

## MEDICAL DEVICE CERTIFICATION

There has been much discussion recently on the BMELIST regarding certification and testing of medical devices. This mostly centred around the availability of type test certificates and the validity and value of such certificates as well as the CE mark and its meaning. I am not able to cover all discussion here but I thought the following discussion from Michael Flood at TGA worth including. If you want to see all the discussion I recommend you join the BMELIST. See Australian Biomedical website <http://godzilla.zeta.org.au/%7Ehbridel/>

"Back in early 1995 the TGA published a draft policy on the electrical safety requirements it planned to introduce for the entry of electromedical devices on to the Australian Register of Therapeutic Goods. That policy document was widely distributed, including on Hilary's web page. It has taken longer than we originally thought, but the requirements should be in place "....real soon now !!" but no later than January 1 1998.

A large part of the delay has been the moves by Australia toward mutual recognition with the regulatory framework of the EU. This has required a complete re-write and amendment to our current listing requirements for ALL therapeutic devices, and electrical safety has only been a small part of that process.

In these moves toward mutual recognition, and eventual harmonisation, the CE mark has figured prominently. Let me clarify some misconceptions regarding the CE mark, as it stands in Australia today.

The regulatory framework in the EU centres around the Active Implantable Medical Device Directive (mandatory since July 1990), the EMC Directive (mandatory since January 1996 (I think)) and the Medical Device Directive (mandatory from June 1998). To place a product on the market in the EU a manufacturer must be able to demonstrate the device is in compliance with the requirements of the appropriate directives (these requirements include not only safety, but biomaterials, risk benefit, side effects, storage and many others). Having demonstrated compliance (and there are a number of mechanisms to do this) the manufacturer can then affix the CE mark to the product.

For medium and high risk devices, (Class IIa, IIb, III or AIMDs) the product design process, the product itself, the manufacturing process, or a combination of some or all of these depending on classification, are subject to assessment and certification by a Notified Body (eg BSi, TUV, etc) before a product is placed on the market.

The general path to demonstrate compliance with the directives is to demonstrate compliance with standards such as IEC 601 (EN60601) or the like, but this is not necessarily the only path. Design and manufacturing processes are assessed to EN46000 (a harmonised EU standard derived from ISO 9000 but specifically intended to apply to quality assurance processes for the manufacture of medical devices). Only when the product (and design and/or manufacturing process) has passed these assessments can the manufacturer fix the CE mark to the product. The CE mark is also suffixed with a number to identify the Notified Body who performed the assessment (eg 0086 for BSi, 0123 for TUV Product Services).

For low risk devices, (Class I under the EU classification system) a manufacturer can self certify their product, PROVIDED they have compiled a technical file containing documentation and evidence to prove the product is in compliance with the requirements of the directive. That file is not assessed by an outside agency prior to placing the product on the market, but is subject to audit at any time by the regulatory agency in the country, and penalties can be applied for placing non-compliant product on the market. In this case the CE mark is easily identifiable because it has no numeric suffix - a Notified Body was not involved in the process.

The only MANDATORY CE marking for medical devices TODAY relates to compliance with the EMC Directive. The Medical Device Directive does not become mandatory until June 1998.

Bottom line, a CE mark attached to a device presented to a prospective customer in Australia today is not necessarily a guarantee that the device has been type tested to IEC 601. Further, the CE mark alone will not satisfy the entry requirements to the Australian Register of Therapeutic Goods for electrical safety and EMC compatibility when our new regs are in place in 1998 - and you can quote me on that !!

Although Australia is moving in the direction of EU harmonisation, where a CE will be sufficient to demonstrate compliance, it will be a couple of years yet before we get there. In the meantime, with the introduction of our new

listing requirements, Australia will be prescribing demonstration of compliance with standards as the ONLY method of demonstrating electrical safety and EMC compliance."

### **ELECTRICAL SAFETY**

To ensure the safety of both the patient and clinical staff, electrically powered therapeutic devices will be required to meet a minimum level of electrical safety prior to listing on the Australian Register of Therapeutic Goods.

Many State Electricity Supply Authorities also require electronic equipment sold within their State to comply with applicable standards and testing devices against relevant standards is often a part of State tendering procedures. Sponsors should contact the various State Authorities to ensure that the device meets all the requirements to be supplied in that State.

Using risk classification, electrical powered therapeutic devices are divided into three categories. These levels are based on the risks of injury as a result of device failure, misuse or absence (e.g. out of service and no replacement available).

Low Risk Devices whose failure or misuse is unlikely to result in serious consequences.

Medium Risk Devices whose failure or misuse would have significant impact on patient care but would not be

likely to cause direct serious injury.

High Risk Life support devices, key resuscitation devices and other devices whose failure or misuse is reasonably likely to seriously injure patients or staff.

### **Examples of devices and the various categories are**

Low Risk Medium Risk High Risk

Aspirators Blood warmers Anaesthesia Equipment

Cast cutters Capnographs Apnoea monitors

Light Sources ECG Monitors Defibrillators

Paraffin Baths Radiant Warmers Ventilators

Electronic Scales Gas Regulators Haemodialysis Equipment

Surgical Tables Ultrasound Imaging Radiotherapy Equipment

Ultrasonic Therapy Endoscopes Electrosurgery Units

Examination Lights Lithotripters Infant Incubators

Surg. Microscopes Phototherapy Resuscitators

NOTE: These lists are not definitive but are intended to indicate the types of devices in each category.

For the purposes of the listing on the ARTG, these categories will be divided into two groups

Group 1 Low Risk ; and

Group 2 Equipment with an electrical patient circuit (applied part), where steps are deliberately taken to reduce the electrical impedance of a connection to the patient, for the purpose of measuring an electrophysiological parameter or delivering therapy

OR

Equipment without an electrical patient circuit, but classified as high risk or medium risk.

### **Group 1 Compliance Requirements**

A certificate of compliance with one of the overseas standards or AS 3200.1:1990 as detailed for Group 2 devices.

OR

A Certificate of Approval or Certificate of Suitability issued by one of State electrical approvals authorities.

OR

A certificate of compliance with Australia/New Zealand AS 3551:1995 issued by a NATA/ JASANZ accredited organisation, either a private organisation or a hospital based Biomedical Engineering department. AS 3551 is a subset of the AS 3200 test protocols which addresses only the fundamental safety aspects of the device, in much the same way as the previous option.

A test report and Certificate of Compliance issued under the rules of the IECCE-CB Scheme.

## **Group 2 Compliance Requirements**

A certificate of compliance with one of the following overseas standards -

International IEC601.1:1988 and amendments

Europe EN 60601.1

Great Britain BS 5724

United States UL 2601

Canada CSA C22.26:601

This certification will only be acceptable if issued by a test house accredited to EN 45001 General Criteria for the

Operation of Testing Laboratories, or ISO Guide 25-1990 - General Requirements for the Competence of Calibration and Testing Laboratories.

OR

A certificate of compliance with Australia/New Zealand AS 3200:1990 and amendments, issued by a NATA/JASANZ accredited test house.

Where part 2 standards exist for specific items of equipment, for example AS 3200.2.4 for defibrillators, the certificate of compliance must include testing to both the part 1 and part 2 standard.

## **ELECTROMAGNETIC COMPATIBILITY REQUIREMENTS**

Electrically powered therapeutic devices are required to comply with the requirements of the Electromagnetic

Compatibility Framework currently being implemented by the Australian Communications Authority (ACA), in conjunction with the TGA for electromedical devices.

By agreement between the two agencies, the TGA will regulate the electromagnetic immunity aspects for electromedical

devices. Sponsors will still be responsible to the ACA for the relevant electromagnetic emission requirements. Full details

of the EMC Framework and compliance requirements are available from ACA offices in the capital cities, or from:

The Manager ,

Radiocommunications Standards , Australian Communications Authority (ACA)

PO Box 78

BELCONNEN ACT 2616

ph: 02 6256 5555

fax: 02 6253 2424

website <http://www.aca.gov.au>

The following is a summary of compliance requirements mandated by both agencies.

### **Electromagnetic Emissions**

This section refers to electromagnetic radiation emitted from the device in question, which has the potential to interfere

with the correct operation of other equipment in the near vicinity.

For the purposes of emission control, no distinction is made between electrically powered therapeutic devices and any other piece of domestic, scientific or industrial equipment. Sponsors of therapeutic devices must ensure products offered for supply in Australia are in compliance with AS/NZS 2064 1 & 2:1992 Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific and Medical Radio Frequency Equipment for electromagnetic emission levels.

AS/NZS 2064 1 & 2:1992 is almost identical to the IEC/CISPR 11 standard, with amendments only to accommodate local differences such as spectrum allocation to broadcast services.

**Electromagnetic Immunity:** This section refers to the immunity to interference with the correct operation of a device, from electromagnetic radiation emitted from equipment operating nearby.

Sponsors are required to ensure all electrically operated therapeutic devices are fully compliant with the immunity

requirements of:

AS3200.1.2:1995 Approval and Test Specification Medical Electrical Equipment Part 1.2 General Requirements for Safety Collateral Standard Electromagnetic Compatibility Requirements and Tests; or

Where a part 2 standard to the AS3200 series of standards, (for example AS3200.2.24 or defibrillators) exists, the

electro-magnetic compatibility requirements specified in the part 2 standard for that device. These will be specified in

Section 36 of this series of standards.

Where a part 2 standard is implemented by Standards Australia at some later date after publication of DR4, the requirements of that part 2 for the device category specified in that part 2 standard, take precedence over AS3200.1.2:1995 - General Requirements for Safety Collateral Standard Electromagnetic Compatibility Requirements and Tests;

The AS3200 series of standards are almost identical to the IEC601 series of standards, with amendments only to accommodate local differences such as local supply voltages and spectrum allocation to broadcast services.

### **Compliance File**

Sponsors are required to maintain a compliance file for a therapeutic device, containing all relevant documentation to support the declaration made in the application for listing on the Australian Register of Therapeutic Goods that the device is electrically safe and it is in compliance with the appropriate standards required. Maintenance of a compliance file is also a requirement of the Electromagnetic Compatibility Framework administered by the Australian Communications Authority to demonstrate a device is in compliance with the EMI/EMC requirements of the Framework.

The compliance file will have five main elements -

description of the device, including photographic documentation (this may be in the form of promotional/application literature);

technical description and specifications;

reference to standards used to demonstrate compliance, both with electrical safety requirements of the TGA and EMC requirements of the ACA;

copies of test reports used to support declarations of compliance;

for EMC compliance only, a signed declaration of conformity (For electrical safety compliance, this declaration is made, and submitted, by the sponsor at the time of application for listing on the ARTG).

This documentation in the compliance file does not have to be supplied at the time of application for entry on to the

Register. The TGA will normally only request documentary evidence when there are specific concerns about particular

devices. The compliance file is, however, subject to audit by the TGA for electrical safety compliance and the ACA for EMC compliance.

Penalties apply under the Therapeutic Goods Act for the provision of false or misleading information, or noncompliance with conditions of listing.

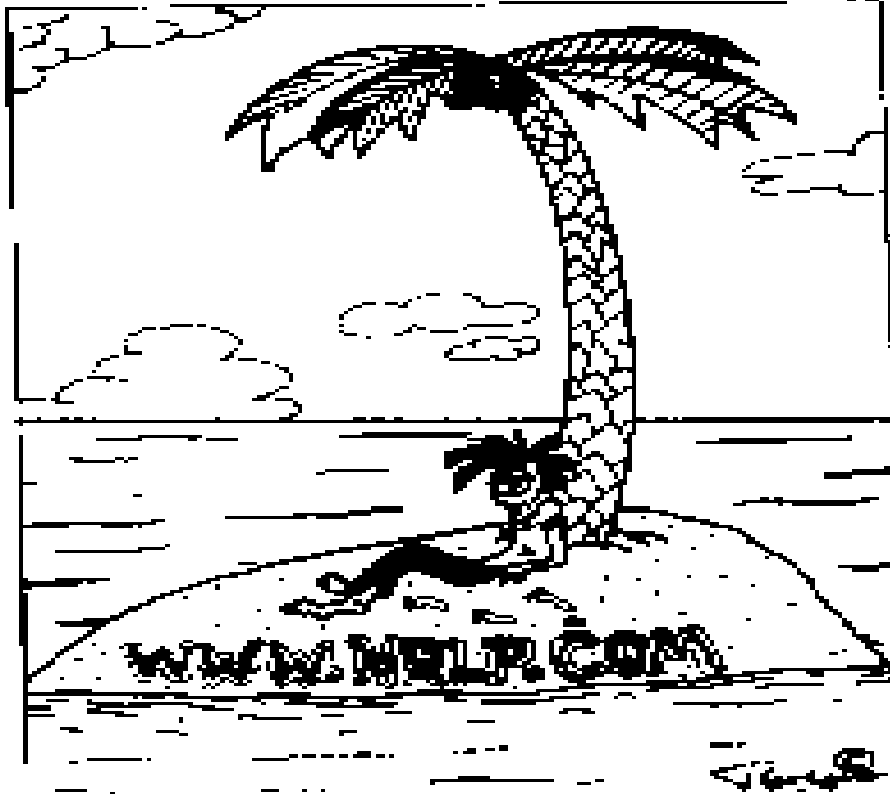
A word of caution however, these new requirements will not be retrospective in the first instance. If a product is already on the Register, the new requirements are not applicable, unless there are demonstrable deficiencies in safety which compromise patient or operator safety."

Thanks to Michael Flood for permission to reproduce his comments.

## **CONFERENCE CALENDAR**

**15th - 19th November 1998 EPSM98 "Relevance Beyond Rationalism" Hobart , Tasmania**

Information on the above are available from the editor or president.



The modern-day S.O.S.

(From San Diego Metropolitan Magazine May 1997)

E. & O. E.

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