

## CONFORMITY ASSESSMENT BRANCH (CAB)

Providing a means of communication on issues affecting the quality, safety and efficacy of materials, equipment, instruments, apparatus, implants and appliances used in health care.

Please circulate to all interested staff

- 1.
- 2.
- 3.
- 4.



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## CARDIAC MONITORING TELEMETRY SYSTEMS

In the December 1997 issue of the Therapeutic Devices Bulletin (page 7), attention was drawn to the imminent introduction of digital television or High Definition Television, and the possible impact on cardiac telemetry systems.

Some cardiac monitoring and other telemetry systems currently operate under a radiocommunications class licence in the VHF II television band between 174 MHz and 204 MHz, ie over the range of Channels 6 – 9A. In general the un-allocated channel space in an area, eg Australian TV channels 6, 8 and 9A have been utilised for telemetry systems. Other systems operate in various frequency bands, generally in the UHF region, above 400 MHz. There are currently ten suppliers of various telemetry systems, and an increasing number of hospitals which are installing this monitoring modality.

There have already been some digital TV test transmissions under taken in Sydney and Canberra. Recent discussions with the Australian Communications Authority (ACA) and the Federation of Commercial Television Stations (FACTS) indicates that the schedule of test transmissions in all capital cities will accelerate early in 1999, as television stations bring equipment on line, and will progress to full time transmission of digital television signals in metropolitan areas by 1 January 2001 and in regional areas by 1 January 2004. These transmissions will occur in the VHF spectrum space where some cardiac telemetry systems are situated, and it is possible users of these systems will experience interference, with the possibility patient safety will be put at risk.

To minimise the risk to patients, cardiac telemetry systems users are advised to:

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- determine, in conjunction with the supplier of the telemetry equipment, the operating frequency of the system;
- contact the Engineering Department of television stations operating in your city, to determine when, and at what channel frequency, they are planning test transmissions;
- if a potential interference problem is identified, develop a contingency plan in conjunction with the television station operator and telemetry equipment supplier, to minimise the risk. This should include identifying a responsible liaison person from each organisation, who is contactable in the event of a problem occurring; and
- have back-up monitoring equipment available if a risk is identified or interference experienced.

The practical effect of the conditions of the class licence for use of this spectrum for medical telemetry is to require the operators under the licence to move to a different frequency if the spectrum is subsequently used for television broadcasting. Users of equipment which operates in the television bands of the spectrum will have to consider modification to operate at a different frequency (if possible) or replacement of systems before 1 January 2001 to ensure patient safety is not compromised. In non-metropolitan areas users will have until 1 January 2004, but will ultimately be faced with the same consideration.

Users of equipment operating in the UHF (generally around 400 MHz) section of the spectrum are not effected by the introduction of digital television.

For further information please contact Mike Flood on 02 6232 8613, facsimile 02 6232 8785 or e-mail michael.flood@health.gov.au

 **YEAR 2000 AND MEDICAL DEVICES – AN UPDATE**

As previously reported in the May 1998 issue of the Bulletin, many computer systems and microprocessor controlled devices have the potential to experience problems in the transition from 1999 to 2000 because of techniques used to store dates within embedded software. The issue is generally referred to as the 'millennium bug' or 'Y2K problem'.

In late September the TGA wrote to 1109 medical device sponsors outlining its expectations of sponsors to address the year 2000 problem in regard to medical devices which they distribute on the Australian market. To the end of October, 80 responses have been received.

The TGA requires every sponsor of a medical device listed on the Australian Register of Therapeutic Goods to furnish

the TGA with written confirmation that each product is year 2000 compliant. Certification is to be provided no later than 31 January 1999. The letter also reminds sponsors that if their devices are not, or will not be year 2000 compliant, devices may be subject to mandatory recall procedures and, ultimately, removal from the ARTG.

Where sponsors determine that it is appropriate or necessary to perform a hardware or software upgrade to the device to ensure year 2000 compliance and there is no safety risk, sponsors can carry out the upgrade and notify the TGA of the action taken or proposed, provided the upgrade is completed by 30 March 1999. After that date, any action taken by the manufacturer will initially be considered a safety related recall for product correction and procedures outlined in the Uniform Recall Procedure for Therapeutic Goods must be followed.

Where a manufacturer or sponsor has no plans to provide upgrades or support for superseded devices which may still be in use, and a deficiency is identified which may compromise patient or operator safety after 31 December 1999, the TGA will require sponsors to issue a Safety Alert to all known users. The alert notice must advise users of all necessary steps to be undertaken to minimise the risk of injury to patients or users – this may include decommissioning the device if that is the only viable option. If requested, the TGA will assist sponsors by publishing the safety alert throughout the State and Federal government recall coordinator's network.

The TGA will not formally endorse any products as Year 2000 compliant.

In assessing sponsors responses to the letter, a number of issues have become apparent:

- to be accepted, responses are to be signed by a TGA recognised authorised representative of the organisation;
- responses should specify the listing or registration number of the device referred to in the letter;
- many responses are of a generic nature and do not specifically address the requirements outlined in the letter issued in September by the TGA.

As a general rule, responses should be restricted to:

- Y2K compliance is not applicable – device is not electrically operated or has no embedded microprocessor technology;
- device is compliant;
- device is not compliant;
- device is not compliant but a program is in place to ensure compliance - details of the program must be provided.

Enquiries to Mike Flood on 02 6232 8613, facsimile 02 6232 8785 or e-mail michael.flood@health.gov.au

## Further Information

Some interesting websites that contain information on the Year 2000 issue in relation to medical devices include:

[www.y2.gov.au/biomed/](http://www.y2.gov.au/biomed/) - Maintained by Bruce Morrison, Director of Biomedical Engineering, John Hunter Hospital in Newcastle - contains manufacturer compliance statements, a growing list of user tested devices along with compliance data and suggested testing protocols.

[pc47.cee.hw.ac.uk/y2k/2000/meddevic/index.htm](http://pc47.cee.hw.ac.uk/y2k/2000/meddevic/index.htm) - A similar list maintained by the Scottish Board of Health

[www.medical-devices.gov.uk/db9704.htm](http://www.medical-devices.gov.uk/db9704.htm) - UK Medical Devices Agency

[www.fda.gov/cdrh/yr2000](http://www.fda.gov/cdrh/yr2000) - US Centre For Devices & Radiological Health, FDA

[www.invisionet.com/bioy2k.htm](http://www.invisionet.com/bioy2k.htm) - US based resource page with many links to other sites

[www.iee.org.uk/2000risk/](http://www.iee.org.uk/2000risk/) - Discussion forum, guidance notes and testing protocols provided by the Institution of Electrical Engineers

### Note:

The list above is indicative only of the material that might be available on this topic. TGA does not purport to advise manufacturers on the steps they should take to achieve year 2000 compliance. Manufacturers should carry out their own research and enquiries to ensure that their products and components supplied by third parties are year 2000 compliant.

## NEW ADVERTISING ARRANGEMENTS AND THE THERAPEUTIC GOODS ADVERTISING CODE

Following a request from the industry and subsequent to the disbanding of the Media Council of Australia (MCA), the Regulations to the *Therapeutic Goods Act 1989* were amended on 24 December 1997 (Statutory Rules No. 400 of 1997). These amendments established a new Therapeutic Goods Advertising Code Council (TGACC) which includes representatives from the community at large. The Council's membership of 12 comprises the therapeutic goods industry (4), health professionals (3), consumer organisations (2), the advertising industry (2) and the TGA (1). The TGACC aims to achieve greater uniformity in advertising approval processes and standards relating to both print and electronic broadcast media.

Amendments to the Regulations also resulted in the establishment of a Complaints Resolution Panel (CRP).

The CRP receives and considers complaints about advertisements, takes appropriate action and makes recommendations to the Secretary/TGA where necessary. It comprises 8 members and these include a chairman nominated by the TGACC, two representatives from the therapeutic goods industry, two representatives from consumer organisations and three persons nominated from professional health care associations.

In addition, the Regulations establish an approval scheme for advertisements for medicines intended for publication or insertion in the mainstream print media. The Nutritional Foods Association of Australia (NFAA) has been delegated to approve advertisements relating to complementary medicines, while the Proprietary Medicines Association of Australia (PMAA) has been delegated to approve advertisements for all other non-prescription medicines.

A review of permissible and prohibited advertising claims for over the counter (OTC) therapeutic goods has been undertaken. The TGA, PMAA, NFAA and TGACC participated in the review.

This review culminated in the TGACC recommending to the Hon. T. Worth MP, former Parliamentary Secretary to the Minister for Health and Family Services, that some amendments to the Therapeutic Goods Advertising Code be made (eg: qualified reference to gout is now permitted, as is a claim of 'may assist blood circulation'). All of the TGACC's recommendations were accepted and the amendments became effective on 5 August 1998.

As the great majority of the new TGAC amendments are of a de-regulatory nature, the effect has been to provide sponsors with a wider scope of advertising claims which may be included in advertisements to the public for non-prescription products.

Copies of the latest TGAC, effective 5 August 1998, are available from:

TGA Publications Office	or	TGA Advertising Unit
PO Box 100		PO Box 100
WODEN ACT 2606		WODEN ACT 2606
Ph: 1800 020 653		Ph: 02 6232 8757

Website: <http://www.health.gov.au/tga>

## DEVICE ELECTRONIC APPLICATION LODGEMENT (DEAL) PROJECT STATUS

The TGA is planning to introduce a device electronic application lodgement system for listable devices. The development of DEAL has been assisted by a working party, which includes industry association representatives,

manufacturers and medical device regulatory consultants. DEAL has evolved from several initiatives:

- internal TGA requests to develop a more integrated system to process and track applications to 'list' devices;
- requests from industry to be able to lodge device applications more efficiently (in keeping with the drug electronic lodgement form (ELF) system); and
- new initiatives such as the proposed changes to device regulation ('harmonisation') and devices application backlog processing.

Through the DEAL application it is proposed to implement:

- a listing process that is co-regulatory with industry through applicant self assessment;
- a GMP preclearance process, independent of the listing application;
- a system that is not simply an electronic form. The software will have 'intelligence' to determine the correctness of the application and instruct the applicant as to the supporting product information requirements;
- sponsor specific information will be current and available on-site to the applicant such that the medical device application can be assessed for information integrity and completeness at the point of application rather than upon receipt at the TGA;
- a review process where a percentage of the applications will be reviewed and assessed prior to listing on the Australian Register of Therapeutic Goods (ARTG).

There are two main modules to the system:

- (1) The first module, which will operate mainly on the sponsor's personal computer, will 'assist' sponsors to accurately complete the application 'form' and allow them to efficiently (ie electronically) lodge it. Data quality, integrity of information compliance with 'relevant' regulatory requirements and standards will be checked on-site as part of completing the application. These standards will be determined from the device classification code.
- (2) The second module, to operate within the TGA, will accept the applications, manage the workflow of applications through the assessment and approval stages and provide a link to the ARTG where the relevant listing number will be assigned and the Certificate produced.

The Application Specification has been reviewed and approved by the DEAL Working Party and has been issued for tender.

Significant issues the system will address include:

- the move from a full submission review process to a co-regulation process;
- implications of harmonisation;

- device nomenclature standards;
- device grouping rules;
- legal/procedural issues concerning 'signatures' on forms, delegations for approvals, archive requirements;
- options for receipt of monies.

Progress of the project will be reported in future issues of the Bulletin.

For further information please contact Mr Michael Johnston, Head of the Australian Register of Therapeutic Goods on (02)6232 8403, facsimile (02)6232 8687 or e-mail: michael.johnston@health.gov.au



## UPDATE ON PROPOSED CHANGES TO MEDICAL DEVICE REGULATION

We are well into the consultation phase for the development of the proposal for new medical device regulatory requirements in Australia. The purpose of the consultation with industry, consumers and the States/Territories is to develop an analysis of the costs and benefits of the proposal to stakeholders. Comments on an information paper have been sought from professional and industry associations as well as people who have expressed an interest in being involved, a stratified sample of the medical device industry has been surveyed about the impact the proposal may have, and comments from State and Territory governments have been sought. The proposal has also been considered by the National Coordinating Committee on Therapeutic Goods (NCCTG) and the Australian Health Ministers Advisory Council (AHMAC). The results of the consultation process will be included in the regulation impact statement which will be considered by the Government together with the proposal.

As reported in the September issue of the Bulletin, the TGA is being assisted in its task by a working party comprising State/Territory, industry and consumer representatives, and the Federal Department of Industry, Science and Resources (formerly the Department of Industry, Science and Tourism). The working party has supported the draft proposal and is scheduled to meet for the third time in December.

More details on the key elements of the proposal can be found in our article on page 9 of the September issue of the Bulletin.

Alternatively, copies of the information paper on the proposed regulatory requirements for medical devices in Australia are available from Rita Maclachlan on 02 6232 8685, facsimile (02) 6232 8687, or email: rita.maclachlan@health.gov.au or Shane Clarke on 02 6232 8576, facsimile 02 6232 8687 or email: shane.clarke@health.gov.au



## FREQUENTLY ASKED QUESTIONS ON THE AUSTRALIA-EUROPEAN COMMUNITY MUTUAL RECOGNITION AGREEMENT (EU-MRA)

The TGA is currently developing a fact sheet on the EU-MRA as well as a Frequently Asked Questions (FAQ) sheet for industry. This information will be available shortly through the TGA Publications Unit and on the TGA website. Two examples of frequently asked questions are included below.

### Are the 'MRA' and the proposed new Australian medical device requirements ('harmonisation') separate initiatives?

**Yes!** The two initiatives are separate and distinct issues

The MRA enables:

- the TGA to assess medical devices manufactured in either Australia or New Zealand for export to the EC, in accordance with the EC requirements; and
- designated European CABs (Conformity Assessment Bodies) to assess medical devices produced in the EC for export to Australia, in accordance with the Australian (or TGA) requirements.

Harmonisation:

is the process whereby the TGA is currently developing a new set of regulatory requirements for the supply of medical devices in Australia. As part of this change, some of the requirements for medical devices will be aligned with the requirements of the EC. For example, medical devices will be classified into four categories (I, IIa, IIb and III) according to a set of rules, and manufacturers will have several options as to how their product will be assessed for conformity. The new medical devices framework is intended to complement the MRA.

### Under the MRA, do CE marked medical devices from the European Union attract special status for entry onto the ARTG?

**No.**

CE marked products comply with EC requirements. The requirements for entry onto the Australian Register of Therapeutic Goods (ARTG) are the current Australian regulatory requirements (refer *Australian Medical Device Requirements under the Therapeutic Goods Act 1989 version 4 – DR4*). Specifically designated European Notified Bodies certify devices manufactured in the EC for export to Australia, and make their assessment against the Australian requirements before products can be considered for inclusion on the ARTG.

Listable device applications made under the MRA will be processed within 5 working days of receipt by the TGA. For sponsors of CE marked listable products, submission of a certificate of conformity to Australia's requirements is required.

Registrable device applications will be subject to an 18 month confidence building period and review of the European Notified Body assessment by the TGA.



## REPORT ON THE 12TH MEETING OF ISO TECHNICAL COMMITTEE 194

International Standards Organisation Technical Committee (TC) 194: Biological Evaluation of Medical Devices, is responsible for the standardisation of the approach to biological evaluation of medical and dental materials and devices together with standardisation of the biological test methods applicable to those materials and devices. Almost 100 delegates from 15 participatory countries attended the 12th annual meeting in Alexandria (Virginia), USA. Countries have either participatory or observer status. Australia has participatory status; Dr Shirley Bolis of the TGA Biomaterials and Engineering Section attended on behalf of Standards Australia.

TC 194 has 15 active working groups that draft new standards as required and regularly revise current standards as new technologies or concerns emerge. These encompass standards as diverse as specific biological tests (e.g. reproductive toxicity) and frameworks for risk assessment procedures.

The chief outcome of this meeting was the realisation that although a prescriptive standard cannot presently be drafted an acknowledgment of immunotoxic effects of certain devices must be formalised. A task force to consider how to deal with this issue was formed and the FDA approach was presented. A new working group was formed to draft a technical report on 'Physico-chemical, mechanical and morphological characterization'. So as to improve the drafting of these standards it was decided that a questionnaire to determine the key issues in evaluation of biological safety of medical devices would be prepared. This would be sent to all regulatory authorities, notified bodies, manufacturers and interested parties

There was substantial comment and discussion in all working groups regarding the reliance of regulatory bodies on Standards, such as with CE marking. There was an urgent need for revamping the drafting mechanism of Standards so as to ensure inclusion of all concerns of biological safety and increasing recognition of the need for global harmonisation of Standards.



## INCIDENT REPORTS

*Incident reports are published in this bulletin to assist health care professionals and sponsors of products work with the TGA to promote the safety, quality and efficacy of medical devices. They are based on information supplied to the TGA that may not be independently verified as to its accuracy, completeness or causal relationship to the product or its supplier.*

*A sample of incidents reported over the last three months, along with outcomes from our investigation process is provided below.*



### **Safety Alert - Abbott Pain Management Pumps.**

A hospital recently reported that an Abbott Pain Management (APM) pump was found to be over delivering when tested by their biomedical engineer. On further investigation, it was found that a faulty AC adaptor caused the problem. The adaptor was delivering about 30Vdc instead of required 12Vdc.

Abbott has advised that there have been no other reports of this nature from any other country. The incident is therefore believed to be isolated. However, there is a need to protect the pumps not only against the remote possibility of a faulty adaptor, but also against the inadvertent use of non-Abbott adaptors that have a compatible plug but output more than 12Vdc. Therefore, Abbott has undertaken the upgrade of both new and existing pumps by incorporating over-voltage protection into the pump circuitry.

There have been 460 Abbott Pain Management Pumps distributed to approximately 60 hospitals. It is estimated that the upgrades will be completed by December 1998. In the meantime, a Safety Alert has been issued to warn users about this issue.

#### **Recommended Action**

Hospitals using APM pumps should have the voltage output of their pump's AC adaptors checked immediately by their hospital biomedical engineer. This check should also be performed as part of the routine servicing of the pump. If any adaptor is found to be delivering in excess of 13Vdc, then the pump and associated adaptor should be quarantined and Abbott Australia should be notified on 1800 225 311.



### **Safety Alert - Patient Deaths Associated with the Use of Restraints**

The TGA has been advised of the death of a patient from asphyxiation, believed to have been caused by becoming entangled in a restraining device used to keep the patient in bed.

Restraints are therapeutic devices but exempt from listing on the Australian Register of Therapeutic Goods under Schedule 5, item 7(g) - *non-powered devices used in general patient care, being devices that do not constitute or contribute to a specific diagnosis, monitoring or treatment of a medical condition, or ....* and item 7(j) - *protective clothing for patients ....*

Research indicates this death from the use of a restraining device is not an isolated event. The US FDA Medical Device Report database lists 126 incidents involving restraints from 1987 to the present, 37 of these incidents from 1985 to the present resulting in patient death. Investigation by the FDA in the early 90's found in all instances the problem was associated with the incorrect use of the device, and not the design of the device. The FDA issued a safety alert to users, and by working in close consultation with the device manufacturers to develop a number of user education campaigns and materials for inclusion with the devices, resulted in a significant lowering in the number of deaths associated with restraints since that time - an average of 4-6 per annum for the period '90 to '93 down to one per annum from 1994.

In Australia, it is now known there have been at least four deaths involving patient restraints since 1988. Inquests into two of these deaths have been completed and have concluded, as in the US FDA investigations, that it is the use or mis-use of the device, and not the design of the device that contributed to the death. Contributing factors appear to be:

- inadequate training of staff in selection and use of these devices;
- inadequate instruction documentation available within the hospital for clinical staff.

TGA recommends that institutions using patient restraints ensure:

- the institution has clearly documented policies on the use of restraints – alternatives to physical restraint, conditions of use for restraints, types of restraints allowed, length of wear time, etc;
- staff are trained in the use of restraints, that in-service training is repeated at appropriate intervals, and that only staff trained in their use are allowed to apply restraints;
- the cause for which a restraint is required is assessed and consider alternatives before the use of physical restraints;
- the use of restraints are only used at the direction of, and under the supervision of a medical practitioner;
- the use of restraints, including reason, authorisation, length of application, etc be clearly documented in the patient record;

- copies of application instructions should be stored and issued with restraints;
- staff read the application instructions, and check the type and size of restraint is appropriate for the patient's condition prior to use;
- attention is paid to the correct method for securing the restraint to the bed or wheelchair to maintain body alignment, but at the same time ensure patient comfort;
- restraint ties are NEVER secured to a fixture of the bed or wheelchair which allows the fixation point to move as the patient moves – for example the vertical bars of a bedrail, or the vertical sidebars of the wheelchair back;
- patients under restraint are observed frequently, and the security of the restraint fixation is checked regularly; and
- patients are regularly removed from restraints to allow for the activities of normal daily living.

Restraints should be considered a temporary solution and their use should be discontinued as soon as possible.

For further information please contact Mike Flood on 02 6232 8613, facsimile 02 6232 8785, or e-mail: michael.flood@health.gov.au

## Therapeutic Goods Administration Incident Reporting and Investigation Scheme Statistics Report

### Device Incident Reports 01/07/98 to 30/09/98

**Number received** 188

#### Type of Problem

Contamination	13
Diagnostic Inaccuracy	1
Electrical	10
Fails TGO/Standard	3
Labelling/Product Info.	12
Material/Formulation Deficiency	52
Mechanical	59
Other	38
Packaging	21
Software	1

#### Cause of Problem

Component Failure	20
Contamination	11
Design	12
Diagnostic Inaccuracy	1
Electrical	2
Inadequate Instructions	4
Labelling	13
Maintenance	4
Manufacture	43
Material/Formulation Deficiency	32
Mechanical	5
Not Device Related	6
Other	23

Packaging/Sterility	15
Quality Assurance	23
Unknown	25
Wear/Deterioration	3

#### Potential Effect

Death	9
No Injury	146
Serious Injury	20
Temporary Injury	13

#### Actual Effect

Death	2
No Injury	163
Serious Injury	8
Temporary Injury	15

#### Source Category

<i>Administrator</i>	
Medical	8
<i>Clinician</i>	
Specialist	7
<i>Government Agencies</i>	
Recall Co-ordinator	2
TGA CAB	2
TGA Laboratories	2

<i>Nurse</i>	
Hospital Based	33
Private	1

<i>Other</i>	
Blood Bank	41
Competitor	3
Hospital Supply Service	57
Other	9
Patient/User	3
Sponsor	11

<i>Overseas Advice</i>	
MDA	1
Other	1

<i>Technical</i>	
Biomed Engineer	3
Biomed Technician	2
Clinical Technician	1
Medical Physicist	1

#### Result of Investigation

Bulletin Article	6
Company Warned	7
Compliance Testing	10
No Further Action	77
Not Investigated	35
Other	11
Problem Not Confirmed	15
Product Improvement	15
Recall/Hazard Alert	12
Refer to GMP	30
Refer to Surveillance	1
Safety Alert	6
User Education	7

**⚠ Patient burns from ECG electrodes in MRI**

A potential problem was brought to the attention of the TGA regarding the use of ECG monitoring with patients undergoing Magnetic Resonance Imaging (MRI) scanning procedures. The intense radio frequency (RF) fields produced by the body coil (the MRI coil assembly which lays on the patient) can induce currents in the ECG leads and these may result in burns under the ECG electrodes. This can be particularly serious if the patient is anaesthetised.

Some ECG leads show susceptibility to the induction of RF currents. However if laid correctly and in accordance with the manufacturer instructions all lead assemblies should perform safely. In the reported case Datex ECG leads, which are not shielded, were affected when placed directly under the body coil resulting in overheating of the electrodes.

It is advisable that operators of MRI ensure that the ECG leads are compatible with the procedure. Most importantly, extreme care should be applied in laying the leads away from MRI body coils following the manufacturer's instructions.

ref: DIR 10949

**⚠ Inflation and deflation of balloons on urinary catheters**

The TGA continues to receive reports of non-inflation or deflation of balloons on urinary catheters. The most common cause of problems is technique rather than a device problem. The following suggestions may minimise problems with balloons on urinary catheters.

**1. Use only sterile water for balloon inflation.**

Saline or other solutions can crystallise or precipitate and block the inflation lumen or non-return (inflating) valve thereby preventing the balloon deflating. Correct deflation can sometimes be achieved by injecting additional sterile water to dissolve or dislodge the blockage. If deflation is not achieved by this method, remove the non-return valve. If this does not allow deflation, the inflation lumen may be blocked at some point between the balloon and the non-return valve. Sterile water can be injected into the lumen, using a syringe and a blunt needle, to dislodge or dissolve this blockage.

**2. Insert syringe into the non-return (inflating) valve carefully.**

Valve jamming can be caused by over inserting the Luer fitting of the syringe into the non-return (inflating) valve. Use only sufficient force to seal the connection against leakage. Easing the syringe out slightly can often cure the jam and allow inflation or deflation of the balloon.

**3. Inflate the balloon only to the manufacturer's recommended capacity.**

The capacity of the balloon should be clearly marked on the non-return valve and the catheter packaging. Sometimes there is an additional manufacturer's instruction on the packaging, such as 'inflate 5cc balloons with 10cc sterile water', which should be followed.

Under inflating the balloon can affect the retention and sealing of the catheter within the bladder.

Over inflating the balloon can block the inflation lumen, when the balloon compresses the inflating lumen. This situation can be resolved by surgical staff inserting a stylus along the catheter drainage lumen, using fluoroscopy techniques, until the balloon is ruptured. This is a technique of last resort before surgical removal of the catheter.

Over inflating the balloon may cause misalignment of the catheter tip and affect drainage.

**4. Clamp catheters only on the funnel area.**

Clamping the catheter between the inflating valve and the balloon can cause a temporary or permanent blockage of the inflation or other lumens. To avoid problems, clamp the catheter only on the funnel area of the drainage or irrigation lumen.

**⚠ Incident reports on defective breast implants**

In the past TGA had requested information on all explanted breast implants to gather data on the status of old implants. Analysis of this data has been difficult as in most cases the implant model and date of implantation has not been identified on the report.

Numerous articles in the recent literature have now clarified issues such as capsular contracture and rupture rates of breast implants, although this is a general estimate rather than a detailed model by model analysis. Because of this TGA has decided not to request incident reports on ALL explanted breast implants.

We are however keen on maintaining an active postmarket vigilance program on breast implants. To this end we would urge all health practitioners to complete a Medical Device Incident Report on all defective implants. We are particularly interested in leaking or damaged new implants and premature failure of old implants.

**Continue sending incident reports on defective devices and equipment.**

In keeping with our overall postmarket focus, Incident Reports on defective surgical and medical equipment should also be notified to the TGA by completing a Medical Device Incident Report.

Additional Medical Device Incident Report Forms can be obtained by calling 1800 809 361. Forms can also be downloaded from the TGA website (<http://www.health.gov.au/tga>) and blank forms can be photocopied if required.

It is only by maintaining a high level of vigilance that we can ensure high quality products and positive outcomes for patients in Australia.

### Examination gloves/therapeutic devices & unintended use

The TGA has received a report of an incident regarding gloves not intended for medical use being used during the administration of chemotherapy. This presents a major Occupational Health & Safety issue for the hospital or facility in the event of any failure of the apparel. The user and the patient could be exposed to cytotoxic substances and subsequent injury may occur. In this situation, the sponsor and manufacturer are no longer responsible for the device as it was being used inappropriately.

The use of gloves, or any other device for any purpose other than their intended use may pose a safety risk to both the patient and the user.

The TGA advises users of therapeutic devices against using them outside their intended scope of use or contrary to the instructions for use.

DIR 10790

### TRANS TASMAN HARMONISATION - COMMON FORM FOR REPORTING MEDICAL DEVICE INCIDENTS.

TGA and the New Zealand Ministry of Health (MOH) are exploring a phased approach to the development of complementary regulatory arrangements across the Tasman. The Trans-Tasman Mutual Recognition Agreement (TTMRA) is intended to facilitate trade and workforce mobility between Australia and New Zealand. Therapeutic Goods have been granted a temporary exemption for twelve months under the TTMRA. Cooperative postmarket activities have a strong basis on historical collaborations between the two agencies. For instance, the regulatory requirements and postmarket monitoring of condoms are currently being aligned.

Recently, a common form for the reporting of Medical Device Incident Reports has been adopted. The forms are used by medical device users to report incidents in order to initiate the investigation of problems associated with the use

of medical devices. The form features the logos of both organisations and the user is directed to send the report to the agency in their country of origin.

The two agencies already exchange information regarding Safety Alerts and Recalls. Common reporting forms will further facilitate the exchange of information. There are plans to adopt common sponsor questionnaires. These questionnaires are sent out to medical device sponsors on receipt of an incident report.

The new forms are available at the TGA Website: <http://www.health.gov.au/tga>, by e-mail request to [iris@health.gov.au](mailto:iris@health.gov.au), or by calling the Medical Device Incident Report Investigation Scheme toll free number: 1800 809 361. Older style forms will continue to be accepted until they are phased out.

### LISTABLE MEDICAL DEVICE NEWS

#### New Application Form in DR4

As of 4 August 1998, TGA released a new guidance document *Australian Medical Device Requirements Version 4, DR4*. This document included a new Therapeutic Devices Application form which sponsors are required to submit when applying to list/register devices or notify TGA of variation to existing Australian Register of Therapeutic Goods entries.

#### Electrical Safety and Electromagnetic Compatibility (EMC) Requirements

Sponsors should pay attention to the new Electrical Safety and Electromagnetic Compatibility (EMC) requirement for medical devices that came into effect on the above date.

The new Therapeutic Devices application form dated May 1998 contains a page dedicated to the new Electrical Safety and EMC requirements and this must be completed for all electrically powered devices. The sponsor, by completing the page is declaring that the product under review complies with the marked standards. Sponsors are not required to submit the certificate of compliance with the application. However the certificates should be available on request along with other relevant information (see Section 1.17 of the DR4 for information on Compliance Files).

This issue has caused a number of processing problems within the Device Listing Section as many applications are still coming in on the old form and Electrical Safety and Electromagnetic Compatibility are not addressed by the applicant. All electrically powered devices must comply with relevant Electrical Safety and EMC standards prior to supply.

Sponsors must complete both the Electrical Safety and EMC sections.

If this information is not provided, the applications cannot be progressed and a letter will be sent to the applicant requesting this information. If the information is not provided in the time allowed, the application will be assessed solely on the information supplied. In such cases, the Listing Section may refuse to list your product because adequate safety has not been established.

Guidance is given in DR4, but it is the sponsor's responsibility to determine the appropriate Electrical Safety and Electromagnetic Compliance requirements for the product. The sponsor need only complete the appropriate page in the application form (or if responding to a request for further information, complete the attached page sent with the request and send it back to the Medical Devices Listing Section within the timeframe allocated).

Please Note:

For EMC, two other Standards are acceptable in lieu of the AS3200.1.2-1993.

They are EN60601.1.2-1993 and IEC601.1.2:1993.

For more specific information regarding requirements for Electrical Safety and Electromagnetic Compatibility you should refer to the appropriate section of the DR4.

To obtain copies of the DR4 document, please contact the TGA Publication Office on 1800 020 653, facsimile 02 6232 8605 or e-mail: TGA-INFORMATION-OFFICER@health.gov.au.



## THERAPEUTIC DEVICE EVALUATION COMMITTEE (TDEC) MEETINGS

The following are some of the main points arising from the first three TDEC meetings of 1998. Common agenda items that are considered at all TDEC meetings include specific registrable medical device evaluations and Problem/Incident report issues.

The first TDEC meeting for the year, held in March (1/98), considered aspects of the harmonisation proposal for medical device regulation and issues of electronic date sensitive medical devices for the year 2000.

At the 98/2 meeting in June TDEC reviewed the requirement for disclosure of flow characteristics of drug infusion devices at low flow rates (see next article this Bulletin).

TDEC met again in September (98/3) and further considered aspects of the harmonisation proposal. Specifically, the classification of registrable medical devices under the new medical device regulatory proposal.



## INFUSION PUMPS - FLOW PROFILE FOR MINIMUM INFUSION RATES

The Therapeutic Device Evaluation Committee (TDEC) has endorsed a special requirement for the registration of low flow rate drug infusion systems to ensure that the characteristics of the flow of infusion are clearly disclosed to the user.

TGA has received numerous applications for the registration of infusion pumps where the characteristics of the infusion at very low flow rates (under 1 ml/hr) were not adequately disclosed. This raised concerns because if such pumps are used to deliver fast acting drugs, intermittenencies of the delivered flow at low rates may result in instability of the patient physiological parameters. This phenomenon was noted in neonates and was reported to the TGA.

The international Standards IEC 601-2-24 'Particular Requirements for Infusion Pumps and Controllers' has now been published and it provides guidance for evaluation requirements of infusion devices in Australia. Although disclosure of Trumpet Curves and Flow vs Time plots is required by the IEC Standard, there are limitations in the requirements for these plots particularly for flow rates under 1 ml/hr.

Beyond the requirements of the applicable International Standards, it is the responsibility of the TGA to ensure disclosure of the characteristics of the device is sufficient to ensure that the user makes the correct decisions on the clinical application of the pump. This is also quoted in IEC 601-2-24 Standard, Appendix AA - Rationale ( page 48/50-102 to 50-108).

At its meeting on 26 June 1998 the TDEC made the following recommendations:

1. The product information (user literature and operator manual) for all types of infusion pumps must comply with the requirements of International Standard IEC601-2-24 - infusion pumps and controllers, and
  - A. include in addition:
    - i) a flow profile which includes a flow vs time graph for the first 2 hours of infusion as per figure 105 of IEC601-2-24, but for the absolute minimum rate, and
    - ii) a cautionary statement to the effect that care should be taken with the use of the pump at low flow rates for drugs with short half lives.
  - B. any statement on the accuracy of the system should only refer to flow rates at and above 1 ml/hr.

TGA is proposing to adopt the above recommendations for drug infusion systems. Any comments on this proposal should be directed to Mr Rodolfo Ferrari on 02 6232 8706, facsimile 02 6232 8785 or e-mail: rodolfo.ferrari@health.gov.au

## DR4 AVAILABLE

The new version of the Australian Medical Device Requirements under the Therapeutic Goods Act 1989 (Version 4 - 'DR4') was launched in August this year. This document provides guidance to sponsors on the information required in support of an application for listing or registration of therapeutic devices on the Australian Register of Therapeutic Goods (ARTG).

DR4 replaces the previous edition 'Requirements for the Supply of Therapeutic Devices under the Therapeutic Goods Act 1989 (DR3)' which was published in September 1993. Since then there have been numerous changes to TGA policy and the legislation and while separate announcements and policy documents concerning changes have been produced there was a need to have the current policy requirements consolidated in a single document.

The cost of the document is \$120 which includes postage and handling within Australia (overseas airmail add \$25) To obtain copies of the DR4 document, please contact the TGA Publication Office on 1800 020 653 or facsimile on 02 6232 8605.

## INDONESIAN DELEGATION VISIT

The Therapeutic Goods Administration hosted a delegation from Indonesia the week of the 12–16 October 1998. The delegation from the Directorate General for Drugs and Food Control, Ministry of Health, Indonesia consisted of the:

Director of Cosmetics and Medical Devices Control – Dr A Faadilah Rivai,

Head of the Sub Directorate of Medical Devices Control – Mr Sedarso, and

Head of Section of Medical Devices Distribution Control – Mr Bahdar Djohan.

As well as spending time at the TGA the delegates visited an industry organisation as a guest of the Medical Industry Association of Australia (MIAA).

## STERILE DEVICE AUDITING COURSE

Following the success of the 1997 auditing course, TGA in collaboration with the UK Medical Devices Agency (MDA), hosted a four day course on 'Auditing Sterile Device Manufacturers' in October 1998.

The course focused on the European Standards applicable to the sterilisation of medical devices using irradiation, ethylene oxide, heat and chemical sterilants. Sterilisation kinetics and validation for each of these methods of sterilisation were discussed in detail.

Some interesting case studies involving problems encountered auditing to the standards were investigated and discussed by the attendees.

The course presenters were Professor Alan Tallentire of Manchester University, Dr Eamonn Hoxey of the MDA and Ms Shelley Tang from TGA.

The 22 attendees came from Australia and overseas including Japan, Norway and Indonesia with a wide range of backgrounds including certification bodies, device manufacturers, hospital sterilising services, TGA and other regulatory bodies.

Auditing course participants and presenters





## SUPPLY AND USE OF THERAPEUTIC DEVICES NOT ON THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

It is timely to remind sponsors and clinicians that, with the exception of exempt or excluded medical devices, it is unlawful to supply or use therapeutic devices which are not on the Australian Register of Therapeutic Goods (ARTG) unless approval has been obtained through one of the appropriate access schemes administered through the Clinical Section of the Conformity Assessment Branch, TGA. This applies to samples imported by sponsors and clinicians as the result of attendance at clinical conferences overseas.

Approval may be granted, where appropriate, through the Individual Patient Usage (IPU) scheme, the Authorised User Approval (AUA) scheme and two Clinical Trial mechanisms.

- IPU is appropriate when a clinician can make a case on clinical grounds to use an unapproved device in the absence of any equivalent device on the ARTG. The essential element is the clinical need of the patient; it is not appropriate as a mechanism to allow a clinician to 'try out' a device.
- The AUA mechanism is suitable when a specialist clinician in hospital practice has a need to use an unregistered device in the management of a series of patients with some rare disease. The clinician must have either ethics committee approval or endorsement by the president of the appropriate specialist society to use the unapproved device. From time to time, as specified by the TGA, the clinician must submit reports on patients treated.
- The final avenue is through a clinical trial. Clinical trials are primarily intended to collect data which may be used to support an application for entry on to the ARTG. The clinical trial is administered through TGA as a Clinical Trial Notification (CTN) or as a Clinical Trial Exemption (CTE). The decision on which avenue should be used is made by the ethics committee of the institution where the trial is to be conducted.

More detailed advice on each of these mechanisms can be found in the *Australian Medical Device Requirements version 4 (DR4)* or by contacting the Chief Clinical Adviser, Conformity Assessment Branch on 02 6232 8615, facsimile 02 6232 8785 or e-mail: [graham.maynard@health.gov.au](mailto:graham.maynard@health.gov.au).



## IMPORTANT TGA TELEPHONE NUMBERS

Medical Devices Information	(02) 6232 8438
General Enquiries	1800 020 653
Reporting of a Medical Device Incident	1800 809 361
Australian Register of Therapeutic Devices	(02) 6232 8588
Advertising Claims	(02) 6232 8664
Manufacturing issues	(02) 6232 8628
Recalls	(02) 6232 8636
Medical Device testing	(02) 6232 8694
Publications	(02) 6232 8610
Switchboard	(02) 6232 8444



## IMPORTANT

Only the NEW Therapeutic Devices application form dated May 1998 (see page 9 of this Bulletin) will be accepted after 1 January 1999.

To obtain copies of the application form please contact the TGA Publication Office on telephone 1800 020 653 or facsimile (02) 6232 8605

## TGA Publications Office

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