IEEE COMMITTEE ON MAN AND RADIATION (COMAR) TECHNICAL INFORMATION STATEMENT "EXPOSURE OF MEDICAL PERSONNEL TO ELECTROMAGNETIC FIELDS FROM OPEN MAGNETIC RESONANCE IMAGING SYSTEMS"

H. Bassen,* D. J. Schaefer,† L. Zaremba,* J. Bushberg,‡ M. Ziskin,§ and K. R. Foster**

Abstract—**Open magnetic resonance imaging (MRI) systems enable performing image-guided medical procedures for long periods of time very close to, or inside, the patient imaging area. Medical personnel can be exposed to relatively high static, gradient, and radiofrequency fields compared to most other MRI systems. The Committee on Man and Radiation of the Institute of Electrical and Electronics Engineers calculated or used existing data on magnetic flux densities and field strengths in or near the patient area to assess occupational exposure levels. Potential exposures to each field type were analyzed and compared to relevant values specified in international exposure limits including those of the Institute of Electrical and Electronics Engineers and the International Commission on Nonionizing Radiation Protection. Exposures of the head or torso of a worker to gradient fields near the center of the patient-imaging area can exceed most exposure limits even for times less than a second. Exposures to radiofrequency fields can exceed limits if sustained exposures (minutes or more) occur to parts of the body. Static magnetic fields used by present Open MRI systems are below exposure limits of all of the standards that address these fields. Overall results of this study suggest that manufacturers and others who program or operate Open MRI systems should take care to ensure that operating parameters produce exposures that comply with the relevant exposure limits. Also, since field levels fall off rapidly with increasing distance, user practices may be implemented that reduce exposures significantly.**
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Key words: magnetic resonance imaging; exposure, radiofrequency; magnetic fields; safety standards

INTRODUCTION

MAGNETIC RESONANCE imaging (MRI), which is in widespread use throughout the world, employs strong electric and magnetic fields [static, extremely low frequency (ELF) and radiofrequency (RF)] in the imaging process. In a traditional MRI system, the patient is placed in a cylindrical volume that comprises the borehole of a large electromagnet. The fields in these "closed" systems are largely confined to the cylindrical region inside the scanner in which the patient is placed because of the geometry of the magnet and the structural design of the system. It is unlikely that hospital staff would be exposed to fields in excess of safety limits because of the general inaccessibility of the patient imaging areas. Some newer imaging systems, by contrast, employ magnet designs that do not completely surround patients during imaging (Fig. 1). This "Open" design can lessen discomfort of the patient due to the feeling of confinement, and also allow medical staff to perform procedures on the patient, guided by MRI. During such interventional procedures, medical staff work in close proximity to the system, and may place their hands, heads, or torsos, or less frequently their entire bodies, in the imaging volume. The rapid increase in the number of MRI guided procedures makes it increasingly important to ensure that hospital personnel comply with exposure limits for such fields. MRI systems that are not specifically "Open MRI" by design can be used for interventional procedures. These systems can expose workers to magnetic fields that are even higher than Open MRI systems, if they are used for interventional procedures. However, the intent of this Committee on Man and Radiation (COMAR) Technical Information Statement (TIS) is not to cover all types of MRI systems that might be used for interventional procedures, now or in the near future.

Members of the COMAR of the Institute of Electrical and Electronics Engineers (IEEE) evaluated the fields that could expose medical personnel such as interventional radiologists, MRI technicians, and others working close to or in the patient imaging region of an Open MRI

* U.S. Food and Drug Administration, Center for Devices and Radiological Health, 12725 Twinbrook Parkway, Rockville, MD 20852; † GE Medical Systems; ‡ University of California at Davis; § Temple University; ** University of Pennsylvania.

For correspondence or reprints contact: Howard Bassen, Center for Devices and Radiological Health, FDA, 12725 Twinbrook Parkway, Rockville, MD 20852, or email at hib@cdrh.fda.gov.

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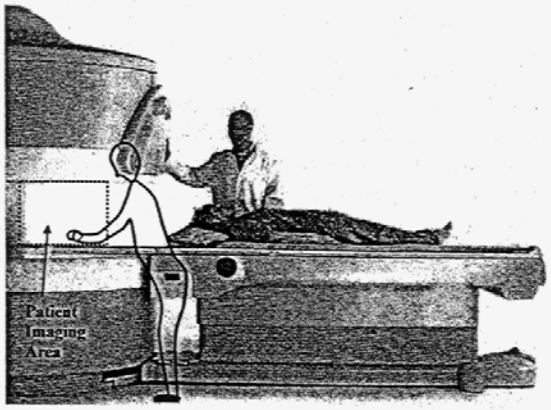

Fig. 1. An Open MRI system.

system. This COMAR TIS reviews the potential levels of exposure to personnel from Open MRI systems in comparison with limits for human exposure to electromagnetic fields. These limits are published by several organizations (those of the IEEE, the International Commission on Nonionizing Radiation Protection (ICNIRP), the American Conference of Governmental Industrial Hygienists (ACGIH) and the European Parliament of the European Union (EU). The IEEE is a voluntary standards-setting organization, while ICNIRP publishes guidelines for other organizations to adopt. These limits apply for occupational exposure situations, as would be experienced by medical personnel, but not to exposures to patients during diagnosis or treatment. The limits are designed to protect against adverse biological effects caused by exposure to fields, but do not consider hazards related to electromagnetic interference to devices or other nonbiological events. Extensive reviews of safety issues related to MRI are found in Shellock and Crues (2004) and ICNIRP (2004). While the ICNIRP 2004 Statement focuses on the protection of patients from potential hazards associated with MR diagnostic imaging, this TIS addresses primarily the protection of medical personnel from routine exposures to strong fields and gradients associated with Open MRI equipment. All applicable human exposure safety standards and guidelines for static, ELF, and RF magnetic fields must be integrated in the employer's (hospital or diagnostic facility) RF Safety Program. If any MR system exposures measured or modeled could exceed prescribed occupational limits, appropriate warning signs should be posted on the facility door and equipment.

MATERIALS AND METHODS

COMAR evaluated existing literature on magnetic field distribution in and around Open MRI systems. Each of the three types of magnetic fields emitted by MRI systems were evaluated (static, gradient, RF). When no data were readily available, we calculated the field distributions. Of primary interest were the fields that could expose personnel rather than a patient. These exposures would usually occur during intervention procedures, except for static fields, which are always present near an MRI system. In addition, we compared occupational exposure levels for these fields to existing magnetic field safety standards. The magnetic and electric fields produced by MRI systems occur in several widely different frequency ranges, which must be considered separately when assessing compliance with exposure limits. MRI requires the use of a strong static magnetic field. For technical reasons, the magnets are nearly always turned on, even when patients are not being examined. The magnetic field is quantified in terms of magnetic flux density, B, expressed in units of Teslas, T, or magnetic field strength, H, in amperes per meter (A m^{-1}). For nonmagnetic materials, including body tissues, the magnetic flux density is simply proportional to the magnetic field strength; 1 A m^{-1} is approximately equivalent to 1.3 μT. Nearly all Open MRI systems operate at 0.7 T or less. One new system has been introduced in some countries that operates at 1.0 T. By contrast, the Earth's magnetic field is about 50 μT. The fields are strongest within the patient imaging area, and fall off rapidly with distance from the magnet. The field levels outside the magnet depend on the design of the system and are usually reported in the system's manual.

For a typical Open MRI system, the static magnetic flux density at a distance of 20 cm from the outer surfaces of the magnets is 0.2 T or less. Because of the decrease in magnetic flux density with distance, this results in a whole-body exposure (which is averaged over the entire body) of a few tenths of a Tesla or less. However, partial-body exposures may be as high as 1 T if the staff person partially enters the imaging area. Determination of the static magnetic field distributions vs. distance was obtained by examining manufacturers' data that must be provided in the manuals and instructions for each MRI system. In addition to the static magnetic field, MRI systems require the use of "gradient" magnetic fields. These fields have much lower amplitude than the static field, but are pulsed (turned on and off) rapidly, depending on the design of the system and on the imaging technique being employed at any particular time. The time rate of change of this gradient field (dB/dt) is potentially significant because it determines the levels of electric fields that are induced within the body. Typical systems employ gradient pulses of millisecond duration, and dB/dt values that are typically in the range of tens of Teslas per second (T s^{-1}). These

gradient fields have a complex frequency spectrum, which extends into the kilohertz range. Only limited data are available about the strength of the gradient fields within and outside Open MRI systems. One group of researchers has reported gradient fields within a 0.23 T Open MRI system that employs gradient pulses of approximately 0.5 ms (0.5×10^{-3} s) duration (Huurto and Toivo 2004). In that system, the peak value of dB/dt of the gradient fields was approximately 20 T s^{-1} in the center of the patient imaging area. No measurements were reported at distances of 1 m from the center of an actual Open MRI system. We calculated the gradient fields in a 0.7 T Open MRI system. We modeled the gradient coil as a Maxwell pair (two loops at opposite ends of the long axis of the patient space, each with a radius of 0.33 m). We used the Biot Savart law that relates magnetic fields to the currents flowing in the coils, which are their sources. In our calculations the gradient fields had a value of 1×10^{-2} T (10,000 μT) in the center of the patient area and fell to 0.5×10^{-3} T (500 μT) 1 m from the center of the patient imaging region. Based on an estimated worst-case waveform of gradient field pulses (0.5 ms width), we calculated a time rate of change of the gradient field in the center of the patient region as 20 T s^{-1} and 1 T s^{-1} 1 m from the center.

MRI systems employ strong RF fields whose frequency depends on the static magnetic field strength. Typically, these frequencies are between 8.5 and 150 megahertz (MHz). However, some experimental "high-field" MRI systems operate at frequencies above 300 MHz. The RF fields are turned on and off in short (millisecond) pulses. The RF fields were calculated for a 29.8 MHz system (corresponding to a 0.7 T static field Open MRI system) along the long axis of the coil in the patient imaging region. To approximate an RF coil for an Open MRI, a modified birdcage arrangement was modeled and the field strengths were calculated with the Biot Savart law. The peak magnetic flux density in the center of the patient imaging region, created by a single RF pulse, was approximately 1×10^{-5} T ($H = 8$ A m^{-1} peak). One meter from the center of the patient-imaging region, the peak flux density of a single RF pulse peak field was approximately 1×10^{-7} T ($H = 0.08$ A m^{-1}). Since safety standards for RF fields are usually expressed in terms of the root-mean-square (RMS) magnetic field strength, H_{rms}, this value was calculated as follows. Operating pulse widths and pulse repletion rates were chosen for estimated worst case conditions. The resulting time-averaged B field (and H field) was about 17% of the peak B field. The resulting time averaged (RMS) field strength (H_{rms}) was 1.4 A m^{-1} at the center of the patient imaging region and 0.014 A m^{-1} at 1 m from the center.

A detailed assessment was performed of the estimated exposure values discussed above for static, gradient, and RF magnetic fields from 0.7 T Open MRI systems compared to several international and national safety limits. The estimated exposure values were compared to safety limits of the ICNIRP (1994, 1998), the IEEE Standards C95.1 (IEEE 1999a) and C95.6 (IEEE 2002), the ACGIH Threshold Limit Values (TLVs) (ACGIH 2004), and the Directive of the EU (EU 2004). The ACGIH document includes limits for occupational exposures to magnetic fields of workers with cardiac pacemakers. This COMAR TIS does not attempt to address the complex subject of electromagnetic interference of medical implants such as cardiac pacemakers. The EU directive is virtually identical to the ICNIRP occupational exposure limits for the particular frequencies relevant to this COMAR statement. Both the ICNIRP and IEEE limits were developed by nongovernmental organizations and have no legal force in themselves. However, many countries have adopted exposure limits that closely follow these guidelines. Both guidelines have two tiers, with higher limits for workers and lower limits for the general public. ICNIRP has separate limits for occupational and non-occupational exposures. The corresponding tiers in the IEEE standards are for "controlled" and "uncontrolled" exposure situations. For exposure of medical personnel to fields from MRI systems, the occupational (or controlled) exposures are of principal interest. It should be noted that all of the above guidelines distinguish, implicitly or explicitly, between "basic restrictions" and "reference levels." The former limits the absorbed power or the induced electric fields within the body; the latter limits the strength of the fields as measured in the environment outside the body. Reference levels are intended to be conservative guidelines to ensure that the basic restrictions are achieved. This distinction is only implicit in IEEE C95.1, which nevertheless has an exclusion clause that allows the local incident field strengths to exceed the general exposure limits, provided that the absorbed power in the body is maintained within appropriate limits.

The biological and physiological bases for the IEEE and ICNIRP exposure standards/guidelines cited above include the following known adverse effects from acute (short term) exposures to electric and magnetic fields. The ACGIH and EU base their standards on the IEEE or ICNIRP standards and do not develop their own biological bases. For exposures to static magnetic fields, the ICNIRP guideline is based on limiting the electrical currents that are induced in the body by physical movement within the static field; the IEEE standards do not address static magnetic fields. For pulsed gradient-field exposures, both ICNIRP guidelines and IEEE standards are designed to avoid nerve and muscle stimulation from the induced electric fields within the body; the standards

differ because of different assumptions about the safety factor to be incorporated into the limits. For exposures to pulsed-RF fields, both ICNIRP and IEEE standards are designed to limit the heating of body tissues. The limits for the IEEE and ICNIRP standards are designed to be quite conservative in offering protection against the specified hazards and should not be confused with the actual threshold exposure for a hazard.

RESULTS

The findings of this study are divided into three parts, corresponding to exposure levels vs. recommended safety limits for static, gradient, and RF fields. For static magnetic fields, the ICNIRP guidelines and the EU document derived from it specify "ceiling values" and maximum average exposures to static magnetic fields. For occupational exposures, the maximum time-weighted average exposure is 0.2 T to any part of the body averaged over the entire working day. Higher exposures would be allowed for shorter times, provided the 8-h average value was maintained below 0.2 T. For example, exposures of 1.6 T would be allowed for 1 h during an 8-h workday. The ICNIRP guideline also specifies ceiling (maximum) limits of 2 T (to the whole body) and 5 T (to the arms and legs). The IEEE does not address limits for exposure to static magnetic fields. In addition, the ACGIH document specifies 8-h time weighted average (TWA) exposure limits shown in Table 1.

For gradient fields the IEEE C95.6 standard and ICNIRP guidelines provide a means for determining the permissible levels for low-frequency pulses. The ACGIH and EU exposure limits do not address complex pulsed waveforms of the gradient fields produced by Open MRI systems. An ICNIRP limit, published in 1998 (ICNIRP 1998), addresses exposure to sinusoidal magnetic fields and some pulsed fields. A more recent ICNIRP document provides guidance for determining compliance of exposures to pulsed fields with waveforms such as MRI gradient fields (ICNIRP 2003). This guidance requires detailed examination of the waveform of the specific gradient pulse in question via measurements with a special electronic circuit or by frequency spectrum analysis on a case-by-case basis. Therefore, an assessment of conformance of gradient field exposures with the ICNIRP special guidance was not performed in preparing this report. IEEE C95.6 provides exposure limits for time-varying magnetic fields over a frequency range between 0 and 3 kHz (IEEE 2002) and is applicable to MRI gradient fields. It also specifies how to evaluate the rate of change of the flux density (T s^{-1}) of single pulses for compliance with its limits. The limits apply for partial-body exposures, with somewhat higher limits for the limbs than for the head and torso. For pulsed fields, the limits specify the RMS field strength, averaged over 0.2-s intervals. Under plausible circumstances, exposures to gradient fields in MRI systems may exceed limits of the IEEE C95.6 standard. For example, for 0.5 ms magnetic field pulses, IEEE C95.6 limits are 18.25 T s^{-1}. Gradient fields of similar dB/dt exist in the patient imaging volume in many Open MRI systems. The standard provides an averaging time of 0.2 s, which corresponds to averaging the field over many gradient pulses. However, this averaging time is very short compared to the duration of a typical exposure. Thus, a medical staff person who even briefly places his or her head in the imaging region of such a system could experience partial-body exposures that exceed C95.6 limits. The EU and ACGIH standards are based on sinusoidal fields and specify simple ways to assess pulsed fields based on limits for fields with sinusoidal waveforms. These limits (30.7 μT) are exceeded significantly at 1 m from the center of the patient imaging area, as well as in the center of this imaging area where fields are 500 and 10,000 μT, respectively.

For radiofrequency fields between 10 and 400 MHz, the ICNIRP reference level for magnetic field exposure (H_{rms}) is 0.16 A m^{-1}. This limit applies for whole- or partial-body exposures, and does not vary with frequency over this range. The corresponding IEEE limit (IEEE 1999a) varies with frequency. For pulsed-RF fields such as

Table 1. Potential occupational exposure levels to static fields near Open MRI devices compared to international and national safety limits.

Measured value of static field	IEEE C95.1-1999 limits	IEEE C95.6-2002 limits	ICNIRP limits (T)	ACGIH limits (T)	EU limits (T)
1 m from edge of patient imaging area: 0.2 T	Not applicable	Not applicable	Short term 2 T = whole body 5 T = arms and legs	Short term 2 T = whole body 5 T = arms and legs	0.2 T
Center of patient imaging area: 0.7 T			0.2 T TWA	0.06 T = whole body TWA (8 h) 0.6 T = arms and legs TWA	

produced by MRI systems, the limit for exposure under controlled conditions (which would apply to occupational exposures to medical staff from MRI systems) is expressed as 16.3/f, where f is the frequency in MHz. These limits apply to field strengths averaged over 6-min periods. Higher exposures are allowed for shorter times provided that the exposure averaged over 6-min periods is within the limits. For an MRI system operating at 30 MHz (similar in frequency to that used by a 0.7 T Open MRI system), the IEEE limit is 0.55 A m^{-1} for whole-body exposures. The corresponding limit for partial-body exposures is 2.5 A m^{-1}. This is higher than the ICNIRP standard. Open MRI systems employ RF fields that approach, or possibly exceed, these limits for long exposures. For example, the RF fields we calculated from a 0.7 T Open MRI system were 1.4 A m^{-1} RMS. Thus, depending on the duration of exposure, a medical staff member who places part of his or her body in the patient imaging area can exceed one or both the ICNIRP and IEEE limits. Short exposures (much less than 6 min) are unlikely to result in noncompliance because of the 6-min averaging time in both limits. Exposures lasting for several minutes or more would probably exceed the 0.16 A m^{-1} reference level in the ICNIRP limits and may exceed the IEEE limits as well (depending on the operating characteristics of the system). Verifying compliance with either guideline in such cases would entail a detailed dosimetric evaluation under those circumstances, to ascertain the absorbed power in the body.

Tables 1, 2, and 3 summarize the exposure levels inside and outside Open MRI systems in comparison with safety limits of the IEEE, ICNIRP, ACGIH, and EU. The ranges for exposure in these tables are estimated exposures at distances of 1 m from the center of the magnet (lowest field strength) or at the center of the magnet in the patient imaging area (maximum field strength).

DISCUSSION

Our studies indicate the following when comparing partial-body exposures from our calculations vs. several international safety standards. During interventional procedures on patients with Open MRI systems, members of the medical staff are exposed to static and time-varying magnetic fields from the MRI system, including gradient, pulsed-RF, and static fields. Estimates of the exposures, from a 0.7 T Open MRI system and measured data, allow a comparison with international (IEEE and ICNIRP) exposure limits. The results of this comparison are as follows. Either whole-body or partial-body exposures to Open MRI static magnetic fields in present use will not exceed the ICNIRP standard; the IEEE presently does not publish a limit for static magnetic fields. Even brief (less than a second) exposures of the head, torso, or limbs of a clinical worker to gradient fields in the center of the patient imaging areas of Open MRI systems may exceed the IEEE limits. Conformance to ICNIRP limits for gradient field exposures from generic Open MRI systems could not be determined. This is because ICNIRP requires a case-by case assessment of the exposures for each specific pulsed field. Brief (less than a minute) exposures of the head, torso, or limbs of a clinical worker to RF fields in the patient imaging areas of Open MRI systems are not likely to exceed the IEEE or ICNIRP limits because of the 6-min averaging time. Longer exposures (minutes or more) are likely to exceed the general guidelines in ICNIRP. In such cases, compliance with the ICNIRP and IEEE limits might have to be confirmed by a detailed dosimetric evaluation of the exposure scenario, taking into account specific operating characteristics of the imaging system.

CONCLUSION

We studied occupational exposures to fields near Open MRI systems vs. several international magnetic field safety standards. Our data indicate that it is possible, under some operating conditions, to exceed the exposure limits of the IEEE, ACGIH, ICNIRP, and EU, particularly from the gradient fields. As a result, manufacturers and others who program the system operating parameters should ensure the systems be operated safely. Appropriate warning, caution, or danger signs should be placed on MR devices, or on room doors, as needed or required by

Table 2. Potential occupational exposure levels to gradient fields near Open MRI devices compared to international and national safety limits.

Gradient magnetic field (computed)	IEEE C95.1-1999 limits	IEEE C95.6-2002 limits	ICNIRP limits	ACGIH limits	EU limits
1 m from edge of patient imaging area: 1 T s^{-1} and 500 μT Center of patient imaging area: 20 T s^{-1} and 10,000 μT	Not applicable	18.25 T s^{-1} Special pulse guidance was addressed in this report	Special pulse guidance was not addressed in this report—See text	200 μT (at 1 KHz)	30.7 μT (at 1 KHz)

Table 3. Potential occupational exposure levels to radiofrequency fields near Open MRI devices compared to international and national safety limits (29.8 MHz). All limits are 6-min averages.

Radiofrequency field computed (RMS)	IEEE C95.1-1999 limits	IEEE C95.6-2002 limits	ICNIRP limits	ACGIH limits	EU limits
1 m from edge of patient imaging area: 0.01 A m^{-1}	0.55 A m^{-1} whole body	Not applicable	0.16 A m^{-1} whole body	0.55 A m^{-1} whole body	0.16 A m^{-1}
Center of patient imaging area: 1.4 A m^{-1}	2.5 A m^{-1} partial body		Partial body not specified	Partial body not specified	Partial body not specified

applicable safety standards. The signs could include those referenced in IEEE Standard C95.2-1999 (IEEE 1999b) or other applicable safety standards. In addition, hospitals and other employers with Open MRIs should educate exposed employees on the exposure standards and the possible health risks from exposures that exceed the limits of these standards. Since field levels fall off rapidly with increasing distance, user practices can be implemented that may reduce exposures significantly. No evaluation of whole-body average occupational exposures was performed, due to the difficulty of evaluating such exposures from available data. However, in the opinion of the authors, whole-body exposures would be considerably below the maximum permissible exposures specified in the IEEE and ICNIRP standards.

Acknowledgments—This statement has been reviewed by the members of COMAR, all of whom have expertise in the general area of the interactions of electromagnetic fields with humans. This final report was approved by vote of the full COMAR membership and by the IEEE EMBS Executive Committee.

Disclaimer—The opinions expressed in this paper are those of IEEE COMAR. They do not represent the policies of the U.S. Food and Drug Administration.

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