Prohibition sign

No access with metallic pieces or watches

Extra examples for the marking introduced for medical devices and other items for safety in the MR environment are introduced in the ASTM standard F2503-05. This relates specifically to markings for MR Safe, MR Conditional and MR Unsafe devices.

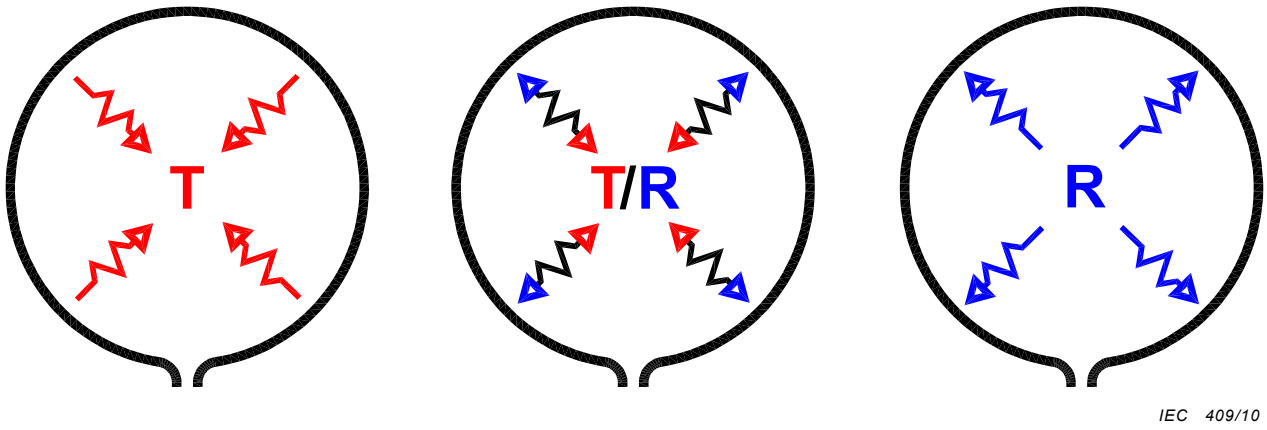

Figure 201.D.101 – Signs indicating a transmit only RF coil, transmit / receive RF coil and a receive only RF coil

Annex AA
(informative)

Particular guidance and rationale

AA.1 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Concerning the Introduction

In the recent years before the realization of the 3rd edition of this standard, a number of publications of general interest to the safety of MR scanners became available. For general guidance reference is given to these publications, see [150, 151, 152, 153][4]. Independent of the specific electromagnetic fields generated in and around an MR scanner, committees as IEEE [154] and ICNIRP [131, 162] have defined exposure limits for the static and time-varying electric, magnetic and electromagnetic field exposure for workers in controlled environments. Shortly after the acceptance of the 2nd edition of this standard ICNIRP published a so-called 'statement' specifically addressing the safety of MR patients [132].

An important new aspect introduced in the 2nd amendment to the 2nd edition of this standard is the fact that the employer of the MR WORKER is now encouraged to define rules and formulate requirements for the MR WORKERS because the EMF produced by the MR EQUIPMENT can result in exposure of workers, which is or will be limited by law. In the 2nd amendment exposure limits for MR WORKERS were introduced, which are equal to those allowed for PATIENTS. All exposure levels allowed for a PATIENT and for an MR WORKER protect them against negative health effects. While exposure for workers may be physically different because of the orientation of the workers as compared to the orientation of PATIENTs the same exposure limits apply. The fact that some exposure limits for PATIENTS are modified in this 3rd edition of the standard does not invalidate this statement. Therefore also in the 3rd edition of the standard the exposure limits for MR WORKERS are equal to those allowed for PATIENTS. The rationale for this choice given in the 2nd amendment is still valid and can be found in the rationale of subclauses 201.7.9.2.101 h) and 201.7.9.2.101 k) of this 3rd edition of the standard.

Concerning 201.3.201 – B_{1+}RMS

B_{1+}RMS is displayed on the CONTROL PANEL to provide a supplemental metric to SAR of the RF power deposition. The B_{1+}RMS value might, for example, be used as a control on allowable RF power deposition in the implant manufacturer labelling for patients with implants.

B_{1+}RMS on the CONTROL PANEL represents the maximal value when averaged over any 10 s period of the sequence, and is estimated at the RF transmit coil centre. The value of B_1 in the calculation is based on both polarization senses in the rotating frame [155].

$$B_1(t) = \sqrt{|B_{1+}(t)|^2 + |B_{1-}(t)|^2}$$

where B_{1+} is the component of the RF field in the rotating frame that is useful for tilting of the nuclear magnetization and B_{1-} is the RF component that rotates counter to the rotation of the nuclear magnetization.

4) Figures in brackets refer to the Bibliography.

Note that for pure circular polarization $|B_{1-}(t)| = 0$ and for linear polarization $|B_{1-}(t)| = |B_{1+}(t)|$.

For a rectangular pulse with duration τ and amplitude $|B_{1+}|$ in the positively rotating frame, the tilt angle θ is

$$\theta = \gamma |B_{1+}| \tau$$

where γ is the nuclear gyromagnetic constant.

Concerning 201.3.207 – ENVIRONMENTAL TEMPERATURE

For this standard the ENVIRONMENTAL TEMPERATURE will be calculated as follows. Let scan room temperature (in °C) = *Tr*. Let scanner PATIENT bore wall temperature (in °C) = *Tb*. Let magnet bore length = *L*. Assume typical PATIENT height *h* = 1,76 m. Assume the coefficient of convection is *hc* = 9,5 W/(m^2 °C). Assume the coefficient of radiation is *hr* = 8,0 W/(m^2 °C). Then the ENVIRONMENTAL TEMPERATURE, *Te*, can be computed as follows.

Let PATIENT skin temperature (in °C) = *Ts* and assume that over the entire surface area, *A*, of the PATIENT energy is dissipated by convection, *C*, to air at room temperature:

$$C = Ahc(Tr - Ts) .$$

NOTE Negative energy implies energy dissipated by the PATIENT. A rather conservative assumption is that PATIENT energy is dissipated by radiation to the bore wall over the entire surface area of the PATIENT.

$$R = Ahr(Tb - Ts) .$$

The total heat lost is equivalent to that lost to a uniform ENVIRONMENTAL TEMPERATURE, *Te*:

$$A(hc + hr)(Te - Ts) = R + C = Ahc(Tr - Ts) + Ahr(Tb - Ts) .$$

Solving for *Te* results in the expression:

$$Te = \frac{hc\,Tr + hr\,Tb}{(hc + hr)} .$$

Concerning 201.3.213 – INTERVENTIONAL MR EXAMINATION

Examples: aspiration cytology, core biopsy, breast biopsy, wires localization, depth electrode placement in the brain for EEG of pallidotomies, chemo ablation, cryosurgery and thermal ablation using laser, focused ultrasound and radiofrequency energy. Can be used in the operating room to guide brain tumour resection after craniotomy. Can be coupled with endoscope procedures providing external and internal localization or visualization.

Equipment example: Open architecture magnets and fast imaging sequences (fluoroscopy). In-room console.

Special sequences examples: Temperature monitoring, keyhole imaging-

Non-invasive visualization and localization. Problem with geometric distortion due to non-linear gradients and susceptibility artefact.

Consequences for MR WORKERs and PATIENT safety: Open architecture permits access to higher levels of all fields (static and time varying magnetic, RF).

Compatibility of instruments: The first step toward practical interventional MRI is development of instrumentation that can function satisfactorily and safely in the fields of clinical MR scanners. There is a potential for accidents caused by magnetically induced force on surgical instruments or monitoring equipment. Image artefacts may be caused by susceptibility differences. Artefacts also depend on pulse sequences (gradient echo gives more). Increase in artefact with field strength. Support instrumentation includes anaesthesia monitoring, lasers, RF generators and tracking systems. Gradients will induce voltage and current and may cause artefacts, therefore loops in cables should be avoided to prevent the danger of EMI between scanner and interventional electronics.

Compatibility of needles, catheters and other instruments developed for interventional purposes (composed of high-nickel stainless steel and other materials) reduce torque from the static field and minimize susceptibility artefacts.

Interventional procedures are increasingly being performed using MR SYSTEMs, so that measurements of bonding resistance and touch voltages should be performed on MR units, just as they are on conventional radiographic systems [146].

There will need to be some differences in procedure, because of the strong magnetic field within the scanning room, but the general principles will be the same.

Touch voltages should be measured using a conventional auto-ranging digital multimeter, equipped with a set of test leads long enough for the meter to be sited outside the scanning room. One lead should be attached to the earth reference bar (ERB), and the other lead, fitted with a sharp pointed probe used to check for touch voltages on any of the accessible conductive surfaces within the scanning room. The probe should be tested to ensure that it does not contain any significant amount of magnetic material by running a test magnet over it.

Measurements should also be made between the earth point on all mains sockets in the scanning room and the ERB. If any devices are plugged into sockets outside the scanning room and then used within the scanning room, these should be supplied from the same phase as any sockets within the scanning room, and the touch voltage on the earths of these sockets also measured. The touch voltage should be less than 10 mV, AC or DC. If a voltage greater than 10 mV is found, the measurement should be repeated using an IEC filter. If the touch voltage is still above 10 mV, the source of the voltage should be investigated. Once it has been established that there are no significant touch voltages present, the bonding resistance should be measured. A battery operated four-wire milliohmmeter should be used, in order that the meter can be kept at a safe distance from the midline of the field during the measurement. The meter should have a resolution better than 10 mΩ, and be capable of performing the measurement at a current greater than 100 mA.

The resistance between the ERB and all accessible conductive surfaces of installed equipment should be less than 100 milliohms. The resistance between the earth point of all mains sockets and the ERB should also be less than 100 mΩ.

Any portable devices should be plugged directly into a conveniently located hardwired socket. Extension mains leads should not be used within the scanning room.

Concerning 201.3.217 – MAGNETIC RESONANCE (MR)

The phenomenon of MR occurs when the frequency of electro-magnetic radiation equals the Larmor precession frequency of the nuclear or electron magnetic moments.

Concerning 201.3.221 – MAGNETIC RESONANCE WORKER (MR WORKER)

The concept of MR WORKERS is related to the level of exposure of this group of workers to the EMFs emitted by the MR SYSTEM. This level may be higher than what is allowed by legal regulations in some countries for workers in general, creating for the MR WORKER the need of special EMF exposure limits as defined in this standard. The EMF exposure limits stated in this document permit the unrestricted presence of the MR WORKER in CONTROLLED ACCESS AREA even during scanning. The level of these limits and the resulting RISKS to the MR WORKER are discussed elsewhere in this annex.

The term MR WORKERS includes all people working near the MR EQUIPMENT in the CONTROLLED ACCESS AREA or equivalent, either in the medical arena where the MR SYSTEM is installed and being operated and serviced or at the MANUFACTURER where the MR SYSTEM is being developed and manufactured. As such the MR WORKER includes but is not limited to the personnel maintaining the MR SYSTEM, the OPERATOR and the medical staff, or the MR WORKER can be the technical personnel at the MR MANUFACTURER, development and manufacturing engineers, installation and service personnel. Both groups of MR WORKERS are equally essential in maintaining the medical benefits for the PATIENTS.

Apart from the MR WORKER, two further groups of individuals exposed to the EMFs emitted by the MR SYSTEM can be discerned. These are MR volunteers and MR PATIENT carers.

An MR volunteer is an individual who has freely consented to an investigational MR procedure authorized by local regulations, and therefore is subject to the limits authorized by the ethics committee. An MR volunteer is therefore not considered to be an MR WORKER according to the definition in this standard.

An MR PATIENT carer is an individual, who supports the PATIENT during an examination and therefore may be exposed to the same level as for PATIENTS. MR PATIENT carers therefore can be informed and screened in the same way as the PATIENT. An MR PATIENT carer, who is not employed as an MR WORKER, is therefore not considered to be an MR WORKER according to the definition in this standard. An MR PATIENT carer who happens also to be an MR WORKER is to be seen as an MR WORKER.

Concerning 201.3.223 – MEDICAL SUPERVISION

MEDICAL SUPERVISION requires a positive assessment by a qualified medical practitioner of the RISK versus benefit for a particular scan, or a decision by a qualified surrogate of the practitioner that the PATIENT satisfies a set of objective criteria, formulated by a qualified medical practitioner, for the parameters of the scan and the condition of the PATIENT. MEDICAL SUPERVISION may entail physiological monitoring of the PATIENT by means of devices designed to measure or assess various physiological states (e.g. heart rate, ECG trace, blood pressure, pulse oximetry; but see cautions in 201.7.9.2.101 b)).

Concerning 201.3.233 – SPECIFIC ABSORPTION RATE (SAR)

The SAR is a function of the frequency (increasing approximately as the square of the frequency), the type and number of radio frequency pulses, the duration and repetition rate of pulses and the type of coil used for transmission. The important biological factors are: conductivity of tissue, specific gravity of the tissue, anatomical region examined, tissue type (e.g. the degree of perfusion) and mass of the PATIENT.

Concerning 201.7.9.2.101 – Instructions for use for MR EQUIPMENT

The instructions for use of MR EQUIPMENT complying with this standard play an important role in providing the necessary information to the RESPONSIBLE ORGANIZATION or OPERATOR.

Regarding the safety of PATIENTS, these documents should contain specific information on the content of programs for pre-screening of PATIENTS, MEDICAL SUPERVISION of PATIENTS in cases of use of the MR EQUIPMENT in controlled modes of operation and emergency procedures.

With regard to the safety of staff, the same documents should contain specific information on the handling of electronic equipment and/or metallic objects in the CONTROLLED ACCESS AREA and the use of cryogen in case a superconducting magnet is used.

Concerning 201.7.9.2.101 a) – Pre-screening of the PATIENT and MR WORKER

Pre-screening of the PATIENT and even the MR WORKER is important because an MR EXAMINATION or just being present near the MR EQUIPMENT can be considered to be a significant RISK [1] [2] for PATIENTS or MR WORKERS who have metallic implants or electrically, magnetically or mechanically activated implants (e.g. cardiac pacemakers) The origin of this RISK is related to the magnetic and electromagnetic fields produced by the MR EQUIPMENT, which may produce strong attraction and/or torque to the metallic implant or may interfere with the operation of active devices.

This applies also to PATIENTS and MR WORKERS who rely on electrically, magnetically or mechanically activated external life support systems.

Scanning PATIENTS with intracranial aneurysm clips is contra-indicated unless the physician is certain that the clip is not magnetically active.

Examination by MR EQUIPMENT, in terms of PATIENT pre-screening, requires particular caution in the following cases:

– PATIENTS with implanted surgical clips (haemostatic clips) or other ferromagnetic materials (which the magnetic field may dislodge);
– PATIENTS engaged in occupations or activities which may cause accidental implantation of ferromagnetic materials, or who may have imbedded metal fragments from military activities;
– PATIENTS with permanent (tattoo) eye-liner or with facial make-up (because severe eyelid irritation has been reported);
– PATIENTS with compromised thermoregulatory systems (e.g. neonates, low-birth-weight infants, certain cancer PATIENTS);
– PATIENTS with metal implants, because these may cause artefacts in diagnostic images due to magnetic field distortion;
– PATIENTS with implanted prosthetic heart valves;
– PATIENTS who are pregnant, because the safety of the MR EXAMINATION has not been completely established for embryos or foetuses. Qualified medical practitioners should determine (after considering alternatives) if the clinical value of the examination outweighs the RISKS.

Concerning 201.7.9.2.101 b) – MEDICAL SUPERVISION of PATIENTS

In terms of the potential need for MEDICAL SUPERVISION of the PATIENT, particular caution is required in performing MR EXAMINATIONS for the following cases:

– PATIENTS with a greater than normal potential for cardiac arrest;
– PATIENTS who are likely to develop seizures, or claustrophobic reactions;
– decompensated cardiac PATIENTS, febrile PATIENTS, and PATIENTS with impaired ability to perspire;
– PATIENTS who are unconscious, heavily sedated, or confused, and with whom no reliable communication can be maintained;

– babies and small infants who cannot be expected to use the audio communication channel provided with the MR EQUIPMENT;

– examinations which are carried out at ENVIRONMENTAL TEMPERATURE above 25 °C.

Concerning 201.7.9.2.101 c) – Emergency medical procedures

Attention should be paid to safety considerations related to the emergency procedures that could be necessary for particular PATIENT conditions. Though this is a subject that is the responsibility of the RESPONSIBLE ORGANIZATION, it may be helpful if the MANUFACTURER gives advice on this matter:

– a recommendation that there should be established a procedure for removing PATIENTS rapidly from the magnet's influence (if necessary, by shutting down the magnet) in case of an emergency;

– a recommendation to establish an appropriate plan for treating, outside the magnet's influence, a PATIENT who requires emergency assistance (because the safe and effective use of electronic or other metallic emergency equipment may be impossible near the magnet).

– a recommendation to establish a procedure for removing PATIENTS from the magnet's influence when an unexpected implant is found. In this case, using the EMERGENCY FIELD SHUT DOWN UNIT may not be appropriate in view of the relative rapid decay of the static magnetic field and a slow removal of the PATIENT from the magnet may be the most appropriate method.

Communication with the PATIENT or monitoring of an anaesthetised PATIENT should be assured throughout the MR EXAMINATION.

Certain PATIENTS may sustain claustrophobic reactions which should be discussed before a MR EXAMINATION is undertaken.

Concerning 201.7.9.2.101 d) – Exposure of the PATIENT and the MR WORKER to excessive acoustic noise

Standards to protect against hearing loss are based on the RISK for permanent noise-induced hearing loss caused by long term occupational exposure. The allowed exposure in the general standard is 80 dB(A) per 24 h. This limit can be increased with 3 dB per factor 2 less duration (i.e. 83 dB(A) per 12 h, 86 dB(A) per 6 hs, etc.). In addition it is ruled in some countries that at daily exposure levels above 85 dB(A) appropriate measures should be taken [3],[4]. This applies for workers.

For PATIENTS this standard requires that the instructions for use point to the need to apply hearing protection when the MR EQUIPMENT is capable of producing noise levels above 99 dB(A), which is derived from the limit of 80 dB(A) defined in subclause 9.6.2.1 of the general standard. This limit is increased by 14 dB, because the exposure duration is 1 h only. Another 5 dB are added because the exposure is given only once instead of daily, which can be derived from Kryter [5]. According to Kryter it is reasonable to assume that permanent shift of the acoustic threshold in occupationally exposed persons is proportional to the total noise energy present over the entire career. In total, the level above which hearing protection is required for the PATIENT is:

$$80 \text{ dB(A)} + 14 \text{ dB} + 5 \text{ dB} = 99 \text{ dB(A)}$$

The requirement is important because modern MR EQUIPMENT can produce noise levels to the PATIENT that are much higher than 99 dB(A). Mc Jury *et al.* [6] recently report levels up to 115 dB(A). The MR EQUIPMENT may produce a noise spectrum with a broad band centered around 1 kHz [7]. However, the design of strong GRADIENT UNITS in new MR EQUIPMENT may lead to higher noise levels as well as higher centre frequencies [8] (see also subclause 201.9.6.2.1). The noise attenuation from the use of properly applied hearing protection (ear muffs or earplugs) usually ranges from 25 dB – 30 dB at 2 kHz. Accidental sub-optimal use or

omission of hearing protection is not an acute safety problem for most PATIENTS [9]. Their typical exposure duration will be much below 1 h and the typical noise level in most scans is much (5 dB – 10 dB) below the maximum value of which the MR EQUIPMENT is capable. However this may not be true in MR EQUIPMENT that can produce very high noise levels. In addition, special care should be taken for the situation in which the PATIENT is given anaesthesia. In that case the aural reflex can be ineffective or much less effective than in conscious PATIENTS, because of the influence of the muscle relaxing drugs on the stapedius muscle in the middle ear [10]. The necessity of the careful use of ear protection especially in that situation has to be emphasized in the instructions for use.

Concerning 201.7.9.2.101 e) – CONTROLLED ACCESS AREA

The installation of a CONTROLLED ACCESS AREA and the appropriate use of warning signs and markings is necessary to control exposure of individuals with medical implants to high magnetic fields, and to prevent the entry of ferromagnetic objects into the CONTROLLED ACCESS AREA (see also rationale to 201.7.9.2.101 j) and 201.7.9.3.101 b)).

(1) Attraction and torque on ferromagnetic materials

NOTE This item refers to areas inside the CONTROLLED ACCESS AREA.

All magnets are surrounded by magnetic fringe fields. The major safety consideration is the development of administrative and physical barriers to prohibit the accidental introduction of ferromagnetic objects into the examination area.

In addition, the field distortions generated by small magnetic objects either in the PATIENT or accidentally introduced and clinging to the inside of the magnet can result in image artefacts. For these reasons, the examination area should be secured against unauthorised entry at all times.

Various HAZARDOUS SITUATIONS, which may be caused by interaction between ferromagnetic materials and the field, are as follows:

– ferromagnetic aneurysm clips or ferromagnetic fragments being displaced inside the body of the PATIENT, damaging surrounding tissue;
– loose ferromagnetic materials, attracted into the magnet, injuring the PATIENT externally; and
– a heavy ferromagnetic object, attracted to the surface of the magnet, trapping a person between it and the magnet.

The attractive force and/or torque exerted by a magnet upon an object composed of ferromagnetic materials is due to the interaction of the magnetic field and the induced magnetisation in the object. This force will therefore depend on the value and on the rate of variation in space of the magnetic field, on the specific magnetic properties of the object's materials as well as on the object's mass and shape.

Similarly, the torque exerted by the magnet on an object depends on the same quantities. It may also be present in the absence of any attractive force in a situation in which the field is perfectly uniform. An object will always experience a torque unless it is perfectly aligned with the field, whereas an attractive force will be exerted only in the presence of a non-uniform field.

Notwithstanding the fact that the force on an object depends on its magnetic nature and on the spatial rate of change of the field, it is more practicable to state the necessary precautions in terms of a field limit value, since measurements of the static field can be performed more easily. The attraction effects usually come into effect when the magnetic fringe field is stronger than 3 mT.

An alternative approach to control the attraction on ferromagnetic materials is described in the ACR Guidance Document for safe MR practices [142]. In stead of just defining field limit values which constitutes the CONTROLLED ACCESS AREA, the MR site is conceptually divided into four zones.

– Zone I, is the region which includes all areas that are freely accessible to the general public.

- Zone II, is the area which constitutes the interface between the uncontrolled Zone I and the strictly controlled Zones III and IV. Typically PATIENTs are greeted in Zone II.
- Zone III, is the region in which free access by untrained persons may result in serious accidents. Zone III is strictly under control by MR personnel and should be physically restricted from general public access by for example key locks. Non-MR personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become MR personnel themselves. Zone III, or at the very least the area within it wherein the static magnetic field's strength exceeds 0,5 mT, should be demarcated and clearly marked as being potentially hazardous.
- Zone IV, is the area which is synonymous with the MR scanner magnet room itself. It is by definition always located within Zone III. Zone IV should always be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields.

Other publications are available describing possible instructions for the design and realization of MR suites. Examples are the MRI Design guide as published by the Department of Veterans Affairs. [156].

Magnets can be classified roughly into the following general types:

– superconducting magnets,
– resistive magnets and
– permanent magnets.

Self-shielded magnets differ significantly from their non self-shielded counterparts with respect to the distribution of the magnetic fringe field. Non-self-shielded superconducting magnets and resistive magnets with an air core solenoid tend to have the same distribution of the magnetic fringe field, except that the intensity of the field differs.

The various types of magnets can be classified in terms of the attraction of ferromagnetic materials as follows:

– Non-self-shielded type magnets

  This type of magnet has the most extensive magnetic fringe field region and, therefore, produces the widest hazardous zone. Since the rate of change of the field is low, the expected forces are less severe. Due to their lower magnetic field, the resistive magnets have a proportionally smaller hazardous region than superconducting magnets.

– Self-shielded type magnets

  The magnetic fringe fields are restricted and therefore the hazardous zone is limited. Nevertheless, due to the significant field gradient, the maximum attractive force exerted by this type is greater than that of the non-self-shielded type.

– Permanent magnets

  The magnetic fringe field region is the most limited, with the smallest hazardous zone as a result. However the field gradient is more significant. Consequently there is a danger that ferromagnetic materials could be attracted even in the zone where the magnetic fringe field intensity is small. In addition, permanent magnets cannot in practice be de-magnetised in cases of emergency, whereas other types of magnet can be de-energised.

2) Effect of the static field on other devices

   The use of warning signs and the definition of a CONTROLLED ACCESS AREA are necessary to control exposure of individuals with medical implants. Generally, areas below 0,5 mT have not been shown to be a potential source of interference, e.g. to cardiac pace-makers [11]. The European Standard EN 45502-2-1 [12] reflects this fact by defining a threshold of 1 mT.

   The controlled access area is set to 0,5 mT in order to provide an adequate safety margin for implants that still use a reed switch or Hall effect switch for control of patient therapy. Typical switches are specified for operation at or above 1,0 mT but

margin is provided for switch tolerances, manufacturing variabilities, and other factors (e.g. component ageing, flux density variations).

Numerous electronic equipment found in a hospital department (e.g. X-RAY TUBES, cathode ray tubes, scintillation cameras, and X-RAY IMAGE INTENSIFIERS) may be affected by magnetic fields above a value of the order of 0,1 mT to 5 mT. Siting a MR EQUIPMENT in an area in which its magnetic fringe field impacts on this equipment may require shielding. Such shielding can also simplify the problems of control of access for safety reasons. It is worth noting that equipment such as television systems and video display terminals are particularly important in this respect because they are becoming more and more common in a medical facility. Computer electronics are generally not affected by the lowest fields. To erase magnetic information, such as that on credit cards requires a relatively low static field. Thresholds as low as 20 mT have been reported.

Since the output of a photo-multiplier tube is affected by the magnitude and orientation of magnetic fields, equipment whose operation is extremely sensitive to the gain of a photo-multiplier tube (e.g. belonging to a scintillation camera or a COMPUTED TOMOGRAPHY system) can be among those affected by the lowest magnetic fields. The entire equipment or individual photo-multiplier tubes can be magnetically shielded, but the large aperture of a scintillation camera will make magnetic shielding difficult in most cases.

Electroencephalographs and electrocardiographs may be used in areas near the MR EQUIPMENT sites, the former being extremely sensitive to time varying magnetic fields and the latter being relatively insensitive. However, quantitative data should be provided by the MANUFACTURER of the electroencephalograph or electrocardiograph equipment.

Concerning 201.7.9.2.101 f) – Liquid and gaseous cryogens

1) Handling of liquid cryogen: helium and nitrogen

   a) Properties of the cryogen

      – detrimental to health (see also item 2);
      – odourless;
      – non-flammable;
      – non-toxic;
      – helium is lighter than air;
      – when evaporating, they produce cold fogs which will spread.

      Nitrogen fog will sink quickly to the floor.

      At ENVIRONMENTAL TEMPERATURE (20 °C), 1 l of liquid helium will produce approximately 810 l of helium gas, and 1 l of liquid nitrogen will produce approximately 700 l of nitrogen gas.

   b) Dangers associated with cryogen

      Incorrect handling of helium and nitrogen can result in:

      – danger of cold injuries;
      – danger of suffocation;
      – danger of oxygen condensation.

      • Cold injuries

      When handling liquid nitrogen/helium, any contact with the skin should be avoided, because of the danger of cold injuries. Splashes on the skin cause skin damage similar to burns. The eyes are particularly vulnerable.

      • Danger of suffocation

      Leaking helium or nitrogen gas will displace the oxygen. An ambient air oxygen concentration of less than 17 % to 18 % is not sufficient for human respiration. The limit of the air oxygen concentration should meet national laws or regulations.

If a cloud of helium or nitrogen escapes into the examination room, it is advisable to immediately evacuate the room and to re-enter this room only after the oxygen content has been verified to be sufficiently high.

- Condensation of oxygen

The surface temperature of containers of nitrogen and helium may be sufficiently low to condense oxygen or oxygen-enriched air, which would add to a fire HAZARD.

If grease, oil or other combustible material is present in the vicinity of containers, the escape of cryogenic gases can lead to the formation of a potentially combustible liquid due to liquefaction of air and concentration of oxygen.

c) Protective clothing

The wearing of protective clothing is essential during all work in conjunction with liquefied cryogen.

Such clothing consists of:

– safety gloves;
– work gloves;
– face shield;
– laboratory coat/overalls (cotton or linen);
– non-magnetic safety shoes.

2) QUENCH

A QUENCH is due to excessive heating of the wires of the magnet immersed in liquid helium (e.g. induced by loss of vacuum, mechanical perturbations, excess external forces, etc).

Superconducting magnets can vent up to several hundred litres of cryogenic gases per hour during normal operation. During the QUENCH, approximately 10 m^3 to 10^3 m^3 of gas at atmospheric PRESSURE can be vented within a few minutes.

Usually, a QUENCH occurs when the quantity of liquid helium becomes insufficient to cool the superconducting coil. Due to the increase in the temperature of the coil, the superconducting wire exhibits normal conductivity, and an excessive boil-off starts.

If proper venting is not used, three effects can occur during rapid boil-off at a QUENCH:

– excessively cooled gases will freeze water molecules in the area adjacent to the magnet, causing a dense white fog;
– air in the room will be displaced by helium, making it difficult, if not impossible, to breathe;
– the helium gas that escapes during a QUENCH is extremely cold and might even freeze objects in its way.

3) Filling of cryogen

In some types of MR EQUIPMENT periodic refill of cryogen is necessary to keep the helium above the safety level to prevent the QUENCH. During the refill, excessive boil-off of cryogenic gas occurs which could cause the same condition as mentioned above. About 10 % to 30 % of liquid helium will be converted to gas during normal refilling.

Concerning 201.7.9.2.101 g) – Operating modes

See rationale concerning 201.12.4.103.

Concerning 201.7.9.2.101 h) – Exposure of the PATIENT and MR WORKER to static magnetic field

Static magnetic fields used in commercial MR EQUIPMENT range in strength from about 0,02 T to 3,0 T. Experimental units now range in field strength up to 10 T. While permanent magnets