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The Alberta Clinical Engineering Society Newsletter

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Presidents Letter

by *Bill Rutledge, President*

Greetings to each of you from your ACES executive in 1999. It is with some trepidation that I have accepted the role of ACES president this year. Sam Itani had been our vice-president and he was prepared to stand for election as president this year, but he has since left the province and we were left without a candidate. We have had some turnover in the executive and the more experienced members had roles which met their interests. When we looked around, I was left as the most appropriate replacement at this time. I am very pleased that Denny Mellott is prepared to be the vice-president this year, and is willing to step into the president's chair next year.

My concerns are primarily twofold. First of all, Brandon Beaudry has been our president for the past two years and has probably accomplished more in those two years than in all the years before that. His familiarity with members and institutions in Calgary and Edmonton helped, but his energy

and enthusiasm carried many of us on the executive along in his wake. We all owe a great big THANK YOU to Brandon for his efforts on our behalf. Unfortunately, I cannot possibly fill Brandon's shoes--he's too hard an act to follow.

My second concern is somewhat more fundamental. I have tried over the past years to be as supportive as I can be to the aims and aspirations of ACES and the technologist members. I have tried to take on the support roles on the executive and let others present issues and lead projects that address their needs. However, I have been dismayed in the past to hear comments that ACES may be too "management" or "engineering" oriented. With Ralph Pongracz joining the executive, and me taking on the president's role, we could be inviting this attitude again. I would strongly encourage each and every member reading this newsletter to consider the efforts your colleagues have put forward in the past and continue to put forward to direct ACES in your interests. We need you to step up this year and help out organizing an event or joining the executive to contribute your ideas and time.

Members of the executive are listed elsewhere in this newsletter. Please contact any one of us to offer some time to your society, or to at least give us your opinions on how the society can better meet your needs.

I will do my best to keep the organization running smoothly, and I look forward to working with all the members of the new executive. Our first meetings have us looking at conducting a joint meeting with IBET from B.C., as well as an evening meeting in June. Please stay tuned, involved and, above all, participating.

New Executive:

- ❖ **President:**
Bill Rutledge
E-mail: brutledge@cha.ab.ca
Phone: 780.407.7552
- ❖ **Vice President:**
Denny Mellott
E-mail: denny.mellott@crha-health.ab.ca
Phone: 403.670.1419
- ❖ **Sec/Treasurer:**
Brian Van Skiver
E-mail: bvskiver@cha.ab.ca

Phone: 780.407.8327

❖ **Education co-ordinator:**

Ralph Pongracz

E-mail:

ralphp@cancerboard.ab.ca

Phone: 780.432.8632

❖ **News Editor and
Communication Chair:**
Kay Henke

E-mail: kmhenke@telusplanet.net

Phone: 403.382.6396

❖ **Professional Development:**
Roy Sharplin

E-mail roys@nait.ab.ca

Phone: 780.471.8746

❖ **Director at Large:**
Robin Fair

E-mail: innocalg@telusplanet.net

Phone: 403.259.4332

❖ **Past President:**
Brandon Beaudry

E-mail: bbeaudry@cha.ab.ca

Phone: 780.407.6711

Health Canada's "Medical Devices Regulations" and Its Impact on Clinical Engineering Practice

By Brian Van Skiver, PEng

On July 1, 1998 Health Canada formally released its new 'Medical Devices Regulations'. With a view to harmonize with other international trading partners' regulatory systems, the new regulations reflect a tougher stance on medical device assessment and tracking within Canada. The

benefit to manufacturers, suppliers, and consumers is the establishment of a single point of entry and evaluation into the Canadian market for medical products. Harmonized standards means a common language for the free flow of medical devices from country to country simplifying commerce. The benefit to Canada's health care industry is a uniform static process by which medical products are reviewed for safety and effectiveness.

So what does this mean for Clinical Engineering? In the areas of medical device mandatory and voluntary standards, our peers in the health care industry typically see us as 'experts' acknowledging the effort our colleagues; the public, manufacturers and other health care professionals have invested in the development of these codes. 'Best practice' for our profession is validated through our awareness of, adherence to, and promotion of the standards. It is commonly understood that the foundation for a standard is its technical and legal credibility.

RISK ASSESSMENT AND CLASSIFICATION

In an effort to conform to international standards, the new regulations are based on a risk assessment process and classification. Medical devices will be reviewed for their possible impact and categorized into 1 of 4 classes ranging from low risk devices (Class 1) to high risk devices (Class 4). This is comparable with how devices have been assessed in Clinical Engineering for the establishment of preventative maintenance schedules and prioritization of response. The regulation applies to all medical

devices or systems with the exclusion of those devices or systems used on animals which subsequently fall under the Food and Drugs Act. Note that the regulations apply to all the constituent parts that make up a device or system – software, hardware, firmware, packaging, labeling, etc. Entrenched within the risk classing process is the concept of acceptable risk.

LICENSING

Prior to July 98, the Health Canada regulations were voluntary for the most part with only those devices posing significant risk as requiring review. After July 98, the Therapeutic Products Program (TPP) formally known as the Medical Device Bureau (MDB) now governs the requirements under the new regulations. Inspectors from the Department of Health under the authority of the Food and Drugs Act will carry out the monitoring and enforcement. The major regulatory license requirements and dates are as follows.

Importers and Distributors:

As of January 1, 1999, any firm wishing to import or distribute medical products in Canada must have an establishment license (renewed annually on Jan 1) to do so. As of November 1, 1998 this requirement was mandatory. Health care facilities, retailers (i.e. Zellers), and manufacturers (distributing through a licensed firm) are exempt from requiring this license.

Manufacturers:

Medical devices manufactured prior to September 1, 1998 have a grace period to February 1, 1999 to be licensed. Products manufactured after September 1, 1998 must have a Medical Device license.

As of July 1, 2001 manufacturers will be expected to comply with 'quality system requirements' as per a 'certified quality system' (i.e. ISO9000). Third

party representatives accountable to the TPP will handle review of compliance.

Medical device licensing is required for Risk Class 2,3 &4 devices. Risk class 1 devices are not required to have a license.

Upon request and as per regulatory timelines, the manufacturer must be able to produce certification of compliance. Class 3 and 4 devices will receive a control number.

In the case where a device no longer provides the original safety and effectiveness characteristics, the license may be suspended or revoked as determined by the Minister (or delegate).

INCIDENT REPORTING

The regulations also provide guidance on incident investigation and follow-up. Upon being made aware of an incident that has either resulted in or could result in an injury, the manufacturer must submit a preliminary report to the Minister no more than 10 days for injury or 30 days for non-injury related incidents. The report details the demographics of the device, history of other incidents, and a course of action. Follow-up by the Minister (or delegate) and the manufacture may cover such areas as design changes, recalls, additional surveillance, etc.

RESEARCH AND DEVELOPMENT

The traditional standards and regulations were difficult to apply to research products in their early to final phases of development. For most institutions, this is not expected to change with the new regulations. Health Canada has indicated that the task of monitoring and patient protection is best administered by the health care institution. Where there

is no ethical review committee in place to guide clinical trials and R&D, Health Canada requires that the submission be made to them for evaluation. It is expected that the conditions found in the regulations for 'investigational testing' will apply. As many of these devices undergo continued refinement during this period, I expect that the new regulations may grant us greater flexibility in evaluating these devices. The onus will be on the manufacturer or investigator to demonstrate to the Minister that the technology and its application is in the best interest of the public and the trial is conducted in the best interest of the patient. Changes in the design, functionality, etc. will require further evaluation by the Minister (or delegate). As we continue to see the advent of clinical trials within the healthcare setting, it is evident that the provisions of the regulations will administer a clearer definition and higher level of scrutiny.

HEALTH CARE PROVIDERS

It is interesting to note that in the last 8 months, I have yet to talk to a manufacturer or supplier familiar with the regulations and its implications (some were not aware that Health Canada regulates medical products). It is also interesting that although Health Canada plays the same role as the FDA with respect to regulating medical devices, they are not recognized for this.

All grace periods have passed. To insure that manufacturers and suppliers are meeting the new regulations, I would advise that the purchasing conditions of your health care institution include licensing proof for both the establishment selling the medical device along with

licensing proof for Class 2, 3, or 4 medical devices.

As has been done since the inception of Clinical Engineering, our members have become the educators and police of medical device standards and regulations. The provision of a 'safe environment' for the patients, public and staff is encouraged through programs like 'incoming inspection' and 'purchasing conditions' where Clinical Engineering plays a key role in the development, promotion and enforcement of these policies. Acting in the best interest of the public, the health care industry has obligated manufacturers to follow these codes. Although the focus of the regulations is on the manufacturers and/or suppliers of medical devices, Clinical Engineering will need to be familiar and conversant with the rules within it.

We Welcome Your Input...

Do you have an opinion? A beef or bouquet? Maybe a great article idea? Please feel free to contact the ACES Newsletter Editor with any comments, concerns, ideas or articles you would like to see published. You can e-mail your information to:

kmhenke@telusplanet.net

Year 2000 Project Update

Submitted by Michael Mah

Here we are about one and a half years into each of our regional Year 2000 projects throughout Alberta. I

have been fortunate to meet with medical equipment Y2k coordinators from most regions in Alberta. Although I will not profess to speak for each of the regions in Alberta I can report, at the last medical coordinators meetings in January 1999, most if not all health authorities have been progressing well.

The Capital Health region has been moving through the same stages as the other health authorities in Alberta. The early stages of the project were primarily the inventory assessment and Y2k testing. The external resources and information gathering structure available to our region did not meet some crucial requirements. Therefore, with the work of Jon Sala, a biomedical technologist at the University of Alberta Hospitals, and an Internet development company we were able to innovate an Internet based database and testing tool. This Internet server permits individuals to enter and view testing results from any site within our region and performs much of the reporting information in real time for regional administration. Additionally, the database amalgamates information from Manufacturers, Equipment Planning, Purchasing and Material Management.

The Capital Health inventory stands at approximately 28,000 pieces of medical equipment and we have testing results covering the 3100 devices that have a date function. With a few exceptions the first equipment-testing phase was essentially complete last October. The challenge until recently was to work with the 1100 devices which had a variety of issues related to the Y2k testing and make recommendations to our region.

In order to manage the large number of non-compliant devices, a database function allowed for the categorization of the equipment into systems. These systems form the equipment into logical groupings, and aid in setting business and patient risk levels. This allows Equipment Planning and Purchasing working with the system information to see the equipment relationships and encourages the identification of possible purchasing benefits.

The present work plan includes moving forth on the recommendations on the non-compliant equipment, and performing the required evaluation, installation, and education on the new equipment entering our region. Clean Management issues and contingency planning will oversee our operations and prepare us for the issues we will encounter next year. As many of you know the largest challenge throughout this project and into the future has been the responsible management of the problem, and not getting caught in the hysteria which has permeated into the most Y2k medical equipment projects. With a few more grey hairs we will enter the millennium not with roar but with a whimper. That being said, do you know where you will be as the clock ticks over onto January 1, 2000?

Regional Updates: Naitline...

Submitted by David Burry

Well... it has been a very busy time and there have been many changes in

the NAIT Biomedical Engineering Technology program.

As many of you already know, Ron Van Vliet has moved on to become the Assistant Administrative Director at Medical Imaging Consultants. I am trying to fill Ron's shoes as the Biomedical Program Coordinator. Ron will surely be missed and we all wish him well.

We are very fortunate to have Roy Sharplin on board as a new Biomedical Instructor. Roy started here at NAIT at the beginning of December 1998 and has taken over the BET-400 Biomedical Equipment course. Roy's enthusiasm and vast expertise adds to the quality of the education the students will receive. I would like to thank the CHA for their understanding and support during Roy's transition from the Royal Alex to NAIT.

The Biomedical program now has it's own classroom/lab. This gives us an opportunity to give the room a "Biomedical flavor". We are currently planning minor renovations including the addition of a headwall system and LIM.

Events for this semester include the 5th annual NAIT Biomedical student/ Industry mixer night on March 1, as well as, NAIT's open house March 12 and 13.

We have many anxious second year students who after two years are finally seeing some light at the end of the tunnel and are looking forward to their one-month practicum in May and then finding gainful employment. The first year students are currently making their way through the new Biomedical course curricula. Changes have been made to first year courses

to efficiently use available hours and reduce course content duplication. We are currently looking at similar changes to second year.

This year as in past years, the Biomedical program is fortunate to have the support of various industry partners. These include equipment vendors and hospital Biomedical staff. These people give unselfishly of their time and equipment, which gives the students a fantastic learning opportunity. On behalf of all NAIT Biomedical staff and students we thank you all.

Regional Updates: Chinook Health Region...

Submitted by Kay Henke RET

The Chinook Health Region--- Where is that anyway? For those asking that question, the Chinook Health Region spans across southwestern Alberta, from Taber, west to the Crowsnest Pass and from Picture Butte south to the Montana border. The 144,000 area residents are served by 10 hospital sites, 15 Community Health sites and numerous long-term care facilities, housing 340 Active Care beds, 45 Acute Geriatric Care beds and 867 Continuing Care beds.

The big news around the CHR is MRI. Funding has been acquired and renovations are beginning in order to accommodate the MRI unit. The Philips Gyroscan ASC_NT is expected to be up and running by midsummer of this year.

In December of 1998, we received a complete ICU full of new Spacelabs

monitoring equipment, complete with networked telemetry, central control stations and laser printer. Service training is underway for Biomed staff to keep us up to date on the latest equipment. A purchase of Baxter infusion pumps was also made to standardize equipment throughout the region.

On the old St. Michael's Hospital site, construction is continuing on the unique, residential style, long term care facility. It is a first of its kind in Canada and is expected to house 210 residents by February of the year 2000.

The Biomed shop is contained in the Lethbridge Regional Hospital (LRH) site. To solve our unique distance servicing problems, we use a van loaded with test equipment which travels at least two days a week. We are in the process of acquiring a second complete set of test equipment to increase our efficiency when techs are simultaneously on the road and in the main shop at the LRH site. We have 3 full-time Biomed people, each responsible for specific rural sites outside LRH and specific departments within LRH.

I look forward to keeping ACES informed as to the goings-on in Southern Alberta! Remember to support your provincial society wherever and whenever possible!

Regional Updates: Calgary Regional Health Authority...

Submitted by Denny Mellott

Clinical Engineering in Calgary is undergoing some major changes. The preliminaries of the long awaited CMMS (Computerized Maintenance Management System) is well under way and should be fully operational by May. Modifications to the Foothills shop are being planned; construction will be starting soon.

On other fronts preparation for 1999 Region-wide Accreditation Survey is underway. The CRHA has been active in preparing for accreditation as a health region in 1999 by the Canadian Council on Health Services Accreditation. The accreditation process provides a means whereby health organizations can assess their performance on an ongoing basis. The accreditation process is based on five principles: (1) Client focus, (2) Empowerment and teamwork, (3) Leadership, (4) Process and results management, & (5) Commitment to quality. The principles are intended to promote an integrated team approach to client/patient care, service delivery and quality improvement. The CRHA will use the accreditation standards as a means of monitoring performance and implementing and sustaining improvements.

Upcoming ACES meetings...

There are tentative plans for ACES Dinner Meetings in Edmonton and Calgary in June. Watch the Web Page for more information!

<http://skynet.uah.ualberta.ca/~aces>

ASET AGM News...

Submitted by Kay Henke RET

On Saturday May 1, 1999 I had the pleasure of attending the Annual General Meeting of ASET (The Alberta Society of Engineering Technologists), held at the Hospitality Inn in Calgary. A couple of the issues they dealt with were a name change, and recognition of technology as a defined practice.

The name will be changed to the "Applied Science and Engineering Technicians and Technologists" of

Alberta (ASETT). Members felt this name would more clearly reflect and recognize the diversity of ASET's current and future membership, without changing the acronym too much.

Among the many esteemed guest speakers in attendance at the meeting was the Minister of the Department of Public Works, Supply and Services, the Honourable Stan Woloshyn. He announced the development of a set of principles regarding Engineering Technicians and Technologists known as Bill 18 and that Bill 18 had passed in parliament. The legislation gives recognition to those ASET members who are practicing at an engineering

level. Such a member will be designated as Registered Professional Technologist and will be eligible to obtain a "permit to practice" from APEGGA (Association of Professional Engineers, Geologists and Geophysicists of Alberta) within the defined scope, provided standard requirements are met.

ASET now has almost 14,000 members in Alberta and there are many chapter meetings throughout the province. Why not check out one in your area? See their Web Page at:

<http://www.aset.ab.ca>

Membership Application

To enjoy the benefits of ACES, and ensure that you continue to receive the ACES newsletter and meeting notices, **Become a Member Today!** Complete the following Information form, and return with payment in the amount \$10.00 to:

The Alberta Clinical
Engineering Society
c/o The University of Alberta Hospitals
Clinical Engineering Room 0D1.00
8440-112 Street
Edmonton, Alberta, T6G 2B7
ATTENTION: Brian Van Skiver, Secretary/Treasurer

Name: _____

Home Address: _____

City/Prov: _____

Postal Code: _____

Ph: (____) _____ Ext: _____

Email: _____

Business Information:

Company: _____

Position: _____

Department: _____

Room: _____
Address: _____

City/Prov: _____

Postal Code: _____

Ph: (____) _____ Ext: _____

Email: _____

New members receive a membership card and ACES PIN
Memberships are valid from January 1st to December 31st.
All members receive equal voting rights.

Newsletter by Email

ACES IS NOW SENDING ALL NEWSLETTERS BY EMAIL.

To be sure you are on the ACES E-mail list forward your Email address to Denny Mellott denny.mellott@crha-health.ab.ca

All Newsletters will now be sent in "PDF" format. To Read a PDF file simply download an Adobe Acrobat Reader from <http://www.adobe.com/prodindex/acrobat/readstep.html>

The Adobe Acrobat Reader software is free and available for all computer platforms. Use of this reader ensures that the document will print correctly formatted on every system with no added expense. If you have any comments or questions about receiving or reading ACES E-mail Newsletters please feel free to contact Brandon

Beaudry at 492-6711.

Archives of the ACES Newsletters are also available on the **ACES Web** site listed below.

MEMBER "*FEED BACK*"

ACES is an organization dedicated to our members and the field of Clinical and Biomedical Engineering. As a member of ACES you are entitled to provide your input into the activities of the committee. Please forward all ideas and comments directly to a member of the ACES Executive. For a list of your executive please see the:

ACES Web Page @

<http://skynet.uah.ualberta.ca/~aces>

Special Recognition

If someone you know has made an outstanding contribution to the field of Biomedical or Clinical Engineering please nominate that person by sending an email message outlining that contribution to brutledge@cha.ab.ca.

