WIRING OF FIXED ELECTRICAL EQUIPENT IN PATIENT AREAS

May 2006

Introduction

Safety requirements for electrical wiring are set out in AS/NZS 3000.[1] Additional requirements for patient areas are set out in AS/NZS 3003.[2] This technical brief discusses the latter requirements in regard to fixed medical electrical equipment such as X-ray systems, gamma cameras, CT, MRI and PET scanners, linear accelerators, dental chairs and dental X-ray units, surgical luminaires and patient examination lights.

Scope of AS/NZS 3003

AS/NZS 3003 applies to electrical installations in patient areas of hospitals, medical and dental practices and dialyzing locations.

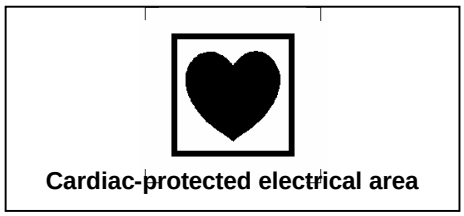
Patient areas are defined in AS/NZS 3003:2003 as:

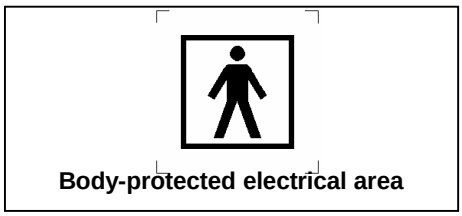
> Locations in hospitals and medical and dental practices in which it is intended that low voltage medical electrical equipment will be used. Locations in patients' homes and other facilities intended for dialysis are also included.

This definition is discussed in more detail below under the heading, "Which locations must be wired to AS/NZS 3003?"

Medical electrical equipment is electrical equipment intended for diagnosis, treatment or patient monitoring that makes physical or electrical contact with patients, transfers energy to or from patients, or detects such energy transfer.[3]

Patient areas are wired and signposted as body-protected electrical areas or cardiac-protected electrical areas as shown:





[1] AS/NZS 3000: Electrical installations. This standard is often referred to as "the wiring rules". The current edition at the time of writing is AS/NZS 3000:2000 with subsequent amendments.

[2] AS/NZS 3003: Electrical installations – Patient areas of hospitals, medical and dental practices and dialyzing locations. This standard is often referred to as "the hospital wiring rules". The current edition at the time of writing is AS/NZS 3003:2003.

[3] Based on definition in AS/NZS 3200.1.0: Medical electrical equipment — Part 1.0: General requirements for safety — Parent Standard.

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Common requirements for body-protected and cardiac-protected areas

The supply wiring to most socket-outlets and some fixed medical electrical equipment in body-protected and cardiac-protected areas must be protected by Type 1 residual current devices (RCDs) or isolation transformers. Known as leakage protective devices (LPDs) both provide additional electrical protection to that specified in AS/NZS 3000.

Socket-outlets on the ceiling or above 2.3 m on the wall do not require LPD protection if they are used for permanently mounted non-medical electrical equipment.

The use of isolation transformers is much more expensive than the use of Type I RCDs. However, the former simply sound an alarm under many conditions in which an RCD would trip the supply.

Other common requirements for body-protected and cardiac-protected areas include colour coding of socket-outlets to differentiate between normal, essential and uninterruptible supplies, and socket-outlets for cleaning purposes. The latter must be provided in each patient area and protected by LPDs that do not protect any other socket-outlets.

Additional requirements for cardiac-protected areas

In addition to the above requirements, each cardiac-protected area is provided with an equipotential earthing system.

Cardiac-protected areas are required for medical procedures in which an insulated electrical conductor is introduced into direct contact with heart muscle while accessible outside the patient's body. [4] Stray current as low as 100 µA flowing through such intracardiac conductors can result in immediate microelectrocution.

To address this hazard the equipotential earthing system minimises the likelihood of more than 0.05 volts a.c. appearing between any electrical equipment or other conductive items that might be connected to, or touched by, the patient, or by a third party who in turn touches the patient or the intracardiac conductor.[5]

All socket-outlets in a cardiac-protected area and any fixed electrical equipment that is located near patients must be earthed to the relevant distribution board via a single equipotential junction (EPJ). Metal fittings located near patients such as medical gas, suction and water pipes, and equipment mounting rails, must also be earthed to the EPJ if they contact structural building metal.

One variation to this system is allowed for permanently wired imaging systems with high current (often 3-phase) supplies. Such equipment is often supplied from a dedicated X-ray distribution board with appropriately sized supply and earthing conductors and may even be wired directly from the main switch board. It is usually convenient to run these active, neutral and earthing conductors together from the distribution board to the imaging system. This is allowable in cardiac-protected areas providing a particularly low resistance conductor is also installed between the main earthing point of the imaging system and the EPJ.

[4] Examples include temporary cardiac pacing electrodes, liquid filled cardiac catheters and swan ganz probes.

[5] The health care facility must also ensure that all electrical equipment within arms length of the patient is properly earthed – in particularly equipment with flexible supply cables or flexible earthing conductors.

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LPD protection of permanently wired electrical equipment

The only permanently wired electrical equipment that requires LPD protection in body-protected or cardiac-protected areas is medical electrical equipment with Type B applied parts that enter patients or contain liquid that enters patients. (Annex A discusses applied parts and their classification and marking.)

Medical electrical equipment that sometimes falls under this requirement includes dental units (chairs) and some angiography injectors.

Which locations must be wired to AS/NZS 3003?

Under previous editions of AS/NZS 3003 the governing body or proprietor of a health care facility was responsible for deciding which patient areas should be wired as body-protected or cardiac-protected areas, taking account of the medical procedures to be carried out and the level of protection provided by the available medical electrical equipment. A safe practice code dealing with these issues is set out in AS/NZS 2500.[6]

However AS/NZS 3003:2003 requires all patient areas to be wired as body-protected areas unless the governing body or proprietor specifies the need for cardiac-protected areas.

The definition of patient areas in AS/NZS 3003:2003 includes the following notes:

1. All patient areas shall be body-protected or cardiac-protected electrical areas (refer Clause 2.1).
2. For hospitals the patient area would normally include areas where the patient may be located for treatment, diagnosis or accommodation, including wards, patient bathrooms and patient holding areas. Transit areas such as corridors and lifts would not normally be included.
3. Low voltage medical equipment includes such items as electric beds, patient lifts, portable infusion pumps and ECGs. AS/NZS 2500 provides guidance on low voltage medical electrical equipment.

Such notes are only advisory and not a normative part of an Australian standard. However:

Note 1: Draws attention to the normative requirement that all patient areas must be wired as body-protected or cardiac-protected areas.

Note 2: Provides advice about which hospital areas would normally be patient areas. While Biomec considers this advice to be very confusing, the issues it raises are not of concern when installing fixed equipment such as that mentioned in the introduction to this technical brief. Whether such equipment is installed in a hospital or any other medical or dental practice, it is clearly medical electrical equipment and as such can only be installed in body-protected or cardiac-protected areas.

Note 3: Provides examples of plug-in medical electrical equipment.[7] However the normative requirement that locations intended for the use of mains operated medical electrical equipment must be wired to AS/NZS 3003 applies to plug-in or permanently wired medical electrical equipment.

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[6] AS/NZS 2500: Guide to the safe use of electricity in patient care.

[7] We interpret “patient lifts” to mean patient lifting devices and not “hospital lifts set aside for patients”. We also interpret “portable infusion devises” to mean “mains powered portable infusion devises”.

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Electrical installation work

Electrical safety regulations in various states specify that all installation work necessary to comply with the wiring rules must be carried out by a licensed electrician, including the installation of fixed electrical equipment. On the other hand, installation of sophisticated medical electrical equipment often requires specially trained technicians who may not be licensed electricians.

Installation and termination of mains supply and earth wiring must be carried out by a licensed electrician as must any activity exposing live mains voltage. Other installation work can be carried out by non-electrically licensed personnel but must not compromise compliance with AS/NZS 3000 or AS/NZS 3003. For example, while non-electrically licensed personnel may install extra-low voltage wiring (such as computer cables and nurse call systems) care must be taken to ensure compliance with the segregation requirements of AS/NZS 3000 when such wiring is installed in a duct that also houses mains voltage wiring and socket-outlets.

Fixed electrical equipment has been described by the Office of the Chief Electrical Inspector – Victoria (now the Energy Safe Victoria):

> The following electrical equipment is regarded as fixed, irrespective of the means of connection (eg: fixed wiring or plug and socket): Equipment which is either fixed in position, recommended to be fixed in position by the manufacturer or provided with means for fixing.
>
> For the purpose of these guidelines, fixed means secured, attached or connected by conduit, metallic pipe-work, duct, bolt, screw, clip, other fastening device or fixed wiring as defined by AS/NZS 3000:2000.
>
> Where equipment comprises a number of discrete components that are required to function as a group or operate in a coordinated manner and are connected to the supply via a flexible cord and plug, the equipment shall be considered to be a part of the fixed electrical installation.

These guidelines also suggest that electrical equipment with a mass of more than 18 kg should be considered as fixed equipment irrespective of whether it is connected by fixed wiring or plug and socket. However, Biomec suggests there items of single-phase plug-in electrical equipment intended to sit benches or trolleys without being screwed down should not require a licensed electrician even when they weigh more than 18 kg.

Upgrading of patient areas

Many locations such as hospital wards, X-ray imaging rooms and dental surgeries that now fall within the scope of AS/NZS 3003 are not currently wired as body-protected or cardiac-protected areas.

There is no requirement in AS/NZS 3000 or AS/NZS 3003, or to our knowledge in any state electrical regulations, that electrical installation must be brought into compliance when a new edition of either standard is published. The question of whether a hospital, medical practice or dentist has a duty of care regarding compliance with new safety standards is outside the scope of this brief, although we have noticed that various professional bodies and accreditation organisations are developing advice and requirements in this area.

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However, various state electrical safety regulations do require all new electrical installation work to be carried out in accordance with current electrical wiring standards. No new electrical installation work can thus be undertaken in a patient area that is not wired as a body-protected or a cardiac-protected area until the area has been upgraded.

This situation applies equally to the installation of a new socket-outlet, dental chair or CT scanner. Patient areas have to be upgraded to body-protected areas before undertaking new electrical installation work.

Inspection of new work

AS/NZS 3003:2003 requires all new installations and alterations to existing installations to be inspected and tested by "persons having the appropriate knowledge and experience and holding relevant qualifications". A typical commissioning check list (report) is set out in the standard. While inspecting and testing is a normative requirement of the standard, the report format is only a recommendation.

The somewhat more detailed inspection and testing protocols we adopt are set out in our Technical Brief No 70. However we use a simple report format that our clients find convenient.

Prescribed electrical work (Victoria)

All installation work in body-protected and cardiac-protected areas is prescribed under Victorian electrical safety regulations – including the installation of new or replacement permanently wired or fixed medical electrical equipment. Such work must be carried out by a registered electrical contractor (REC) using licensed electrician(s). The "Disconnect/Reconnect Workers Licence" does not cover installation of new electrical equipment or fittings. Inspection and testing must be carried out by a suitably licensed Class M electrical inspector. Both the electrician and the inspector must sign a prescribed certificate of electrical safety which must be logged with Energy Safe Victoria. For more details see Annex B or go to:

http://www.ocei.vic.gov.au/industry/coesafety.html

Repairs to permanently wired or fixed medical electrical equipment that expose live mains conductors must also be carried out and certified by a licensed electrical worker. Repairs that only involve the replacement of like-for-like components are not prescribed work and can be certified by a person with the "Disconnect/Reconnect Workers Licence" who signs a certificate of electrical safety without involving a licensed electrical inspector.

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ANNEX A

MEDICAL ELECTRICAL EQUIPMENT – APPLIED PARTS

Applied parts of medical electrical equipment are parts that contact patients.

Not all applied parts contain electrical conductors that contact patients and some applied parts only make superficial, casual electrical contact. However, other applied parts form a permanently attached, low resistance electrical connection between the equipment and the patient, eg: electrodes placed on or in the body to measure physiological potentials or deliver measured amounts of electric energy, metal conductors that enter patients, and tubes that carry conducting liquid between equipment and patients.

Because the application of some applied parts significantly increases the risk of electrocution and serious burning in various types of electrical accident, all are classified and marked as follows to indicate the degree to which they limit current if mains voltage were to be applied between the equipment and the patient:

Applied part	Current limitation at mains voltage
 Type B	None required – electrically conductive Type B applied parts may be directly earthed within the medical electrical equipment. In a mains voltage shock, the current will only be limited by the patient resistance.
 Type BF	Maximum 5 mA – well above the pain threshold but below the level for electrocution or serious burning for current entering and leaving the patient other than directly via the heart.
 Type CF	Maximum 50 μA – almost below the perceptual threshold and below the level for electrocution, even for current concentrated directly through the heart.

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ANNEX B

ENERGY SAFE VICTORIA ARTICLE

This article was recently prepared by Energy Safe Victoria for distributed to registered electrical contractors and licenced electricians throughout Victoria. It is reproduced here with the permission of Energy Safe Victoria.

Beware 'Ignorance is not Bliss'

ELECTROMEDICAL INSTALLATIONS

Registered Electrical Contractors (REC's) and Licenced Electricians need to be aware of the specific requirements of the Wiring Rules when carrying out electrical work in patient treatment areas of hospitals and medical and dental practices. Instances of REC's incurring financial loss have been noted by Energy Safe Victoria as a result of contractors treating such installations as accommodation facilities when tendering for new work and failing to consider the special requirements of AS/NZS 3003:2003 (Electrical installations – Patient areas of hospitals, medical and dental practices and dialyzing locations). Problems also arise when companies undertake to supply and install fixed medical electrical equipment such as diagnostic imaging systems and dental units without anticipating the extent of work required to comply with AS/NZS 3003.

A major consideration of AS/NZS 3003:2003 concerns electric shock hazards to patients and medical personnel. Other safeguards against thermal, mechanical and radiation hazards must also be heeded. Another important consideration is loss of electrical supply in areas where medical electrical equipment is used to support or replace vital body functions. Measures are required to maintain electrical safety by specifying the class of medical electrical equipment and the wiring system required for particular medical procedures. Of particular concern is the use of medical electrical equipment with conductive 'applied parts' such as ECG electrodes, or parts that enter patients. Particular electrical hazards exist because this equipment is often used in or under wet conditions and applied parts are often designed to adhere or remain in place with very low electrical resistance. Additional microshock electrocution hazards occur when applied parts are introduced into direct contact with the heart. Electrical installations, and the use of electrical equipment in these areas, must be designed to prevent the likelihood of macroshock and microshock electrocution hazards to the patient.

AS/NZS 3003 defines 'patient areas' as locations in hospitals and medical and dental practices intended for the use of mains powered medical electrical equipment, and locations in patients' homes and other facilities intended for dialysis. Such areas must be wired as 'body-protected electrical areas' or 'cardiac-protected electrical areas'. Most socket-outlets and some medical electrical equipment must be protected by 'leakage protective devices' (LPDs) in the form of high sensitivity fast RCDs[1] or isolation transformers.[2] The protective earthing system in cardiac-protected electrical areas is arranged as an equipotential earthing system and extended to include structurally connected non-electrical fittings in the patient vicinity.

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[1] The Type 1 RCDs used as leakage protective devices (LPDs) in cardiac-protected and body-protected electrical areas are three times more sensitive than the normal RCDs used to protect wiring to socket-outlets and nearly ten times faster under low leakage conditions.

[2] Isolation transformers that are used as leakage protective devices (LPDs) must be provided with line isolation monitors (LIMs) and overload monitors.

Patient areas include operating theatres and procedure rooms; intensive care, high dependency and coronary care units; diagnostic imaging units, radiotherapy rooms, etc, and any areas in which electrical equipment is used for diagnosis or treatment. Within acute hospitals this usually includes wards and many other locations. Dental surgeries and dialyzing locations must be wired to AS/NZS 3003:2003 wherever they are located. Many areas in medical consulting suites and physiotherapy and chiropractic practices must be wired to this standard.

Advice on whether a patient area should be wired as a body-protected or a cardiac-protected electrical area is set out in AS/NZS 2500:2004 (Guide to the safe use of electricity in patient care). Under this code of practice, all patient areas should be wired as body-protected electrical areas unless the owner of the facility specifies the need for cardiac-protected electrical areas.

It has become apparent that many dental surgeries do not comply with the requirements of AS/NZS 3003:2003 even though they are clearly intended for the use of medical electrical equipment and should be wired as body-protected electrical areas. Although many dental chairs and dental X-ray units are connected to supply by plug-in means, this does not relieve the installer or operator from strict compliance with this standard. The ESV website www.esv.vic.gov.au contains information on the application and installation of equipment using plug and socket devices as the method of connection to an electricity supply. Fixed medical electrical equipment must be installed by a Licenced Electrician, irrespective of whether it is connected to the electricity supply by a plug or permanently wired.

The Electricity Safety Act 1998 requires persons undertaking electrical installation work for profit or gain to be Registered as an Electrical Contractor and engage Licenced Electrical Installation workers to carry out the electrical work. However, persons who are regularly and directly employed in premises owned or occupied by the employer, such as a Hospital, are exempted from holding Registration as an Electrical Contractor.

Many types of diagnostic imaging equipment, radiotherapy units, surgical luminaires, etc, constitute fixed medical electrical equipment and must be installed by a Licenced Electrician. Electrical contractors that wire body-protected or cardiac-protected electrical areas under a contract that includes the provision of a submain or final subcircuit specifically for the supply of such equipment must take appropriate steps to ensure this supply is not switched on until a certificate of electrical safety has been signed for the associated and connected fixed equipment.

A Licenced Electrician who signs a certificate of electrical safety covering the installation of fixed medical electrical equipment must accept responsibility for all the associated electrical installation work (and not simply for ‘connection to supply’) and must ensure that other work carried out by non-licensed personnel does not compromise compliance with AS/NZS 3000 (Wiring Rules) or AS/NZS 3003.

In Victoria the requirements of Clause 7.11.6 (*Electromedical treatment areas*) of AS/NZS 3000:2000 where electrical installations fall within the scope of AS/NZS 3003 are mandated, and compliance therewith is required by the Electricity Safety (Installation) Regulations 1999. The installation and alteration of this type of electrical work is considered to be ‘Prescribed Electrical Installation Work’ and must be inspected by an ‘M’ class licenced electrical inspector before use. The repair and maintenance of an individual component part of the installation on a like-for-like basis is generally deemed to be ‘Non Prescribed Electrical Installation Work’ and does not require inspection – however, such work may be subject to an audit.

Major changes in the current edition of AS/NZS 3003 include mandatory colour coding of socket-outlets, provision of cleaning outlets in each patient area, and restrictions on the type of leakage protection device (LPD) used to protect any uninterruptible power supply (UPS). New cardiac-protected electrical areas must employ ‘0.1 ohm equipotential (EP) earthing systems’ and connection of EP junctions to multiple distribution boards is now clearly specified.

The EP earthing system in an existing cardiac-protected electrical areas must fully comply before it can be altered to accommodate new fittings (eg: new socket-outlets) or new equipment (eg: a new diagnostic imaging system). Minimum lettering sizes are now specified for various

marking requirements. A new version of the standard is proposed for publication in mid 2006 and will address certain anomalies and conflicts and clarify the location patient areas.

Inspection and testing of new body-protected or cardiac-protected electrical areas must be completed and a certificate of electrical safety signed before the area is handed over for clinical use. This also applies before power can be turned on to alterations to electrical installations in patient areas.

It is important that REC's and licenced electrical workers avail themselves of current editions of relevant Australian Standards. Further information on electromedical installations may be sought from 'M' class licenced electrical inspectors, consulting biomedical engineers or Energy Safe Victoria.

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