

The Society for Medical &  
Biological Engineering  
S.A.  
Incorporated



PO Box 19, Woodville, SA 5011  
<http://www.smb.e.asn.au>

# NEWSLETTER

## APRIL 2001

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### Affiliations

*Australian Federation for Medical and Biological  
Engineering  
International Federation for Medical and Biological  
Engineering*

## SCIENTIFIC MEETING

Wednesday 9 May 2001

Meeting Room 1 (Telehealth Room)  
Women's and Children's Hospital  
(See directions on page 2)

5-30pm Refreshments  
6-00pm Presentation

## THERAPEUTIC GOODS LEGISLATION CHANGES TO MEDICAL DEVICE LEGISLATION

Mr Mike Flood  
Biomedical Engineer  
Therapeutic Goods Administration

After six years of development and consultation, the Therapeutic Goods Amendment (Medical Devices) Bill 2001 has finally entered the Parliament. Debate will take place in the Winter Session, with implementation in September 2001.

The legislation provides a whole new framework for the Regulation of medical devices in Australia. Developed on the principles of the Global Harmonisation Task Force, the framework introduces a set of essential principles to demonstrate safety of a medical device and a classification and evaluation system based on risk associated with use.

Mike Flood is a biomedical engineer, and currently Chairman of the College of Biomedical Engineering within the Institution of Engineer, Australia. Working at the Therapeutic Goods Administration, he currently manages the Evaluation Unit for Registered medical devices. Of recent times, he has also been working as part of the team developing the processes for implementation of the new legislation. He is also a member of Study Group 1 of the Global Harmonisation Task Force, the group charged with developing a harmonised regulatory framework for international application and a number of Standards Development Committees at Australian and International Standards Organisation.

Mike will outline the new framework, how it differs from the current situation, and its likely impact on the biomedical engineering and environment in the short and long term.

At this meeting the Memorandum of Understanding between the SMBE and the IEAUST College of Biomedical Engineering will also be signed. This document cements closer ties between the two bodies and promotes more interaction between the two.

### **Directions to Meeting Room 1**

Enter hospital from the Kermode Street entrance and take stairs to next floor. At top of stairs turn left down corridor. You will see a glass walled area called the Play Deck. Take first corridor to the right keeping the Play Deck on your right hand side. This corridor leads to a "Y" junction. Take right hand fork of "Y". Immediately on your left will be the main lecture theatre.

Proceed about 30 metres past this and turn down the small corridor to left. Meeting Room 1 is off this corridor.

# **Design of an Automated Perfusion Pump**

**James J Higham**

**Department of Gastroenterology  
Repatriation General Hospital**

## **Abstract**

The design and construction of an automated perfusion pump commenced as part of an industrial affiliates program in 1998 that continued through to a final year project in 1999, both as part of a biomedical engineering degree at Flinders University. This work has continued this year through a NHMRC funded research position in the Department of Gastroenterology at the Repatriation General Hospital.

(Full article in separate file)

## **Drager/SMBE(SA) Biomedical Engineering Encouragement Award**

Nominations are being sought for this very worthwhile award for 2001.

### **PHILOSOPHY**

This annual award is to be made as a means of acknowledging and encouraging excellence amongst Biomedical Engineering practitioners.

### **PROCESS**

The recipient shall be selected by the council of the SMBE (SA) and a representative of Drager Australia from amongst candidates who shall:

*Be nominated by a peer who deems them worthy of such recognition, and,*

*Author a short technical or topical article on a subject either nominated by themselves or chosen from a list provided by the council for publication in its newsletter.*

### **THE AWARD**

The award shall comprise a funded visit to the annual SMBE (NSW) technicians seminar.

### **CONDITIONS**

Open to all BME practitioners, from within SA and the NT, be they SMBE members or not. The recipient must be in a position to attend the seminar, in either their own or employers time. The award may be forfeited if this requirement cannot be fulfilled. The nomination by a peer must give a clear indication or evidence of the nominees abilities, skills, motivation or commitment that, in their mind, sets them apart and makes them deserving of particular recognition.

Individuals holding position on the council of the SMBE (SA) at the time of judging are ineligible for consideration.

All entrants are eligible for minor awards of complimentary SMBE (SA) membership for a one year period.

The SMBE (SA) council reserves the right to not make the award whether the submitted articles have been published or not.