ACCE News

May 1994

American College of Clinical Engineering

President's Report

Joseph F. Dyro, Ph.D.

The College is alive and well. It is steadily growing in size, gaining in wisdom, and increasing in sensitivity to members' needs. ACCE is embarking upon exciting new programs. These last few months have seen the adoption of changes in the bylaws, regular newsletter schedules, a membership brochure, a membership directory, liaison with more societies, increased recognition by peer societies and governmental bodies, and initiatives in education and communication. Much of this is detailed in this Newsletter. I will single out here the particularly strong efforts of the Board. Particular mention goes to Denver Lodge who, as Chairman of the Advocacy Committee, spearheaded the Advocacy Awards Program. The annual meeting will see the presentation of the first awards resulting from that program. Wayne Morse designed a great brochure and continues to print a fine newsletter. Ethan Hertz labored diligently on bylaws.

The leadership of ACCE is assured through the stalwart efforts, energy and breadth of experience and creativity of Tom Bauld. The nomination process for the new board will be completed at the annual meeting. You should all have received the slate of candidates approved by your board. The board has approved a plan developed by our education committee chair, Jim Wear, to hold a National Clinical Engineering Workshop. The time and location will be announced shortly. Jim Wear, Al Jakniunas, Tom Bauld and I have recently begun to share our ideas concerning a clinical engineering information system and the use of the electronic highway to facilitate this. Please get in touch with Al if you are interested in pursuing this.

"It was the best of times, it was the worst of times"
Charles Dickens, A Tale of Two Cities

Clinical engineering has never enjoyed the recognition it has now. Wide spread acceptance of clinical engineering in the management of medical device technology is on the rise. Not all healthcare organizations are enlightened, however. Some of our members have expressed concern over employment and the future of clinical engineering. Unfortunately, short-sighted attacks and slash management strategies have undone a lot of good in the name of short term gains. Remember, though, that the body's reaction to moderate stress is largely beneficial. A word of encouragement and a challenge to those feeling the squeeze is in order. To the clinical engineers feeling the effect of the gardener's pruning hooks on their organizational tree, be aware that ridding trees of pernicious, parasitic suckers makes good horticultural sense. Wisdom is needed to discern wheat from the chaff so that the good is not made to suffer while eliminating the bad. Imparting that wisdom to those who shape organizational structure in this healthcare delivery system, is a challenge to us all. Tremendous opportunities exist for those who take the initiative and take advantage of the changes afoot in the organizations that utilize the technology of which we have unique and special knowledge.

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If you are one of those few asking what ACCE is doing for you, I say, pitch in yourself. You are ACCE. What are you doing for yourself and your fellow members? Clinical engineering success stories, solid examples of productivity gains and advocacy efforts are needed now more than ever. Contributions to the newsletter, committee involvement, utilization of the bulletin board will yield dividends. But we all have to do it.

Great changes have occurred on the personal front. Taking the presidential prerogative to pen whatever I want in the President's Message and in the interest of saving postage, I hereby tell all readers of this newsletter and all ACCE members that I have embarked on a new trail. Having successfully developed and guided a department over the last 14 years, my intense interest in promoting medical device advancement through application of clinical engineering and biomedical engineering skills has given rise to a new job at Stony Brook. As Director of Biomedical Engineering, my full efforts will be upon directing the BETA program, Biomedical Engineering for Technology Advancement. I created BETA about two years ago as means by which University Hospital, the Medical Center and the University at large could reach out to the industrial community, combine talents, and spur the economy through development of medical device technologies. The concept caught on and here I am. I encourage anyone interested I these efforts to get in touch. Reach me by telephone, fax, letter, e-mail, semaphore, carrier pigeon, or personal presence. However you wish to communicate, do so. I'll be happy to share my experience in this rewarding application of clinical engineering expertise. Refer to our new directory for my new address and phone number.

For me the great leap forward was actually a great leap upward, out of the basement and onto the first floor with a grand window and clear view of sky, trees, grass and lots of industrious students and faculty scurrying to and from classes on the campus of Stony Brook, the flagship of the SUNY system.

I look forward to meeting you all at our 4th annual meeting, May 24, 1994, at the Washington Hilton. Come at 7 p.m. to socialize a bit before we get down to business.

BMET May Need Chloroflurocarbon Certification

by Joseph P. McClain

The United States Environmental Protection Agency (EPA) has established a mandatory technician certification program under Section 608 of the Clean Air Act (CAA). There is a possibility that some Biomedical Equipment Technician's (BMETs) who repair refrigerated centrifuges, frozen section microtones, biological refrigerators or any appliance that uses ozone depleting compounds such as chloroflurocarbons (CFC) may have to be certified by November 1994. According to Debbie Ottinger, Regulatory Analyst of the United States Environmental Protection Agency, BMETs may still work on the equipment without certification provided that they do not attempt to penetrate or service the refrigeration system. Ms. Ottinger also stated that Ethylene Oxide Sterilizers that use CFCs as a carrier are not covered under Section 608 of the Clean Air Act because they are not being used as refrigerants. Even if the Clinical Engineering Manager contracts equipment subjected to the law out for repair he or she may still be required under the law to write the contracting specifications requiring that only certified technicians repair the health care facilities equipment in order to protect the organization from being subjected to a non-compliance finding.

The Agency has developed four types of certification. They are:

Type I: For servicing small appliances.

Type II: For servicing or disposing of high-or very high-pressure appliances, except small appliances and MVACs.

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Type III: For servicing or disposing of low-pressure appliances.

Universal: For servicing all types of equipment.

An appliance is defined by the EPA as any device which contains and uses a class I (CFC) or class II (HCFC) substance as a refrigerant and which is used for household or commercial purposes, including any air conditioner, refrigerator, chiller, or freezer. EPA interprets this definition to include all air-conditioning and refrigeration equipment except that designed and used exclusively for military purposes.

Maintenance, service, or repair refers to services that involve the removal of the appliance compressor, condenser, evaporator, or auxiliary heat exchanger coil.

On March 30, 1994, the EPA issued a list of 57 approved certification programs. Technicians are required to pass an EPA-approved test given by an EPA approved certifying organization to become certified under the mandatory program. Technicians must be certified by **November 14, 1994.**

The EPA plans to "grandfather" individuals who have already participated in training and testing programs provided the training and testing programs are...

- approved by EPA and
- provide additional, EPA-approved materials or testing to these individuals to ensure that they have the required level of knowledge.

Although any organization may apply to become an approved certifier, EPA plans to give priority to national organizations able to reach large numbers of people. EPA encourages smaller training organizations to make arrangement with national testing organizations to administer certification examinations at the conclusion of their courses.

Under section 608 of the Clean Air Act, EPA has established regulations that:

- Require service practices that maximize recycling of ozone-depleting compounds (both chloroflurocarbons [CFCs] and hydrochlorofluorocarbons [HCFCs] during the servicing and disposal of air-conditioning and refrigeration equipment.
- Set certification requirements for recycling and recovery equipment, technicians, and reclaimers.
- Restrict the sale of refrigerant to certified technicians.
- Require persons servicing or disposing of air-conditioning and refrigeration equipment to certify to EPA that they have acquired recycling or recovery equipment and are complying with the requirements of the rule.
- Require the repair of substantial leaks in air-conditioning and refrigeration equipment with a charge of greater than 50 pounds.
- Establish safe disposal requirements to ensure removal of refrigerants from goods that enter the waste stream with the charge intact (e.g. motor vehicle air conditioners, home refrigerators, and room air conditioners).

For further information concerning regulations related to stratospheric ozone protection, please call the Stratospheric Ozone Hotline: 800-296-1996. The Hot line is open between the hours of 10:00 AM and 4:00 PM Eastern Time.

National Engineers Week

Thomas J. Bauld, Ph.D.

The annual celebration of National Engineers Week occurred from February 20-26, 1994. The Michigan Society for Clinical Engineering (MSCE) put together a major event with six Southeastern Michigan hospitals hosting a portion of the technical program. The co-chairs were Steve Henning of Botsford Hospital and Byranne Patail of William Beaumont Hospital. Titles of sessions included the Impact of the Safe Medical Device Act, Minimally Invasive Surgery, 18 Lead Arrhythmia Monitoring, Computer Aided Facilities Management, Glucose Monitors, and Equipment Troubleshooting for Nurses. Several service schools for medical devices and personal computers were included in the program.

FDA Issues

Tom Bauld, Ph.D.

Are you prepared for the visit of an FDA official who may soon be investigating the compliance of your institution with provisions of the SMDA? Now that healthcare institutions are subject to SMDA regulations, the determination of how well it is being followed won't be far behind. Implementation of Device Tracking has produced some very elaborate and elegant schemes for the entire process from initial ordering of tracked devices to the actual implantation in patients. There is still no announced date for the release of the Final Regulations about Device Problem Reporting. It has been over three years since the release of the Tentative Regulations, and over two years since formal comments were due to the FDA.

Are you using the HIMA forms for device tracking, those provided by the manufacturers or self-designed forms? Is there any interest in a standard form similar to the one the FDA developed for Device Problem Reporting?

MedWatch Partner

Tom Bauld, Ph.D.

ACCE has submitted the application form to become a MedWatch Partner. That means we agree to support the concepts of user reporting and promote active reporting within our membership. The ACCE certainly supports and encourages active dissemination of information relating to defective products so that corrective actions can be taken. For those institutions with an active User Device Problem Reporting process, it would be valuable to HEAR FROM YOU as to how you have incorporated the voluntary MedWatch reporting with your mandated reporting where devices may have caused or contributed to patients being injured or killed.

Safety Lead Wires: Opinion

Tom Bauld, Ph.D.

The campaign to eliminate the exposed metal tips on all types of lead wires used for the acquisition of any electrophysiological signal may be more costly than any other single recall. My mailbox is filled with repeat communications from all manner of vendors. Some firms have mailed their alert package to every possible address their company has ever mailed anything to at our institution, including some from ten or more years ago. As our Medical Center includes a pediatric hospital, we were sensitive to the issue of accidental electrocution especially during apnea monitoring of infants. Over a year ago, the University of Michigan Hospitals converted all our ECG cables to a bright green safety style at a considerable capital cost. Over $25,000 was needed to ensure that we retired every one of the old cables. Now that we have, we are reluctant to paste the 'required' labels on the front of all of our patient monitors for the following reasons: 1. No one will read them anyway, and 2. There will soon be zero availability of non-safety lead wires, and 3. It will require either a very long time until we see all the monitors for a scheduled inspection, or it would be labor intensive to do all the monitors at one time.

Furthermore, to eliminate in a wholesale manner that style lead on EEG, EMG and all other signal cables has not been demonstrated to have any impact on the safety of our patients, but will carry a significant cost. These devices are used by highly trained professionals in diagnostic areas for relatively short times and do not allow unsupervised access by siblings or the patient's themselves. Clearly there is some need to consider a phased and gradual approach to such a changeover.

Is anyone out there tracking the risk-benefit of this activity? Does anyone care?

Proposed Clinical Engineer Productivity Reports

Tom Bauld, Ph.D.

The following is offered as a proposal for a new ACCE activity in support of CE's. It is intended to provide a method to collect and distribute a wide variety of implemented cost-saving ideas for others to learn and benefit from.

Objective: The ACCE shall develop and publish one hundred current examples of quality and cost effective activities of practicing clinical engineers. Single summary pages shall be created for a loose leaf binder format with separations by area of activity. We will add examples as developed. Distribution of the first 20 examples may be through the ACCE News. As more examples are developed, we will produce and sell a bound book.

Rational: We can provide concrete examples to administrators, clinicians, educators and clinical engineers to demonstrate the value of clinical engineering. We would use examples and terminology that emphasize the engineering and analytical aspects, but are stated directly and clearly with no jargon, so that other disciplines can readily understand them. This is a way to really share what you have developed with your peers.

Actions Needed: We need feedback from members if they feel this will be a worthwhile activity that they will both contribute to and will look forward to receiving as a benefit. All suggestions for content, format, distribution methods, etc. are welcome. Contributing an idea or example for future publication will be the best feedback. Please use the suggested format below.

Volunteers are needed to review submissions and guide the development of this compilation of CE accomplishments.

If interested, please contact Tom Bauld at (313) 936-5056 or use the Internet. Tom's E-Mail address is Bauld@umich.edu. Send copies of any submission to Tom Bauld at University of Michigan Hospitals, 1500 E. Medical Center Drive, Ann Arbor, MI 48109-0002.

CLINICAL ENGINEERING PRODUCTIVITY

Report Format

Topic Title _____

Name _____

Affiliation _____

Date Implemented _____

Category _____

General outline of the project: (How, why and who initiated the project or idea, duration.)

Annual cost savings (or cost avoidance) or quality improvement.

List specific steps in detail.

Clinical engineering component: (What was uniquely contributed by a CE? Can the work be related to the CE Definition?)

Describe the possibility for replication elsewhere.

Clinical Engineering Cost Containment Possibilities

David Simmon

There are many ways available to contain costs of Clinical Engineering programs. Some are more obvious than others, but selective usage of available resources and alternative methods of contract negotiation and management can pay big dividends in cost control. Following is a series of possibilities that have been proven to be effective in reducing and/or containing costs. This is by no means an exhaustive list but does provide several possibilities to consider.

A. Alternative Sources of Staffing

It is possible to use non-staff personnel to provide additional manpower for Clinical Engineering support. Some examples are: 1. Use of state funded vocational rehabilitation individuals; 2. University co-op students; 3. Use university affiliated services to perform services or fabrication of small specialty mechanical parts; 4. Use work study students to perform more routine testing, inspection or minor repairs; 5. Use volunteers for clerical work or routine preventative maintenance inspections; 6. Use patients who may be in rehabilitative programs or other long term care programs to the extent that they are interested and capable.

B. Open Purchase Orders

Initiate open purchase orders with selected repeat use vendors for parts or service. Such orders can be placed with electronic or mechanical parts suppliers, or service representatives where rapid response is required on a more frequent basis where response time can be significantly reduced by avoiding time consuming purchase order preparation and placement. These types of purchase orders usually have a fixed upper limit which can be adjusted as needed.

C. Alternative Service Contract Arrangements

- Full Service - vendor provides scheduled preventative maintenance and demand repair services; usually at a fixed annual price. Parts may or may not be included, as specified.

- Preventative Maintenance Only - vendor provides preventative maintenance at specific intervals for an annual fixed price. Parts needed for preventative maintenance are generally included.

- Repair Services Only - vendor provides unlimited repair services for a fixed annual fee. Parts are generally billed separately.

There are a variety of other service contract arrangements. Following is a sample of some of those options.

Incentive Based Agreements

Includes scheduled preventative maintenance with a limited credit from discounted parts and service. After the credit is used up, additional parts and services are billed at the same discounted rate up to a predetermined cap.

"First Call" Contracts

Vendors will discount normal full repair service contracts if the Clinical Engineering department will take the first call on equipment problems.

"Limited Call" Contracts

Vendor provides parts and a limited number of service calls for a significantly reduced price.

"Bundled Discount" Contracts

Vendor services are provided at no cost or very low cost if the hospital commits to use the companies reagents, IV sets, or other consumables.

Negotiated Bid Contracts

Where competition is available, the hospital may invite proposals from vendors in the form of a Request for Proposal (RFP). In this way the hospital may set it's own terms and requirements and select the lowest acceptable proposal from equally qualified vendors.

D. Contract Cost Comparisons

Each type of service contract option can be compared to a full service contract as follows:

- Preventative maintenance only should cost 10-30% of full service contracts.

- Repair services only (unlimited calls) should cost 70-90% of full service contracts.

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- Limited call contracts should cost 30-80% of full service contracts depending on the number of calls specified. The fewer the calls, the lower the price.

- Bundled discount contracts should be provided free to 15% of full service contracts.

- Negotiated bid contracts should cost 15-30% less than full service contracts that are priced as sole source provider. Competition makes the difference and forces the contract price down.

- Incentive based contracts should cost 15-40% less than full service contracts.

- First call contracts should cost 20-30% less than full service contracts.

E. Biomedical Technician Education

The very best way to reduce or eliminate service contract costs is to train BMETs to repair the equipment in house. Manufacturer training, wherever possible, should be made a part of the terms and conditions of purchase.

Advocacy Awards

Denver Lodge

The following individuals have been nominated by ACCE members, voted on by active Advocacy Committee members, and approved by the ACCE Board on April 20, 1994, to receive the first annual ACCE Professional Development & Achievement Awards for advocacy of the profession of Clinical Engineering. They are:

1994 ACCE Professional Development Awards:

Cesar A. Caceres, MD
For editing the book The Practice of Clinical Engineering, 1977, Academic Press, New York, NY. $300.00 (Historical)

Denver A. Lodge, ME, CBET, CCE
For the article, "Someone Must Guide Tech Acquisition," Modern Healthcare, Dec. 7, 1992, Vol. 22, No. 49, p. 21. $300.00

Lee O. Welter, MD & Nicholas J. Pollard
Jointly for the article, "The Essential Role of the Hospital Clinical Engineer", Michigan Hospitals, Nov. 1974, p. 14-30. $50.00 (Historical)

1994 ACCE Professional Achievement Awards:

Gerald Goodman, MSEE, MHA, CCE
For the article, "The Profession of Clinical Engineering", Journal of Clinical Engineering, Jan/Feb 1989, Vol. 14, No. 1, p. 27-37. $300.00 (Historical)

John G. Webster & Albert M. Cook
Jointly for editing the book Clinical Engineering, 1979, Prentice-Hall, Englewood Cliffs, NJ. $50.00 (Historical)

George I. Johnston, PE, CCE
For the article, "A Basic Clinical Engineering Model for Developing Nations", Journal of Clinical Engineering, Jan/Feb 1993, Vol. 18, No. 1, p. 41-46. $50.00

ACCE Bulletin Board Update

Mo Kasti

The ACCE Bulletin Board (BB) has been in place since August 1993. While normal BB activity ranges from 20-50 calls/week, our BB total activity since September 1993 is a disappointing 79 calls!!!

Still, the following interesting topics are being discussed:

- **Employment trends of clinical engineers**
  Discussion, facilitated by Binseng Wang, addresses the issues of the trends of CE job losses and suggestions on what to do about it.

- **Benchmarking ideas in clinical engineering**
  Discussion, facilitated by Rick Hampton & Craig Bakuzonis, addresses ideas on what measures or benchmarks are being used in the Clinical Engineering field.

- **Work order documentation**
  Alan Lipshultz, is surveying if anyone has implemented a work order documentation where the techs enter and/or close their work orders.

- **ACCE membership expectations**
  Discussion, facilitated by Mo Kasti, surveys the ACCE members about their expectations of the ACCE.

Thanks to all the facilitators of these discussions.

There is one file residing in the library ready to be downloaded by interested members:

- The ACCE updated bylaws.

If you have not taken the time to check out and be in on the discussions, please join in as soon as possible. We are always looking for new topics, or you may want to upload any work you are interested in sharing with others!

The ACCE Bulletin Board was designed to help you network with your colleagues. Use it to your advantage.

As a reminder, the ACCE BB is part of the ECRInet. You can access it by dialing (215) 825-9284.