



## Indicator 18:

### Medical equipment and resources are available and maintained to meet patient needs

The following is an update of the guidance notes for Indicator 18 for CORNERSTONE® practices working on the current 2011-2014 *Aiming for Excellence*.

It is a guide only and is not a comprehensive or exhaustive tool on the topic, or a method of verifying compliance with the standard.

**At this stage the criteria remain unchanged.** The standard itself is under review and a new version will be available in July 2016.

## Guidance notes

All medical equipment and resources must be suitable for supporting comprehensive primary care, safe resuscitation and safe performance of any additional procedures offered in your practice.

The adequacy and appropriateness of basic equipment may be determined by your practice's circumstances and you must be able to justify any omissions.

All essential medical equipment and supplies listed in Appendix 1 must be available when needed, and competency in the use of the equipment should be current.

If a defibrillator or an electrocardiograph is not available in your practice, an agreement should be in place for your practice team to access the equipment when needed. Clinical team members should be appropriately trained to use them.

**An electrical medical device is any piece of medical equipment as defined by the Medicines Act 1981 that involves an applied part to a patient and that part is electrically connected to equipment that has a power source that is earthed.**

When using or operating any type of equipment including electrical medical devices it is important to assess the following factors:

#### 1. Environment:

- Is the place you will be using the equipment configured for the purpose?

## 2. Equipment safety:

- Is the equipment safe (demonstrated by acceptance testing before new equipment is released and maintenance activities like annual testing and performance verification, etc)?
- The equipment needs to be in working order.
- If using electrical medical devices, is appropriate RCD protection used?
- If the equipment is from overseas, does it meet NZ and/or international standards and is it compatible with NZ power, 230 Volts 50 HZ?

## 3. Training and competence:

- Does the operator know how to use the equipment?
- Is the operator using the equipment safely?
- Instructions and rules around its use are provided.

### Using Residual Current Devices (RCDs) in your general practice

Residual Current Devices (RCDs) are commonly used as a safety device to minimise the risk of electric shock.

RCDs used to provide safety in medical procedures are more sensitive to reflect the bypassing of the skin's resistance.

RCDs work by monitoring the flow of electricity out of the phase wire and returned up the neutral wire. The current in the wires must be balanced.

If the RCD senses a fault to earth (ie an imbalance) the RCD shuts off the power supply to the electrical equipment. It works on the assumption that this imbalance is caused by some of the current taking an unintended route, such as through a person, causing an electric shock.

It is recommended that all electrical outlets supplying an electrical equipment (other than electrical medical devices) in your practice (eg kitchen fridge, heaters, computers) is protected by standard 30mA RCDs. You should keep documentation for this.

**Any items that are portable devices (ie not a computer that always sits on a desk) should be visually checked before each use. If it looks broken the item should be removed from service following the practice's procedures.**

See over page for your options for RCD protection.

All electrical medical devices must be protected by medical grade 10mA (Type 1) RCDs

Your options for RCD protection for general practice:

There are a range of options to provide the appropriate RCD protection for electrical medical devices.

These include:

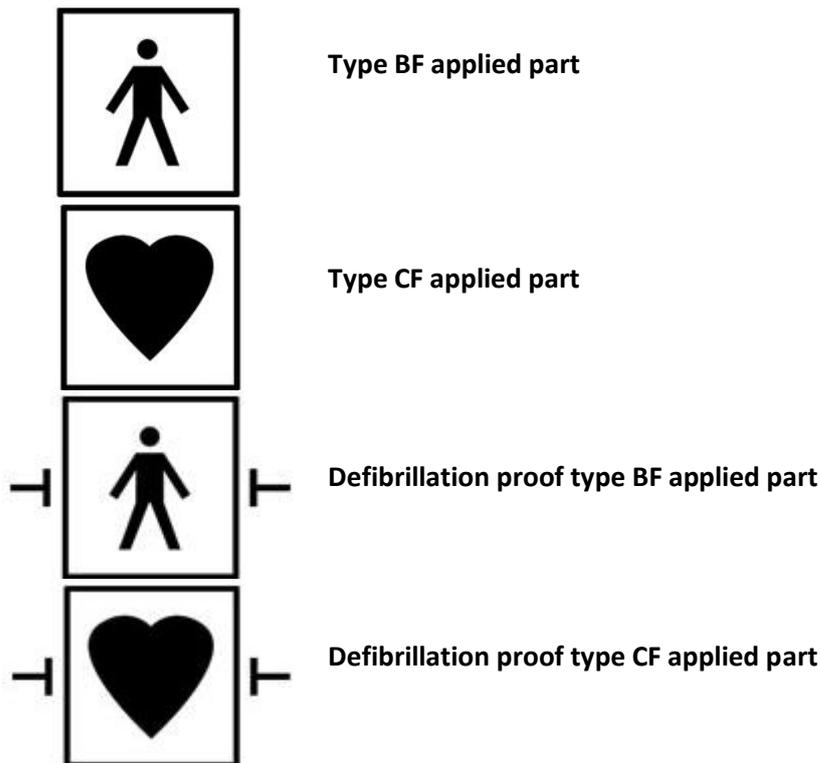
- Setting up designated Body Protected Area(s) in your practice.
- Installing 10mAmp Type 1 RCDs in locations where the electrical medical device may be used. You can:
  - Retrofit 10mAmp Type 1 RCD devices to standard wall mounted power sockets.
  - Use a portable or inline 10mAmp Type 1 RCD protector (pictured). This type of RCD can be hard wired into the cable of the electrical medical device ensuring you will always have the RCD protection wherever the device is plugged into. These RCDs need to be turned on every time the power is turned on. It is recommended that all users, after turning the power on, press the reset button and look for the red light/indicator then press the test button (the RCD should click and trip and the red indicator disappear) then press the reset again. **If the RCD does not trip then it should not be used.**
  - Fit 10mAmp Type 1 RCDs to the switch board.
- Some electrical medical equipment (eg ECG) may already have protection built into them. Their 'applied part' (the part of the medical device which comes into physical contact with the patient) is separated from earth (called 'floating'). When this is the case, the unit should display a BF or CF symbol indicating its safety standard. **If this symbol is displayed, you do not need sensitive 10mAmp RCD protection.**



**Use caution as some of these items can be left attached to a patient while a defibrillator is in use and some can't.**

See over page for the symbols to look for.

Look for these symbols:



**Note that socket outlets protected by a Type 1 RCD, whether on the switch board or the socket itself, should only have one device plugged into them.**

If the RCD is remotely installed from the socket outlet it is recommended that the socket outlet is readily identifiable to the user. This can be in the form of a label saying Type 1 10mA protected or similar wording.

Note for 10mA RCD:

Schools also use 10mA RCDs. But they are of a different type. **Ensure that when protecting medical equipment that your practice only uses 10mA Type 1 RCDs.**

### Vaccine refrigerators

The vaccine refrigerator should have an independent power point and surge protection. The switch should be of a type that has a flap that needs to be moved before it can be switched off. The surge protection can be provided on the switch board, or a plug in type, or the power point can be changed to a surge protected type.



Make sure you check regularly (as part of your daily checks of temperature etc.) that the power is on. Consider wiring the refrigerator in a manner that makes it immediately clear to your practice

that the power is off (eg to the room lighting circuit). Then if the lights go off, you know there is a problem with the refrigerator.

See the [Immunisation Handbook](#) for more detail.

### Electrical medical devices testing and servicing

Electrical medical equipment/devices must be inspected, tested and serviced in accordance with AS/NZS 3551 (at least annually), other relevant standards and the manufacturer's operating instructions.

**All electrical medical devices need to be inspected annually to specifications set out in AS/NZS 3551:2012.**

It is recommended that for other electrical devices such as examination task lighting, electric beds, sterilisers, heaters and office equipment, RCDs (30mA) are used to provide increased protection to patients and staff.

Calibration and Validation:

Calibration is the process that confirms the quantitative accuracy of instruments or equipment (eg scales, sphygmomanometers).

Validation is the process of confirming the effectiveness of the equipment that it is achieving the required outcomes (eg steriliser/autoclave).

**You will need to keep records of annual servicing, calibration and validation of key pieces of equipment in your practice.**

Testing RCDs:

RCDs should be tested regularly to ensure that their capacity to 'trip' is still functioning. This is something that the practice staff can do.

You can test your socket outlet or portable RCDs by plugging in a small electric appliance (such as a lamp). Press the "test" button. If the appliance turns off, the RCD is working. If it stays on, get your RCD checked by a licensed electrician. Make sure you press "reset" once the test is complete.

#### → Links to Indicator 19

The practice team is committed to ensuring health and safety in the workplace

Equipment that is NOT electrical medical equipment can use 30mA RCDs

#### → Links to Indicator 15

The practice ensures effective infection control to protect the safety of patients and general practice team members

It's a good idea to test switchboard RCDs every six months by checking that it trips when the "test" button is pushed. However, be aware that tripping circuits will turn off the power to any appliances on that circuit (be careful with your vaccine refrigerator). So appliances with electronic clocks will have to be reset. For this reason, it's a good idea to test your switchboard RCDs when changing to and from daylight saving - when clocks have to be reset anyway and it will be about six months since the RCDs were last tested. See [Residual Current Devices](#) for more information.

Make sure you keep a dated and signed record of any RCD testing.

This can be in electronic format and electronically signed.

In addition, all 10mAmp Type 1 RCDs should be regularly (annually) tested by an electrician by proper test equipment and documented. The testing details can be sent by email for your records.

**Make sure you keep a dated and signed record of any RCD testing – electronic is acceptable.**

Your electrical testing records should include:

1. Who did the testing
2. What equipment was tested (list what was tested)
3. What they are claiming (eg it is safe, it has been verified it is performing properly, etc)
4. What the basis/evidence for the claim is (eg test results, etc).

Body Protected Areas:

**[Body Protected Areas](#) need to be inspected annually by someone appropriately qualified.** On each occasion the Body Protected Area signage will need to be updated with the latest inspection date.

Required documentation:

The practice should hold:

- a register of the medical equipment with a schedule and reminder process to ensure everything is current
- a copy of the annual medical equipment servicing report (this should be certified and dated)
- a record confirming the date when RCDs have been tested

### Body Protected Area

In some situations the practice may decide to set up areas specifically dedicated for using electrical medical devices that are used to diagnose, treat, or monitor a patient. These areas are referred to as a Body Protected Area.

Specialised services such as X-ray, minor surgery (involving diathermy and monitoring) or even a plaster room may benefit from the use of Body Protected Areas.

The features of a Body Protected Area are:

1. use isolating RCDs (10mAmp Type 1)
2. use socket indicators (lights on/off) and
3. RCDs need to be accessible in the body protected area/room or be labelled with lights on the switch board in accordance with AS/NZS 3003.

**The specific requirements for Body Protected Areas are described in a joint Australian/New Zealand standard AS/NZS3003 (2011).**

A general practice may not need to set up Body Protected Areas to use electrical medical devices if they are following safety standards as outlined above.

However if a practice is setting up Body Protected Areas within the practice **then is it essential that advice and direction is received from a suitably qualified person.**

Where the practice has deemed an area is a Body Protected Area, this area is to be certified and maintained in accordance with AS/NZS 3003. Keep a documented record of assessment by an authorised person. You will need the correct sign on the wall with correct, current stickers.

It is the responsibility of each general practice to ensure they have checked their individual requirements to ensure compliance with the relevant legislation or Standards.

### New builds

These options for protecting patients and members of the practice team also apply for new builds.

It is up to the PCBU (see Indicator 19) to decide how to achieve electrical safety in their workplace. They can use other things like RCDs or portable RCDs as above to achieve electrical safety. If they choose to put in a [body protected area](#) it needs to comply with AS/NZS 3003.

It is suggested that for a new build you install 30mAmp RCDs on all outlets that have not otherwise been set up with 10mAmp Type 1 RCD protection.

### Safe storage of medical equipment, medicines and pharmaceutical products

The [Medicines Act 1981 – Section 47](#) states:

Storage and delivery of medicines

1. No person who is in possession or in charge of any prescription medicine or restricted medicine shall put it—
  - a) in any cupboard, box, shelf, or other place of storage in which articles of food or drink are stored or kept for ready use; or
  - b) in any place to which young children or unauthorised persons have ready access.
2. No person shall pack any medicine, or prepare it for use, in any room, or on any table or bench, that is used for the purpose of packing, preparing, or consuming any food or drink.
3. Except as otherwise provided in any regulations made under this Act, no person who is in possession, for the purposes of any business, of a prescription medicine or a restricted medicine that is kept for the time being within any building or vehicle shall leave that building or vehicle unattended, unless they have taken all reasonable steps to secure that building or vehicle, or the part of it in which the medicine is kept, against unlawful entry.

## Resources

- [AEDs in your community](#)
- [Electrical \(Safety\) Regulations 2010:](#)
  - [Clause 25 Specific installations, fittings, and appliances deemed to be electrically safe](#)
  - [Clause 60 Certain installations must comply with Part 2 of AS/NZS 3000](#)
  - [Clause 75 Periodic assessments of certain installations](#)
  - [Clause 91 Periodic assessment of electrical medical devices](#)
- [Worksafe NZ \(Energy Safety\)](#)
- [Energy Safety – Using RCDs \(2006\)](#)
- [The Medicines Act 1981](#)
- [Residual Current Devices](#)
- [National Guidelines for Vaccine Storage and Distribution 2012](#)

## Additional resources

- [AS/NZS 3000:2007 Electrical installations \(known as the Australian/New Zealand Wiring Rules\)](#)
- [AS/NZS 3003:2011 Electrical installations - Patient areas](#)
- [AS/NZS 3551: 2012 Technical management programs for medical devices and Amendment 1: 2005](#)
- [Electrical safety regulations 2010](#)
- [Standards New Zealand. AS/NZS 2500: 2004 Guide to the safe use of electricity in patient care](#)