reports on reproductive outcomes, and sporadic studies of other outcomes.

Overall, few occupational studies have focused specifically on effects of static magnetic field exposure, and exposure assessment have consequently been poor or non-existent. Results from studies that have estimated static magnetic field exposure have not indicated any increased cancer risks, but they are generally based on small numbers of cases and crude exposure assessment. Control of confounding has been limited, and it is likely that the "healthy worker" effect has influenced the results.

A few studies have reported results on reproductive outcomes among aluminium workers and MRI operators, but limitations in study designs prevent conclusions. A problem in epidemiological studies of static magnetic fields is that workers in exposed occupations are also exposed to a wide variety of other potentially harmful agents, including some known carcinogens.

By contrast, for ionizing (as opposed to non-ionizing) radiation the epidemiological and other evidence is on a firmer foundation and, consequently, the recommendations of recognized bodies such as the International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency (IAEA), the International Radiation Protection Association (IRPA) and the National Council for Radiation Protection (NCRP) on limits for occupational and general public exposures are considered to be more robust.

In conclusion, the evidence available from epidemiological studies is not sufficient to draw firm conclusions about potential health effects of static magnetic field exposure at the higher levels, i.e., hundreds of mT and higher. However, at low to very low levels of exposure to static magnetic fields, there is no credible evidence (epidemiological or other) to support the contention that such exposures are potentially harmful to humans.

4. Take-Home Message

Given the present state of knowledge, there exist no scientifically reliable evidence, epidemiological or other, that exposure to the very low-level static magnetic flux densities likely to be encountered by close contact with the overlay and underlay materials which are the subject of this study, i.e., levels below 200 μT, are in any sense harmful to humans, including those fitted with medical implants.

Table 4.1. ICNIRP/ WHO/ EC recommended reference limits for static magnetic fields in units of milli-tesla (mT)

Nature of Exposure/ Risk	**Recommended Flux Density Limit**	
	General Public (mT)	**Occupational (mT)**
Continuous exposure	40	
Spatial peak (acute) exposure	400	
Potential adverse indirect effects	< 0.5	
Time-weighted average (working day)		200
Spatial peak (ceiling value) exposure to head and trunk		2,000
Spatial peak (ceiling value) exposure to legs		8,000
Attraction/ projectile risk near fields >100 mT	3	3

5. Appendix I - International Commission on Non-Ionizing Radiation Protection (ICNIRP)

The ICNIRP is an international commission specialized in non-ionizing radiation protection. The organization's activities include determining exposure limits for electro-magnetic fields used by devices such as cellular phones. ICNIRP is an independent non-profit scientific organization chartered in Germany. It was founded in May 1992 in Montreal, Canada, when the General Assembly of the International Radiation Protection Association (IRPA) approved the ICNIRP charter. This charter defines the work of the ICNIRP and governs its relationship with IRPA. Amendments to the charter require the assent of at least two-thirds of the membership of the Commission and at least two-thirds of the members of the IRPA General Assembly. The activities of the ICNIRP are governed by statutes, formally approved at the Commission Meeting held in October 2008 in Rio de Janeiro, Brazil (ICNIRP, 2008).

The mission of ICNIRP is to screen and evaluate scientific knowledge and recent findings toward providing protection guidance on non-ionizing radiation, i.e. radio, microwave, UV and infrared. The commission produces reviews of the current scientific knowledge and guidelines summarizing its evaluation. ICNIRP provides its science-based advice free of charge. In the past, national authorities in more than 50 countries and multinational authorities such as the European Union have adopted the ICNIRP guidelines and translated them into their own regulatory framework on protection of the public and of workers from established adverse health effects caused by exposure to non-ionizing radiation.

ICNIRP consists of a main commission which membership is limited to fourteen to ensure efficiency and four Standing Committees of each up to eight members covering the fields of epidemiology, biology and medicine, physics and dosimetry, and optical radiation. Its members are scientists employed typically by universities or radiation protection agencies. They do not represent their country of origin nor their institute and cannot be employed by commercial companies.

ICNIRP is widely connected to a large community working on non-ionizing radiation protection around the world. Its conferences and workshops are strongly supported. ICNIRP presents its draft guidelines online for public review and comment before publication. It is formally recognized by the World Health Organization (WHO) and the International Labour Office (ILO) as partners in the field of non-ionizing radiation. Its advice is requested by many national and multinational organizations such as the European Union. Standard bodies also refer to ICNIRP health protection guidance for setting appliance standards.

To preserve its independence from vested interests ICNIRP applies fundamental principles as provided by its charter and statutes; it does not receive financial support from commercial entities. Its funding consists solely of periodical or project grants from national and international public bodies and to a lesser extent of the income derived from its publications and scientific congresses and workshops. Members are not permitted to be employed by commercial entities. To enforce this rule, they are requested to file a declaration of personal interests and report any changes as they occur. Declarations of interests are publicly available on the ICNIRP website.

ICNIRP's activities are of scientific nature and deal with health risk assessment only. Policy or national or international risk management are considered outside of its scope. Balanced evidence-based health risk assessment requires screening the totality of the available science in an evaluation process. In this process the published literature is carefully read and interpreted in light of a set of quality criteria widely agreed by the scientific community. For example, in regard to mobile phone use and cancer incidence, ICNIRP offers the opinion that, while one cannot be certain, the trend in the accumulating evidence is increasingly against the hypothesis that mobile phone use causes brain tumours. ICNIRP base this opinion on grounds such as there being (i) no convincing evidence from laboratory studies or from epidemiology, (ii) no plausible mechanism identified, and (iii) only limited data available for long-term usage (Matthes, 2013).

Despite or because of the wide use of ICNIRP guidance, it has encountered some criticism. The Council of Europe has stated: "it is most curious, to say the least, that the applicable official threshold values for limiting the health impact of extremely low frequency electromagnetic fields and high frequency waves were drawn up and proposed to international political institutions (WHO, European Commission, governments) by the ICNIRP, an NGO whose origin and structure are none too clear and which is furthermore suspected of having rather close links with the industries whose expansion is shaped by recommendations for maximum threshold values for the different frequencies of electromagnetic fields". This author is of the opinion that the Council’s criticism is unfair – a view clearly shared by the large number of governmental organizations and other bodies that have adopted ICNIRP’s recommendations and guidelines.

6. Appendix II - Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

This EC Advisory Committee deals with questions related to emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies.

Examples of potential areas of activity include potential risks associated with interaction of risk factors, synergic effects, cumulative effects, antimicrobial resistance, new technologies such as nanotechnologies, medical devices including those incorporating substances of animal and/or human origin, tissue engineering, blood products, fertility reduction, cancer of endocrine organs, physical hazards such as noise and electromagnetic fields (from mobile phones, transmitters and electronically controlled home environments), and methodologies for assessing new risks. It may also be invited to address risks related to public health determinants and non-transmissible diseases.

7. References

ACGIH (2001). Documentation of the Threshold Limit Values for Physical Agents. American Conference of Governmental Industrial Hygienists (ACGHI), ISBN:978-1-607260-45-5, 7th Ed.

ACGIH (2016). 2016 TLVs and BEIs. American Conference of Governmental Industrial Hygienists (ACGHI), ISBN:978-1-607260-84-4, 272 pp.

AGNIR (2008). Static Magnetic Fields: Report of the Independent Advisory Group on Non-ionizing Radiation. Documents of the Health Protection Agency, Centre for Radiation, Chemical and Environmental Hazards, Chilton, Oxfordshire OX11 0RQ, UK, RCE-6, May 2008, 143 pp.

AGNIR (2012). Health Effects from Radiofrequency Electromagnetic Fields: Report of the Independent Advisory Group on Non-ionizing Radiation. Documents of the Health Protection Agency, Centre for Radiation, Chemical and Environmental Hazards, Chilton, Oxfordshire OX11 0RQ, UK, RCE-20, April 2012, 333 pp.

AGNIR (2014). Programme of work and topics addressed by the Advisory Group on Non-ionizing Radiation. Updated 28 July 2014. 3 pp.

Dorfman, Y. G. (1971). Physical phenomena occurring in live objects under the effect of constant magnetic fields. In: Kholodov, Y. A. (ed.), Influence of Magnetic Field on Biological Objects, Springfield, VA, National Technical Information Service, Report JPRS63038, pp. 11–19.

EC Directive (2013). Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the Minimum Health and Safety Requirements regarding the Exposure of Workers to the Risks arising from Physical Agents (Electromagnetic Fields). Official Journal of the European Union, 29.6.2013, L 179, 1–21.

EC Recommendation (1999). Recommendation 1999/519/EC of the Council of the European Union of 12 July 1999 on the Limitation of Exposure of the General Public to Electromagnetic Fields (0 Hz to 300 GHz). Official Journal of the European Communities, 30.7.1999, L 199, 59–70.

Feychting, M. (2005). Health effects of static magnetic fields - a review of the epidemiological evidence, Prog Biophys Mol Biol., Feb–Apr 87(2–3), 241–246.

Gaffey, C. T., and Tenforde, T. S. (1981). Alterations in the rat electrocardiogram induced by a stationary magnetic field, Bioelectromagnetics 2, 357–370.

Heinrich, Angela, Szostek, Anne, Nees, Frauke, Meyer, Patric, Semmler, Wolfhard, and Flor, Herta (2011). Effects of static magnetic fields on cognition, vital signs, and sensory perception; a meta-analysis, J. Magnetic resonance Imaging 34, 758–763.

IARC (2002). IARC monographs on the evaluation of carcinogenic risks to humans, non-ionizing radiation, Part 1: static and extremely low frequency (ELF) electric and magnetic fields. World Health Organization International Agency for Research on Cancer, Monograph, Vol. 80, 429 pp., IARC Press, Lyon, France.

ICNIRP (1998). International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz). Health Physics 74(4), 494–522.

ICNIRP (2008). Statutes of the International Commission on Non-Ionizing Radiation Protection (ICNIRP), Approved at the Commission Meeting, 13-14 October 2008, Rio de Janeiro, Brazil. 12 pp.

ICNIRP (2009a). International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines on limits of exposure to static magnetic fields. Health Physics 96(4), 504–514.

ICNIRP (2009b). International Commission on Non-Ionizing Radiation Protection (ICNIRP) Fact Sheet on the guidelines on limits of exposure to static magnetic fields published in Health Physics 96(4): 504–514; 2009. 3 pp.

ICNIRP (2010). International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz – 100 kHz). Health Physics 99(6), 818–836.

ICNIRP (2014). International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz. Health Physics 106(3), 418–425.

ICNIRP (2017). International Commission on Non-Ionizing Radiation Protection (ICNIRP) Statement on diagnostic devices using non-ionizing radiation: existing regulations and potential health risks. Health Physics 112(3), 305–321.

IEEE (2002). IEEE Std C95.6-2002 (Reaff 2007), Institute of Electrical and Electronic Engineers IEEE Standard for Safety Levels with Respect to Human Exposure to Electromagnetic Fields, 0 to 3 kHz.

Jeheson, P., Duboc, D., Lavergne, T., Guize, L., Guerin, F., Degeorges, M. and Syrota, A. (1988). Change in human cardiac rhythm induced by a 2-T static magnetic field, Radiology 166, 227–230.
Kanal, E., Shellock, F. G. and Talagala, L. (1990). Safety considerations in MR imaging. Radiol. 176, 593–606.

Keltner, J. R., Roos, M. S., Brakeman, P. R. and Budinger, T. F. (1990). Magnetohydro-dynamics of blood flow. Magnetic Resonance in Medicine 16(1), 139–149.

Kovacs, Phillip E., Valentine, Richard L., and Alvarez, Pedro J. J. (1997). The Effect of Static Magnetic Fields on Biological Systems: Implications for Enhanced Biodegradation, Critical Reviews in Environmental Sciences and Technology, 27(4), 319–382.

Matthes, Rudiger (2013). EMF Safety Guidelines – The ICNIRP View. ITU Workshop on Human Exposure to Electromagnetic Fields, Turin, 9 May 2013 (Chairperson, ICNIRP Commission, 2012–2016).

Mavrogeni, S. I., Poulos, G., Kolovou, G. and Theodorakis, G. (2017). Magnetic resonance imaging conditional devices. Luxury or real clinical need? Hellenic Journal of Cardiology, doi:10.1016/j.hjc.2017.01.001.

New, P.F., Rosen, B. R., Brady, T. J., Buonanno, F. S., Kistler, J.P., Burt, C. T., Hinshaw, W. S., Newhouse, J. H., Pohost, G.M. and Tavera, J. M. (1983). Potential hazards and artifacts of ferromagnetic and non-ferromagnetic surgical and dental materials and devices in nuclear magnetic resonance imaging. Radiol. 147, 139148.

SCENIHR (2015). Opinion on potential health effects of exposure to electromagnetic fields (EMF), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), European Commission (Issued 20 January 2015).

SCENIHR (2013). Preliminary opinion on potential health effects of exposure to electromagnetic fields (EMF), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), European Commission (Issued 29 November 2013).

SCENIHR (2009). Preliminary opinion on potential health effects of exposure to electromagnetic fields (EMF), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), European Commission (Issued 19 January 2009 and 6 July 2009).

Schenck, J. F., Dumoulin, C. L., Redington, R. W., Kressel, H. Y., Elliott, R. T. and McDougall, I. L. (1992). Human exposure to a 4-tesla magnetic field in a whole-body scanner, Med. Phys. 19(4), 1089–1098.

Shellock, R. G. and Crues, J. V. (2004). MR procedures: biologic effects, safety, and patient care. Radiol. 232, 635–652.

Tenforde, T. S., Gaffey, C. T., Moyer, B. R., and Budinger, T. F. (1983). Cardiovascular alterations in Macaca monkeys exposed to stationary magnetic fields: Experimental observations and theoretical analysis, Bioelectromagnetics 4, 1–9.

UC EH&S (2017). University of California, Berkeley, Office of Environment, Health and Safety, Non-ionizing Radiation Safety Manual, 18 pp.
http://ehs.berkeley.edu/laser-safety/non-ionizing-radiation-safety-manual module4

WHO (2006a). Environmental Health Criteria 2006, Static fields. World Health Organization, Geneva, Monograph, vol. 232.

WHO (2006b). Backgrounder on electromagnetic fields and public health: static electric and magnetic fields, March 2006, World Health Organization, Geneva, 4 pp.

"This report is provided on a confidential basis for the benefit of airmid healthgroup's client pursuant to the agreement between airmid healthgroup and its client. A right of action arising under this report cannot be assigned. airmid healthgroup's responsibility under this report is limited to proven negligence and will in no case be more than the testing fees. The results shown on this test report refer only to the sample(s) tested unless otherwise stated, under the conditions agreed upon. Anyone relying on this report should understand all of the details of the engagement. Only the client is authorised to publish, copy or make this report available to any third party, and then only in its entirety. This report or the airmid healthgroup limited name or logo cannot be included in any materials, including any legal, publicity or advertising activities relating to the tested product or service without the explicit written consent of airmid healthgroup ltd."

Report written by:	**Report reviewed by:**
	Vivienne Mahon Digitally signed by Vivienne Mahon DN: cn=Vivienne Mahon gn=Vivienne Mahon c=Ireland l=IE o=airmid healthgroup limited ou=Science e=vmahon@airmidhealthgroup.com Reason: I am approving this document Location: Date: 2017-03-06 17:19Z
Professor Peter Mitchell PhD MRIA	Vivienne Mahon PhD

End of Report