ACCE News

Vol. 7, No. 5 - September 1997

American College of Clinical Engineering

Annual Conference 1998

Mark your calendars now for the first Annual ACCE Conference on Clinical Engineering, Saturday, May 30, 1998, Plymouth Meeting, Pennsylvania. A full day of selected topics in engineering and management issues will be presented by the top professionals in the business. Lots of opportunity for open discussion of critical issues with the faculty. The campus of ECRI, in suburban Philadelphia, will be an invigorating setting for this important event.

BMET Task Force

SBET dissolved recently leaving thousands of disenfranchised biomedical engineering technicians without the organizational support needed to continue the forward momentum of their professional growth. ACCE President Frank Painter, with unanimous Board approval, appointed a task force to explore ways by which ACCE can assist our fellow members of health care technology community. As he works with his task force, Chair Dennis Minsent, welcomes all to share their perspectives. Call him at (248) 858-6073.

Teleconferences '97

The next ACCE Teleconference for 1997 is on October 16. Tom O'Dea will speak on *Building Teamwork between CE staff and maintenance staff.* This year's series of lunchtime lectures on critical issues in clinical engineering continues the tradition of high quality, informative presentations by the world leaders. Call Jim Wear (501)771-1775 for information and the schedule of upcoming lectures and speakers.

Actual Teleconference Testimonial

Thanks, for a great ACCE Teleconference presentation, Frank. It was one of your best. Well laid out, concise, hit the mark, full of good solid material, based on theory and practical experience and timely. Well done! Nick Noyes

Medical Technology Management in Orlando

ACCE and ASHE again join forces to present an Advanced Clinical Engineering Workshop in conjunction with the ASHE's annual **Medical Technology Management Conference**, November 11-12. Orlando, Florida is host city for this event that premiered last Fall in Chicago. The event's faculty, featuring many ACCE members, will present lectures on technology management, asset management and leading-edge technologies. To be held in conjunction with the American Heart Association Meeting, MTM promises to draw a large attendance. For reservations and details, contact Patti Costello, One North Franklin, Chicago, IL 60606. Tel: 312-422-3807, fax: 312-422-4571.

ACCE Editor Scans the Globe for *ACCE News*

This issue of *ACCE News* is dedicated to clinical engineering as a profession that knows no national boundaries. Although your editor has scoured the world for stories on clinical engineering (see right), the reports that fill the pages of this issue of the *News* come from ACCE members filing reports from their countries or about countries in which they have worked. ACCE's members hail from ten countries. *From the Penalty Box*, Dave Harrington suggests that the direction of clinical engineering may be given by those outside the U.S. Al Levenson exposes ACCE's humanitarian side as he writes about our International Committee's Mission and our work for Carelift. Bob Morris relates colorful tales of oversees volunteerism. Sam Miller thanks ACCE for landing a travel grant for a Ukrainian BME. ACCE member from Italy, Enrico Nunziata, files a report on Mozambique. Roberto Ayala underscores the American in ACCE with a report from his corner of America, Mexico. *Our Profile in Clinical Engineering* this issue features Tom Judd, an unrelenting force behind much of ACCE's international outreach. Read and enjoy!

ACCE News

ACCE Mission

1. *To establish a standard of competence and to promote excellence in Clinical Engineering Practice.*
2. *To promote safe and effective application of Science and Technology to patient care.*
3. *To define the body of knowledge on which the profession is based.*
4. *To represent the professional interests of Clinical Engineers.*

President's Message

To increase productivity, work less and play more golf! One perfect afternoon this summer, Joe Dyro and I met for a brainstorming session on clinical engineering. The last meeting of this sort, on the Bridgeport-Port Jefferson Ferry shuttling back and forth from Connecticut to Long Island, was a huge success, producing an in-depth analysis of the ICC certification process and a paper for presentation. This time we tried one of Connecticut's finer golf courses. Again significant clinical engineering productivity gains were realized in a somewhat unconventional setting. Out of hundreds of golfers that day, the starter paired us with two particular fellows who would make my day. My job at Novamed involves establishing communication with the people running medical devices support programs. I wanted to meet with the people at Philips which has one of the largest programs. Scheduling meetings of this sort can be difficult and time-consuming for a host of reasons. The starter made it all happen by pairing us with Philips' Director of Strategic Customer Support Programs and Director of Customer Support Programs. Over a refreshing soda following an enjoyable round of golf and discussion, we got the ball rolling for serious communication to take place on issues of mutual interest. Trust me. Play more golf!

Frank R. Painter

ACCE News

ACCE News is the official newsletter of the American College of Clinical Engineering (ACCE).
ACCE News is a benefit of ACCE membership; nonmembers may subscribe for $50. To subscribe call (516)751-7244.

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Letters to the Editor

Good Intentions

Dear Editor, Various members of the Board have received comments, questions, and complaints regarding the *News From ACCE* insert sent with some copies of the July '97 issue of the *ACCE News (vol. 7 no. 4)*. A special executive council meeting was held to discuss these issues. While we are confident the intent was in great cause and all of us try to promote ACCE to new members, the insert misrepresented ACCE 's mission. As ACCE board members we would like to address the following statements made: (1) *Tired of Playing second fiddle to BMETS?* - Clinical Engineers and BMETs are partners in the Clinical engineering field and the ACCE does not like to create any division among these partners. BMETs and CEs are welcomed to join the ACCE; (2) *ACCE is an organization of clinical engineers only* - This is absolutely not true! ACCE's mission is to promote the clinical engineering profession independent of titles and all professionals involved in the process of delivering clinical engineering and technology management services are welcomed to join the ACCE. We have room for everyone!! (3) *ACCE wants you to be an active part of the Only American Organization...* - ACCE is an international organization that is active internationally and is proud to have international members. The ACCE Board of Directors would like to apologize to those who may have misconstrued the editor's good intentions. We sincerely hope that readers would take advantage of all ACCE has to offer and help us to maintain our clinical engineering diversity by joining ACCE today!!

ACCE Board

ACCE INTERNATIONAL COMMITTEE MISSION AND GOALS

Mission Statement: *To promote the advancement of clinical engineering worldwide in the belief that improved management of healthcare technology will contribute to the betterment of healthcare for all people, regardless of national origin, color or creed.*

Goals:

- To facilitate the exchange of information and ideas among members of the international clinical engineering community through bulletin boards, newsletters, e-mail and other media as available and appropriate;
- To assist foreign clinical engineers in their search for information on technical issues, training programs, management techniques, and special needs;
- To provide educational opportunities for foreign clinical engineers through workshops, publications, internships, and visits to well established clinical engineering programs;
- To educate healthcare decision- and policy-makers of the advantages of incorporating clinical engineers in the management of healthcare delivery;
- To promote certification of clinical engineers in the international community as a means to verify professional competency and advancement of professional standards;
- To assist the ACCE Inter-Society Committee in establishing and maintaining communications with non U.S.-based clinical engineering associations and societies.

ACCE members and workshop participants assembled under the flags of the Americas, Pan American Health Organization, Washington, DC, June, 1997

Clinical Engineering in Mexico

Roberto Ayala, cmt@mail.dsinet.com.mx

Clinical engineers are found in less than 2% of all hospital institutions in the country. About 80% are concentrated in Mexico City, and almost 75% work in private for-profit hospitals. The average clinical engineering department has two technicians. We are in the process of creating a BMET career. The average degree of organizational level for a clinical engineer is department head. There are only 3 or 4 managers or directors. Mexico has five clinical engineers certified by the International Certification Commission. All clinical engineers are at the stage of leaving the service-support age and entering the technology management era. We are lobbying the government for increased support for clinical engineering. Mexico has three universities that grant degrees in biomedical engineering, two of which have the specialty of clinical engineering.

The National Congress of Biomedical Engineering which will take place in the city of Colima, in the state of the same name, is sponsored by *Sociedad Mexicana de Ing. Biomedica* (SOMIB), *i.e.*, the Mexican Society of Biomedical Engineering, and Colima University. Since its inception, the Congress has featured presentation by and for clinical engineers. Over the last four year, however, the Congress has dedicated one or two full days solely to clinical engineering.

There is much need for clinical engineering in Mexican hospitals. It is difficult to attract clinical engineers since private companies offering sales and service are able to provide better economic opportunities for the engineer seeking a job. The average annual salary for a clinical engineering department head is $ 9,000 U.S. While this may seem bad, we remain enthusiastic about our future. We know the future will be brighter as we establish better contact with ACCE. We are happy to say that much has been learned by clinical engineers in this country from the ACCE workshops, from publications, and from informal interaction with fellow ACCE members.

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XX CONGRESO NACIONAL DE INGENIERIA BIOMEDICA

Que se celebrara los dias 22, 23, 24 y 25 de Octubre de 1997 en la Biblioteca de Ciencias Miguel de la Madrid Hurtado de la universidad de Colima.

- *Conferencias Magistrales*
- *Mesas Redondas*
- *EXPOTECNOMED 97*
- *Sala de Exposiciones*
- *Foros Abiertos*
- *Cursos de Actualizacion*
- *Presentacion de trabajos libres*
- *Actividades Culutales*

TEMATICA

Instrumentacion Biomedica Ingenieria Clinica
Procesamiento Digital de Senales e Imagenes Biomedicas
Biofisica Audiologia Redes Neuronales y Sistemas Expertos

Centros de Informacion e Inscripcion

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Editor's Note: ACCE members Roberto Ayala and Adriana Velazquez together with their colleagues in SOMIB are working hard to make the clinical engineering component of the 20th National Biomedical Engineering Congress, October 22-25 in Colima, Mexico. They were kind enough to extend me an invitation to speak at this important event. For those interested in attending the announcement follows below. Spanish is the official language of the Congress.

Brazilian Clinical Engineering

Saide Jorge Calil

Aware of the lack of recognition of clinical engineering, the Ministry of Health created PROEQUIPO, a program with the following objectives: (1) establish clinical engineering and BMET courses; (2) generate safety standards for medical devices; (3) create medical device management and maintenance centers to support several groups of small hospitals; (4) control the quality of medical devices traded in Brazil; and (5) create medical device certification laboratories.

The government sponsored several meetings to explain clinical engineering to hospital administrators, county health secretaries, medical doctors, technical school directors and university president. In 1992, three universities and one medical school established a one-year clinical engineering course, following the curriculum defined by PROEQUIPO. Three technical schools started a BMET course, following a Ministry of Health proposal. The proposal called for a 2 1/2 year BMET course and a three-month course for technicians already degreed in electronics. By the end of 1997, 150 clinical engineers and about 250 BMETs will have been trained throughout the country. The last course was so successful that the Brazilian army asked one of the technical schools to train about 50 army sergeants, with telecommunication background on medical equipment repair and preventive maintenance.

Safety programs have the full backing of hospital administrators. Several clinical engineering groups are influencing purchasing decisions and are beginning to incorporate safety standards such as IEC-601.

PROEQUIPO's objective of controlling internal trade of medical devices was achieved with the help of clinical engineers. They defined a list of requirements that must be met by Brazilian manufacturers and foreign suppliers before devices can be sold within the health system.

Less successful was PROEQUIPO's attempt to establish maintenance centers. The object was to have one clinical engineering center to support hospitals within a 70 mile radius. The center would be financed by the government to buy tools and equipment and to support one clinical engineer and two BMET for a period of around 6 months. After this period, the center would support itself by selling maintenance services to the hospitals and as a consequence, compete with local companies. Despite the financial support from the Ministry of Health and some State Health Secretaries, only one center is succeeding. Experience is showing that the 6- month support period is not enough. A 12-month period with decreasing support may be more realistic. The successful center is totally autonomous, selling services and maintenance contracts to several hospitals within its orbit. Political antagonisms from mayors of different counties have hampered the establishment of additional centers. Many public hospitals belong to several small counties within the orbit of the center.

Development of a network of medical device certification laboratories is still pending, delayed by lack of funding. Brazil has only one certification laboratory for medical devices. However, the government is already requiring the certification of high risk equipment. With about 400 medical device manufacturers in Brazil, one certification laboratory is not enough.
In spite of drawbacks, the growth of clinical engineering far exceeds the expectations of those who helped to set up the medical equipment program. Today, it is quite common to hear state and county health secretaries declaring the need for more clinical engineers within the health system.

In 1994, with the support and encouragement of members of the American College of Clinical Engineering, five Brazilian clinical engineers became certified. With continued support this group blossomed into the Brazilian Board of the International Certification Commission a most significant sign of coming of Brazil coming of age in the field of clinical engineering.

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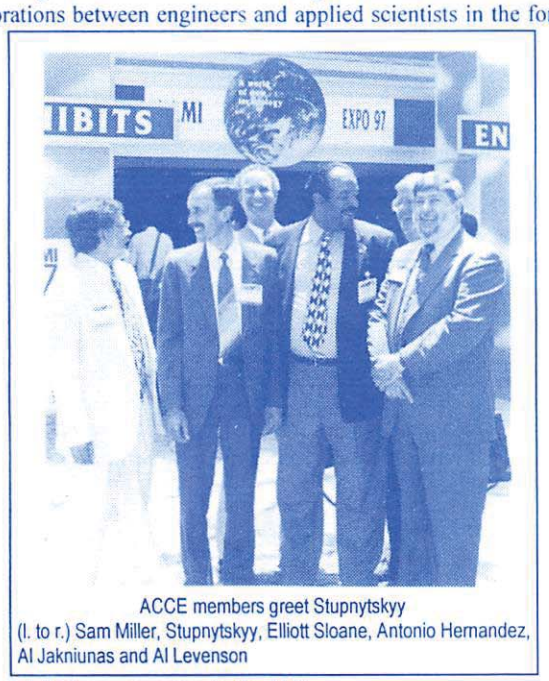
ACCE Helps Ukrainian BME

Sam Miller, samiller@localnet.com

ACCE members helped biomedical engineer, Ihor Stupnytskyy, Ph.D. of Lviv, Ukraine to win a $2500 travel grant to attend the ACCE and AAMI Annual meetings last June. This grant by the U.S. Civilian Research and Development Foundation (CRDF) is made to scientists and engineers from the Newly Independent States (NIS) of the former Soviet Union who have not yet visited the U.S. for participation in selected meetings of industry associations and scientific and engineering professional societies. The program's goal is to establish or strengthen scientific and entrepreneurial collaborations between engineers and applied scientists in the former Soviet Union and their counterparts in the U.S.



ACCE members greet Stupnytskyy
(l. to r.) Sam Miller, Stupnytskyy, Elliott Sloane, Antonio Hernandez, Al Jakniunas and Al Levenson

Sam Miller, ACCE member from Buffalo, met Dr. Stupnytskyy on a visit to Ukraine in 1994. When this grant opportunity arose, Sam encouraged him to apply for the grant and write a paper on his commercial biomed service company, TEXMED, formed to support hospitals in western Ukraine following the breakup of the Soviet Union's centralized support system. Sam acted as his host, traveling with him to the ACCE and AAMI meetings, hospitals in Washington, The John Hopkins Hospital in Baltimore, MEDIQ/PRN near Philadelphia, a legal consulting firm in New York City, and several hospitals in Buffalo. Ihor is interested in collaborating with U.S. researchers and industry for R&D and marketing of medical devices he has developed and for marketing U.S. devices in Ukraine. He hopes for follow-up grant support from CRDF to assist in this effort under a new program called "Next Steps to the Market".

Contact Dr. Stupnytskyy at ifs@healthnet.lviv.ua. For information on CRDF contact Sam Miller at samiller@localnet.com
http://www.mmaweb.com/jsmi

Italian ACCE Member in Mozambique

Enrico Nunziata, SPARVIER@FILEITA.IT

Editors Note: ACCE Member Enrico Nunziata sends the following report from his native Italy.

Since leaving the States I have been a clinical engineering consultant. From Politecnic of Turin, Italy I went to Ohio State University (OSU) where I obtained an M.S. in Biomedical Engineering under Prof. Herman Weed. At OSU Hospital's Department of Anesthesiology, I learned much from the fine Biomedical Engineer, Roger Dzwoncek. After an assignment with Project Hope, I worked with a French consulting company on worldwide assignments. Over the last ten years I have maintained my collaboration with the OSU Division of Cardiology developing software for RR interval and BP variation analysis. The software is in clinical use at OSU, Pavia Central Hospital and Brescia Central Hospital.

At this moment, I am the coordinator for a hospital equipment maintenance project in Mozambique sponsored by an Italian health care consortium. I have three collaborators, 2 technicians and 1 engineer, all trained in biomedical engineering. As we improve the system, our major areas include policies making, inventory management (nomenclature standardization), on-the-job training, formal training, maintenance information systems, medical equipment acquisition and maintenance management systems, hospital equipment repair and spare parts acquisition. To aid the Ministry of Health in its plan to purchase in the near future equipment for the whole country, I am developing specifications for equipment purchasing based on hospital occupancy.

This Fall I enroll in a health economics distance learning course from the Aberdeen School of Public Health. The real cost of maintenance intrigues me. For example, can developing countries afford it and do they need it? Developing country medical equipment management is a complex problem. For example, what does standardization mean for a developing country with scarce resources? Drawing from the example of Mozambique, centralized purchases assured standardization whereas unmanaged free market policies can result in a menagerie of diverse devices.

The organization for which I work is the *Direzione Generale per la Cooperazione allo Sviluppo* (DGCS), i.e., the General Direction for Cooperation to Development under the *Ministero Affari Esteri* (MAE), the Ministry of Foreign Affairs. DGCS technical branch is *Unita' Tecnica Centrale* (UTC), Central Technical Unit, with experts in such fields as health and agriculture. Countries such as Mozambique where DGCS is operative have Local Technical Units (UTL) with a Coordinator and technical advisers in the area of major intervention. I have served for the last six months as Health Coordinator.

Many Italian agencies are concerned with worldwide health care. Some projects are financed by the Italian Government and controlled directly by the UTL and the local embassy for the DGCS. These projects use experts from Italian public institutions or, more commonly, consultants. Some projects are financed by the Italian Government but executed by Non-Governmental Organizations. If the projects involve building infrastructure, private company serve as the executive agent. Other projects financed by the Italian government and executed by other agencies include a large project in Gambia, a large rural development project in Salvador, Central America, and in Mozambique. The World Bank finances invests in some of these projects in part. The country in which Italy is involved is determined at the political level.

Brazilian Board Born

. The International Certification Commission has approved the Brazilian Board of Clinical Engineering. Members are as follows: Paulo S. Palombo Camargo, Chairperson; Sérgio S. Mühlen, Chair-elect; Lúcio Flávio Brito, Secretary/Treasurer; Marcial C. Martins, Voting Member; José C. da Cunha, Voting Member; Binseng Wang. Non-voting Member; Augusto S. de Melo, Non-voting Member.

ACCE News

Assignment Egypt

Adventures in Teaching Trouble Shooting and Repair in Developing Countries

Robert L. Morris, morris@ohsu.edu

The particular general strategy used to repair devices varies with the circumstances. In a hospital where labor is the most expensive component of repair, the strategy generally used is to replace modules or subassemblies. In a graduate school or research environment, usually there is a shortage of money but graduate students are relatively inexpensive. Therefore labor is chosen and parts costs are minimized. The same is true in developing countries. There is usually no shortage of labor but there is almost always a paucity of hard currency. Even given money, one must still deal with customs, complex paperwork and the unavoidable long delays. These and other problems tend to drive engineers and technicians in developing countries to troubleshoot to the component level and then attempt repair. Resources taken for granted in the United States, free trade publications, junk mail, Yellow Pages, and 800 numbers, don't exist. Information is difficult to obtain and is not generally freely shared.

Ironically the successful engineer and technician in a developing country must be better at the basic skills of technology than their average American counterparts. For example, while teaching troubleshooting and repair in Egypt, a large electromagnet was brought from the ophthalmology department for repair. The magnet was used to remove ferrous particles from the eyes of patients. Upon examining the device, several interesting facts emerged. The device had been made for the German Army and used in World War II by the Africa Corps. It had found its way to a hospital in Cairo where it had been in use ever since. It had finally failed.

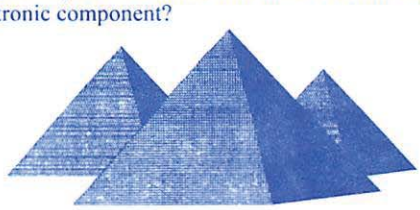
It was a simple enough device. A large transformer with a lower voltage, center tapped secondary supplied AC to a large stacked selenium rectifier for conversion to DC. The DC was then applied to a large coil with an iron core extending from the center to a rounded point that could be directed towards the patient's eye. A few sniffs revealed the faint odor of rotten eggs. This odor of hydrogen sulfide is a tell-tale sign of failed selenium rectifiers. The transformer secondary was disconnected from the rectifier The RMS voltage at the secondary leads was then measured The voltage was 80 VAC RMS from each side to the center tap. The rectifier consisted of approximately 10 square metal plates about 8 inches on a side. Round spacers and washers separated the plates. There was an electrical connection at each end of the stack and one from the center.

How to repair the magnet? With little possibility of finding a replacement selenium rectifier, we sought the characteristics of a selenium rectifier? Couldn't we simply replace it with silicon power diodes? I strongly emphasize going back to the basics when faced with a particularly difficult troubleshooting and repair task. Ponder the problem and propose possible solutions. If you can't think of at least five different ways to solve the problem, you do not understand the problem. Go back and think about the problem and its possible solutions. Presently possible solutions appeared: (1) purchase a replacement; (2) discontinue use of the electromagnet; (3) redesign the power supply using modern devices; (4) purchase a newer power supply; (5) substitute silicon diodes for the selenium diodes; (6) find a custom manufacturer who will make a new selenium stack; (7) salvage another selenium rectifier stack from old unused equipment; (8) do nothing; and (9) repair the selenium rectifier stack itself and reinstall it.

Returning to basics, the last solution works best. A selenium diode is a member of the class of devices called metal oxide rectifiers. Most metal oxide rectifiers went out of fashion when silicon diodes became available. Most metals oxidize. Oxidized iron is rust. Oxides have the property of passing electrical current easier in one direction than the other. Thus they can be used to make diodes. The forward voltage drop of a selenium diode is greater than that of silicon. The equivalent resistance of a selenium diode is also quite a bit higher than one made of silicon. This means that the V vs. I curve of the selenium diode has a lower slope than that of silicon. Also, the turn-on is not nearly as abrupt as with silicon. The reverse voltage rating of a simple selenium diode is 30 to 40 volts. Putting the diodes in series creates higher reverse ratings. They are simply stacked until a desired reverse rating is obtained. The square metal plates are for heat dissipation and their size is a good indication of the relative forward current rating for the selenium diode. Each plate is part of a single diode. From the above characteristics, substituting silicon diodes without also putting some resistance in series would probably destroy the transformer or magnet coil. The series resistors would have to be sizable power resistors and would get hot. Some kind of heat sinking would be necessary. Buying a new power supply would cost money not available and take too long.

Many would choose to simply not use the device. We chose to repair the rectifier as the quickest and least expensive solution. The repair consisted of unbolting and disassembling the stack and finding the particular diode that had failed. Students then removed that section and reassembled the stack. It was the same as before but had one fewer diode in one leg. It was reinstalled. The device was checked out and returned to service.

What was the effect of removing a single diode from the stack? It clearly reduced the reverse voltage rating of the composite diode but otherwise did not change anything. Since the stack consisted of 2 diodes to make a full wave rectifier and there were 10 plates, each diode was made up of 5 sections. This would mean that the reverse rating was at least 200 volts. The assumption that the German engineers who designed the device for the military knew what they were doing and used diodes with a large safety margin in the reverse voltage rating was thus verified. The entire process of troubleshooting and repair took about four hours. When is the last time you repaired an electronic component?



Clinical Engineering in Estonia

Siim Aid, siim@cut.ee

Editor's Note: The following article was excerpted from a message Siim Aid posted on the internet.

Up to now I have been one of the "silent listeners" on the internet in the company of colleagues. I have been satisfied with sitting in a dark corner, listening to more experienced colleagues around the table. But I must emerge from the shadows to say that I have gained more important information and information about where to get the information during the last month than I usually gain during a year. It is wonderful to feel the shoulders of friends over thousands of miles

I would like to express my gratitude to all participants: to "askers" for formulating the topics of common interest, to "answerers" for dividing their experience, thus pouring their knowledge to the vessel of our common knowledge especially Hilary - Miss BmElist - a good angel in Biomedical skies and the other creators and supporters of this wonderful idea.

I am working in Tartu University Hospital, in the small, very Nordic country of Estonia. Located under the stomach of Scandinavian "dog" or "lion" peninsula, Estonia gained independence some 5 years ago after 50 years of Soviet occupation. This obstacle is important, as it is the reason, why I and my colleagues are rather silent listeners than active conversationalists in the list.

Estonia's is rapidly replacing obsolete medical equipment with modern western technology. For the past 50 years, one centralized organization installed, serviced and maintained all medical equipment. Trained in Russian and reading manuals in this language, technicians serviced Russian-made equipment. Now, English is replacing Russian. People, good in technology, are not always good in languages. Russian-made equipment, while simple, was obsolete. Hospitals had no quality assurance and equipment maintenance programs. Presently we have technical departments in only two of more than 100 health care facilities. The employees of this previous centralized organisation are mostly employed by OEM's and independent service organisations. At the very beginning of independence our hospitals did not feel the need for such a shield against the commercial world as in-house departments usually do. Now the situation is rapidly changing. Qualified biomeds are scarce. Most are self-taught. OEM's training centers, test equipment, instruments, and services from western countries are too expensive for our hospitals.

I entered the biomedical engineering field on 1975, after studying from physics in Tartu University. The first thing I maintained was the angiographic laboratory of Siemens, the first specialized angiography in Estonia and the first Western made major installation. After that I went through a wide span of different "the firsts in Estonia" - patient monitor, functional diagnostic complex,barotherapeutic equipment, ultrasound scanner, CT scanner. Since Russian medical technology is 10 to 15 years behind the West, "the firsts" were West-made. "The firsts" appeared at University Hospital. I was about the only biomedical engineer who could read and understand the manuals, written in English or German. As the situation is rapidly changing, I am glad to loose this strange "monopoly".

As an employee of the above mentioned centralized organization, I serviced a wide range of different Russian and Eastern European-made x-ray and electromedical equipment. Now my main concern is a CT scanner, donated as humanitarian aid to Estonia, brought from USA. Other objects of my concern are donated devices whose service is severely hampered by the lack of maintenance documentation.

I advise our Health Care Ministry on technology. This voluntary duty is time consuming. The transition to western technology is made complicated by the limited budget, lack of qualified technical personnel and lack of a regulatory and legislative foundation. I am creating a modern quality assurance system for hospitals, creating a training center for medical equipment at Tartu University, supporting in every way possible the collection and dissemination of biomedical engineering information, and promoting the idea of hospital-based technical support of the medical staff.

I am especially thankful for information received on test procedures, test equipment, spare parts, medical equipment standards, and textbooks on management, finance and clinical technology.

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Clinical Engineering in Bulgaria

I. Daskalov and I. Dotsinsky

Biomedical and clinical engineering are established professions in Bulgaria with a long tradition. Ancestors of both professions were the engineers who introduced x-ray and electrical therapy instrumentation the country prior to World War II. They established services and maintenance units and were representatives of foreign manufacturers. Around 1956, local production of electrotherapy instrumentation was started. Several years later an Institute of Medical Engineering was established, with the task of development and production control of medical instrumentation. A research and clinical engineering unit was created also within the former Medical Academy, today Medical University.

Presently, about 800 engineers and technicians in the field of clinical engineering practice within separate service units in large hospitals and as representatives of foreign manufacturers.

Biomedical and clinical engineering education began in 1974 as a specialization within electronic engineering. With support from the European Community (EC) supported TEMPUS project, graduates in medical electronics now number about 45 yearly. Close collaboration of the Faculty of Electronic Engineering and Technology and the Centre of Biomedical Engineering of the Bulgarian Academy of Sciences foster educational and research activities with jointly supervised Doctoral. and Diploma theses and common projects. Links with several industrial groups are maintained. TEMPUS enabled about 10 Bulgarian students to attend an international postgraduate biomedical engineering course at the University of Patras (Greece). Bulgarian professors share teaching responsibilities. An international postgraduate curriculum in Medical Radiation Physics supported by TEMPUS was initiated in 1995. In collaboration with local specialists, an Inter-University Centre for Education and Training in Medical Physics and Engineering established in Plovdiv.

Some clinical engineers take part in the activities of the National Society of Biomedical Physics and Engineering which was founded in 1971. The Society is a collective member of the European Organization of Medical Physics (EOMP) and the International Federation of Medical and Biological Engineering (IFMBE). Good contacts are maintained with these two organizations, as well as with the International Organization of Medical Physics (IOMP). IOMP and IEEE EMBS have donated many books and journal issues to the Society. Holdings are kept in the University Hospital "Queen Joanna" and in the Centre of Biomedical Engineering. The Society maintains good contacts with organizations in Germany, Czech Republic, Poland, Hungary, Greece, and Turkey. Presently about 60 members participate in the two sections of Biomedical Physics and Biomedical Engineering.

Society activities include national conferences, distribution of information on scientific conferences and symposia abroad, revisions of new books, approbation of dissertations or publications, celebration of anniversaries of important scientific events, participation in the education and especially postgraduate training of Medical Physicists and Engineers in Bulgaria and abroad, consultation to the Ministry of Health and other government agencies on acquisition of special instrumentation and organization and distribution of clinical physics and engineering services.

The political changes in Central and Eastern Europe have affected the status and activities of clinical engineers and medical physicists. Hospital services, acquisition of modern equipment and instrumentation, and local production have declined. Young specialists emigrate to developed countries. Severe financial difficulties prevent participation in congresses, conferences, and symposia within the country and especially abroad and impede the organization of postgraduate courses and special meetings. The extremely bad conditions of health care organizations deter young engineers from the profession. Fortunately, in the past several years international relations spurred mainly by the actions and financial help of international organizations have improved. In spite of emigration and Bulgaria's economic problems, we are optimistic for a better future, this optimism rooted in the considerable scientific and technological experience and competence of our engineers.

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ACCE News

ACCE Aids Carelift

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This past spring, ACCE members joined Carelift International in two separate missions to assist in that humanitarian organization's goal of providing appropriate technology and training to hospitals and clinics in developing countries. In April, I joined a team comprising the Executive Director of Carelift and two other consultants, a physician and a radiological engineer, in a two-week visit to the central Asian country of Kazakhstan. One purpose of the visit was to identify local independent and hospital-based service organizations and to evaluate their capability to adequately support the quantities of medical equipment donated by Carelift International.

Levenson files his report

Carelift, working with the Soros Foundation in Kazakhstan, has been charged with the responsibility of helping the Kazakh people to establish service and training centers that will ultimately become self-sustaining, for-profit entities. These centers, whose primary task will be to support the myriad devices received in donation or purchased new. Carelift will help with primary and specialized training of trainers both on-site and at selected hospitals in the U.S.

The team visited three cities in search of potential sites: Almaty, the capital (formally Alma Ata), Akmola in the north and Chimkent in the south. Typical of many former-Soviet countries, clinical engineering activities in Kazakhstan are generally poorly supported but, nevertheless, represent an admixture of hospital-based and independent service companies. Most are derived from the former Soviet Medteknika organization (then responsible for procuring and maintaining the medical instrumentation for all healthcare institutions). Many hospitals and independent service organizations were evaluated and several possible collaborative sites were identified. The site(s) ultimately selected will be made by the Soros Foundation Organization in Kazakhstan with Carelift's guidance and recommendations.

A wide spectrum of capabilities and talents was observed among the engineers and technicians throughout the visit. Some were trained in St. Petersburg, Russia in that country's preeminent institutions for medical instrumentation and research, while many more had been trained at various institutions in Kazakhstan and other schools in the Newly Independent States (NIS). Sadly, the level of test equipment available to most facilities would not easily facilitate the troubleshooting and repair of solid state semiconductor technology.

Later, in June, another group from Carelift International was joined by ACCE member Elliot Sloane of Mediq PRN on a visit to the Eastern European countries of Moldova and Bulgaria. Moldova is the site of a successful technical training center that was established by Carelift International more than two years ago. At that time, Sloane was part of the team that selected the Moldavan training site and has since been involved in an ongoing evaluation process to ensure that the center is meeting its objectives. In Bulgaria, Sloane and his traveling companions visited several hospitals in the city of Sofia, again, with the objective of finding a suitable training site. Impressed by the significant talents and skills of the Bulgarian engineers and technicians, Sloane saw great potential for a service and training center despite the poor economic conditions in Bulgaria.

Carelift International's commitment to the medical communities in developing countries has been made possible, in great part, by the generous funding of The Soros Foundation. The Foundation exists to help former Soviet states develop free market economies by funding basic and advanced training programs designed to provide understanding and skills in economics, technology and international relations.

ACCE Guidelines for Donation

Used medical devices have been donated from developed countries to less developed ones for decades. This recycling of goods accomplishes several important objectives. In developed countries, it helps to reduce waste and landfills, as well as increase the rate of introduction of new technologies. In developing countries, physicians gain quicker access to sophisticated technologies and, most important of all, less privileged patients gain wider access to better care.

Unfortunately, not all donations achieve their goals. Often, donated equipment is not or cannot be used by the recipients. Reliable data is not yet available, but it is believed that as much as one third of all donations do not achieve their eventual goals, wasting precious time and resources. Many factors contribute to this reality. Some donors are so anxious to get rid of their unwanted hardware , they pay little attention to the equipment's condition, availability of parts, documentation, supplies, and operator training in the recipient country. Some international relief organizations are forced to concentrate on the volume rather than the quality of donated goods in order to gain publicity and please corporate donors. On the other side, many recipients do not screen carefully what they ask for nor invest enough time and resources to plan and support what they get. Sometimes they are spoiled by the notion that they can always ask for another one and discard what they do not want or failed to maintain. Finally, the lack of communication between the donor and recipients before the shipment of goods is probably the single most important reason many donations did not work out well.

The American College of Clinical Engineering has addressed these problems and has developed a solution. A committee composed of ACCE members with significant international experience, generated a document entitled *Guidelines for Medical Device Equipment Donation.*

ACCE *Guidelines* help Friend Ship

The objective of the *Guidelines* is to improve the effectiveness of efforts to donate medical devices to developing countries. Through the promulgation of the *Guidelines* it is anticipated that those organizations engaged in the donation of medical devices will achieve the following:

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Clinical Engineering Profiles

Tom Judd

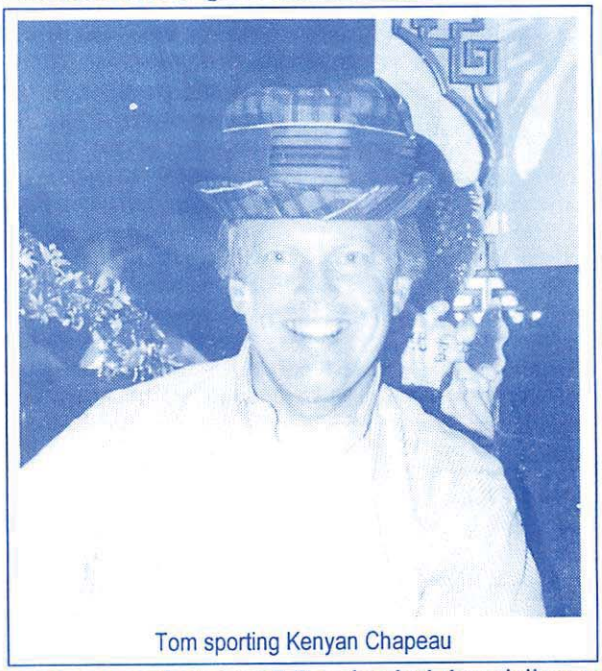
Tom has been blessed by the Creator, the First Engineer. With blessing comes responsibility. Fortunately, this is not a burden when the Creator owns the results. With family responsibility come purpose; and with purpose comes hope.

Tom and Ann celebrated 25 years of marriage in June. He was born in Sacramento, CA but raised in Richmond, VA. Visions during high school about pre-medicine quickly turned to airplanes after a late-hour appointment to the Naval Academy. After graduation in 1972, he and his Alabama-bred wife headed for Monterey, CA and grad school in aero engineering. Navy jet training and wings came next, but also internal wrestling with an assignment to drop nuclear weapons. The wrestling ended when vision problems were discovered in night bombing training; the change bringing Tom back to the Naval Academy to teach with a sense of peace about the Creator being in control. Two sons were born in Annapolis, a tremendous joy. Today, Ryan is a senior at Vanderbilt and Nathan a sophomore at Furman University; their dad enjoys giving them "basketball lessons" when they are home. Ann brings stability to this group when not teaching English as a second language.

The return to the Academy to teach electrical engineering marked a change in focus back to medicine, coupled with a desire to repay our country's investment in him in some other way. Three years of studying BME at Johns Hopkins preceded leaving the Navy in 1979, at which time getting a real job in the emerging field of clinical engineering was a natural next step. CE experiences followed at Johns Hopkins, Baptist Medical Center, and a CE-Tech shared services in Jacksonville. Innovative service management of medical imaging and clinical labs led to work with the fledgling CE group for Hospital Corporation of America (HCA) in 1988. Two years later, he was managing CE for 21 hospitals in 7 states. Choosing not to be promoted and move to Nashville led to an exciting 2 years as a CE consultant, first with HCA (strategic technology planning emphasis) and then with military healthcare in Washington, DC. This time with the military was also a joy, getting to work with so many fine CE colleagues and to finally feel a sense of repayment for the government's earlier investment. In DC, he co-authored *Medical Technology Management* with good friend Yadin David at the urging of SpaceLabs' Wayne Morse.

Never having been in a hurry to grow up, it was natural for Tom and Ann to work with high school kids at church shortly after marriage. Kids ask such tough questions and need real answers about life. They also need adults to walk alongside them through the difficult years. It turns out the Creator has those answers and walks with us, as well. Tom has had the opportunity to participate in these lessons about life with kids and families from the inner city to countries around the world. Professional and "these home life activities" began to intertwine soon enough. Tom helped launch CE professional societies, locally in 1980, state-wide in Florida in 1985, and ACCE in 1990. He obtained a PE in 1980, a CCE in 1984, and then chaired the US CE Board of Examiners. While Chair, Tom learned of the World Health Organization's 1986 report of CE in developing countries. With colleagues he determined to see how U.S. CE's could learn from and assist international CE friends. Ten years later and after a bunch of certification, workshop, and other neat stuff (thanks mostly to ACCE), Tom has grown closer to many U.S. colleagues involved in this work as well as CE's from 50 countries. Together, they have seen the tide of worldwide CE professionalism and healthcare improving. Of course, it has a long way to go but we are privileged to be among those who can help find real solutions.

Tom says, "What really turns me on is helping people discover how to use their Creator-given talents in different kinds of venues, way beyond our comfort zones." Tom has had the privilege to work since 1992 in Soviet Central Asia with a healthcare team from the U.S. that is assisting the Minister of Health solve maternal and child health problems as well as to make progress with economic development issues. There has been a tremendous sense of purpose in this work and evidence of impact.



Tom sporting Kenyan Chapeau

The return to Atlanta in 1992 marked a time of reengineering his CE's career. TQM/CQI principles and facilitation interest had been nurtured during the time with HCA and military healthcare; U.S. healthcare was ripe for the proper application of this stuff in the context of society getting better clinical outcomes for their healthcare investment dollar. Technology in healthcare began to be understood as the combination of devices, drugs, and medical procedures that in some optimal combination could be used to heal someone. All of our CE training and experience could be used in helping whatever healthcare organization we choose to hang out with to find Deming's "right people to do the right things to get the right results." For Tom, this turned out to be Kaiser Permanente in Atlanta. As Director of Quality, he is improving the care for a population of nearly a quarter million metro residents. "What do I want to do when I grow up? I think that Ann and I, in the not too distant future, will be involved internationally in teaching and facilitation in healthcare and business, assisting other folks to make the most of their Creator-given resources. It turns out that this gives people hope."

ACCE Guidelines *(continued from page 8)*

- identification of standards of quality
- acceptance of established standards
- increased collaboration with other organizations donating medical devices
- enhanced medical device utilization through improved education and communication

The *Guidelines* are directed to both suppliers and recipients of donated medical devices. The first section details the suppliers' responsibilities and the second section details the recipients'. The Guidelines can be obtained by contacting Morse Medical, Inc. at morsemed@wolfenet.com.

Brazil *(continued from page 4)*

Clinical engineering in Brazil still has a long way to go, however. Some of the barriers to overcome include small numbers of clinical engineering departments, low salaries, lack of certification laboratories, lack of medical equipment standards, lack of medical device incident and accident control and reporting systems, scarcity of clinical engineering information, and paucity of literature adapted for the Brazilian reality. Nevertheless, if somebody had declared 6 years ago that clinical engineering would be at the stage it is today he would have been labeled a mad optimistic visionary. Perhaps, this was how the members of the PROEQUIPO team were known when it all began.

Editor's Note: Saide Jorge Calil is a teacher at the Universidade Estadual de Campinas UNICAMP. He has worked in clinical engineering since 1987 and has served as adviser to the Brazilian Ministry of Health since 1990. He was part of the group that proposed the curriculum of the specialization course for clinical engineering in Brazil.

FDA Assures House *(continued from page 13)*

proper operation and, further, may use the two-digit year format. Such products might be affected by the "Year 2000" date change. An example of non-embedded software is a computer program used to plan radiation therapy treatments delivered using radioactive isotopes as the radiation source (teletherapy or brachytherapy). These treatments possibly could be affected if the computer program used to calculate the radiation dose parameters uses only a two-digit year representation. The calculation of the length of time since the source was last calibrated could be in error and thus lead to an incorrect treatment prescription. Other examples of non-embedded software devices include: conversion of pacemaker telemetry data; conversion, transmission or storage of medical images; off-line analysis of EEG data; digital analysis and graphical presentation of EEG data; calculation of rate response for a cardiac pacemaker; perfusion calculations for cardiopulmonary bypass; and calculation of bone fracture risk from bone densitometry data. While there is a chance that the two-digit format may affect the performance of these software devices, we believe that the "Year 2000" risk will be mitigated through proactively working with manufacturers.

In light of our review of the impact of the "Year 2000" on some medical device computer systems and software applications, CDRH is preparing to send a letter to all medical device manufacturers to ensure that manufacturers address this issue and review both embedded and non-embedded software products. We will remind manufacturers that, in addition to potentially affecting the functioning of some devices, the two-digit year format also could affect computer-controlled design, production or quality control processes. We will request that the manufacturers review the software used to determine if there is any risk.

CDRH will recommend specific actions to ensure the continued safety and effectiveness of these devices. For currently manufactured medical devices, manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the "Year 2000" date change. If these analyses show that device safety or effectiveness could be affected, then appropriate steps should be taken to correct current production and to assist customers who have purchased such devices. For computer-controlled design, production and quality control processes, manufacturers should assure that two-digit date formats or computations do not cause problems beginning January 1, 2000.

In our letter to industry, we will remind manufacturers that under the GMP regulation and the current Quality System Regulation (which became effective June 1, and incorporates a set of checks and balances in manufacturers' design processes to assure a safe, effective finished product), they must investigate and correct problems with medical devices that present a significant risk to public health. This includes devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. As a result of our letter, we expect manufacturers who identify products which have a date-related problem which can pose a significant risk to the patient to take the necessary action to remedy the problem. This might include notification of device purchasers so that their device can be appropriately modified before the "Year 2000." Manufacturers who discover a significant risk presented by a date problem are required to notify CDRH and take appropriate action. Again, we do not anticipate any significant problems with individual medical devices, however, we want to ensure the continued safety and effectiveness of these devices. For future medical device premarket submissions, manufacturers of devices whose safe operation could be affected by the "Year 2000" date change will be required to demonstrate that the products can perform date recording and computations properly, i.e., "Year 2000" compliant.

MedWatch Publication Available

The Spring 1997 *FDA User Facility Reporting Bulletin* has been posted on the internet (www.fda.gov/cdrh/fusenews.html).

The issue contains articles on:
- Adverse Reactions to Natural Rubber Latex
- Natural Rubber Latex Allergy: A MedWatch Success Story
- How FDA Regulates Gloves
- FDA Scientists Study QA Tests for Latex Gloves
- FDA Clarifies Latex Terminology
- Glove Quality and Selection Criteria
- FDA Alerts Users of Reusable Medical Devices

If you would like a copy of the bulletin faxed or mailed to you please contact Gale White at 301-443-0117 or GWhite@bangate.fda.gov.

ACCE Board Highlights

August 13, 1997

Jennifer C. Ott, JCOttSLU@aol.com

President Frank Painter reported the election of Dennis Minsent and Ken Taylor (Members-at-large) and Jeff Secunda (First Vice-President). The board unanimously approved Painter's called for the development of a task force to determine how ACCE can assist the former members of the recently disbanded Society of Biomedical Engineering Technicians (SBET). Dennis Minsent (Chairman), Dave Simmons, Yadin David, Joe Dyro and Jim Wear were appointed to the task force. Painter appointed Tom Judd to work with Jeff Secunda and Brian Porras to coordinate ACCE involvement with the upcoming Medical Technology Management Conference in Orlando (November 11-12, 1997). The ACCE Board unanimously approved the plan to organize and develop the first annual ACCE Conference 1998. ACCE will submit several nominations to the FDA for membership on device evaluation panels. Painter appointed Elliot Sloane, representative to AAMI. **Second Vice-President**, Mo Kasti, continues to work with AFSMI's President in developing their Medical Services track. **Treasurer** Bryanne Patail reported a favorable balance as a result of workshops, grants, gifts and teleconference. **Secretary** Jennifer Ott will include mailing address, business phone, fax and e-mail for all members in the upcoming Directory. Ott distributed a Response Guide to streamline ACCE response to inquiries. **Advocacy Committee** Chair, Tom O'Dea submitted a draft plan of action to the Board for consideration. The **Education Committee** reported that teleconferences are on schedule. Volunteers are needed to assist Chairman Jim Wear in developing and promoting future series. The **International Committee** is negotiating with Hong Kong for an Advanced Clinical Engineering Workshop there in 1998. Dyro reported that the **Newsletter**, *ACCE News*, has been sent to members on schedule for the past year. Tom O'Dea will assist Caroline Campbell with advertising. **Membership Committee** Chairman, Bill Betts announced 19 new members this year. Many applications are under review and will be presented at the next board meeting. The Board will meet next on October 8, 1997.

Meetings

New York Metropolitan Area Clinical Engineering Directors Group

Ira Soller

The New York City Metropolitan Area Clinical Engineering Directors Group, consisting of Directors of Biomedical/Clinical Engineering Departments representing all of the major medical centers in the greater New York City area, met on 8116/97. A presentation on *Non-invasive Arterial Thermometry* and its ability to detect infections earlier was given by Francesco Pompei, President of Exergen, with the assistance of John Miller, Director of Sales. This was followed by member discussion which included upcoming JCAHO surveys, clinical engineering management under difficult economic environments, and BMET training. The meeting was hosted by ACCE member Mike Mirsky of St. Luke's Roosevelt. The next meeting will be held on Tuesday October 28, at 6 PM. For meeting information, or Manufacturers/vendors interested in making future presentations, contact Group Coordinator Ira Soller, Director of Biomedical Engineering, State University of New York, Health Science Center at Brooklyn, 450 Clarkson Ave, SMIC Box 26, Brooklyn, NY 11203, (718) 270-3192; (718) 270-3194 Fax

Thoughts on ACCE While Attending the American Association of Physicists in Medicine Annual Meeting

Tom O'Dea, odeat@msn.com

I had the opportunity to present at the annual meeting of the American Association of Physicists in Medicine (AAPM) in Milwaukee on July 27-31, 1997. While there, I was struck by both the similarities and the differences between AAPM and ACCE. I relate for your consideration thoughts in the following three areas:

Organization - Both groups seem organized similarly, with AAPM being significantly more developed in the number of members attending. There seemed to be more of a scientific flavor to the presentations and discussions Questions of organizational relationships in the health care organization arose in general, but not in specifics, in contrast to the ACCE and AAMI meetings

Attitude - The members of AAPM, who are quite active in both diagnostic and therapeutic radiology, seemed unaware that there were such people as clinical engineers. They lumped all CE functions with "service". Yet when I asked individuals if they thought that service was a proper area of AAPM activity, they said no.

Relationships - The primary success of AAPM in the health care setting seemed to be in the relationships they have established with physicians, government, and the broader physics community. The American College of Radiologists accredits physicists and they seem to have very close physician relationships both in diagnostic and therapeutic radiology. They are very active on FDA/CDRH panels and many recommendations call for accredited physicists to report on devices and procedures annually. Finally, AAPM is joined to the larger body of physicists by membership and interactions with the American Institute of Physics.

ACCE might learn from AAPM especially in the relationships area.

ACCE Teleconferences 1997

James O. Wear, wear.james@forum.va.gov

The ACCE Teleconference Series for 1997 is listed below:

Date	Topic and Speaker
October 16	Building teamwork between CE staff and maintenance staff *Tom O'Dea*
November 12	Preparation of RFPs for outsourcing clinical engineering services *Bill Betts*

ACCE News

Accident Investigations Share the Gained Knowledge

Marvin Shepherd, marvins523@aol.com

Clinical engineer, you are unique. You alone have the education and training to perform and coordinate a competent, device-related incident investigation. It is true that investigations frequently require the expertise of a variety of health care specialists such as nurses, physicians, and respiratory therapists. Support may also be drawn from mechanical engineers, electron microscopists, or industrial hygienists. However, your education in the scientific approach of analyzing an event, gathering evidence and reasoning back to a "cause" began in college Physics 101. Combining depth and breadth of knowledge of medical device performance and safety with experience in investigative techniques, an individual emerges more capable than any other to perform incident/accident investigations.

Many CEs perform investigations. Unfortunately, they rarely publish the circumstances surrounding an event, their conclusions regarding the event, nor their recommendations for preventing future events. This gained knowledge may be shared by a few close to the event, but is lost to the other practicing CEs who could prevent such an event in their own facilities. This is incompatible with one of ACCE's goals to "...promote the safe and effective application of science and technology to patient care." Device-related investigations place the CE directly in the clinical arena in the extremely important role of identifying device-associated risks and in enhancing patient safety by making recommendations that can reduce future risks.

Over the past five years, I have investigated an average of 10 device-related accidents a year. It has been a rare investigation in which I haven't learned something new. I share some of these events so that others might benefit from my own experiences. I encourage others to share their experiences. In so doing, clinical engineers, exercising their unique talents, will enhance patient safety. In sharing, include (1) event description; (2) event findings; (3) identification of cause, and (4) recommendations to prevent recurrence. Obviously no names, location of the health care facility, or other personal information is necessary nor desirable. As a template, consider the following event which occurred about a year ago in an acute care hospital.

Description of the event ➡ An adult female in the end stages of cancer entered an emergency room (ER). A registry nurse connected the patient to several devices including a cardiac monitor. The patient was monitored visually over a period of about 1 1/2 hours. The last time the nurse entered the room the patient was dead and no rate alarms had sounded.

Event findings ➡ The cardiac monitor was tested and found to meet the manufacturer's performance and safety requirements. The cardiac monitors were about 10 years old and required that a specific button be pressed to activate the heart rate default alarms. The registry nurse said that she thought that the monitor default rate alarms activated when the monitor was powered "on." On the surface, this would appear to end the investigation. However, several other facts emerged affecting the recommendations for preventing future events.

Of four nurses interviewed in the ER, two said that the default alarms of the monitors were automatically set when the monitor was powered "on" and two said that they knew that an additional button had to be pressed. One of the two that said that the default alarms came on automatically volunteered to demonstrate the fact. She connected electrodes to herself and connected the EKG cable to the monitor. Without pressing any other buttons, she waited until her EKG was visible. Once her EKG was visible, she removed one of the leads from the electrode and the alarm sounded----the leads "off" alarm. She mistook this alarm for the heart rate alarm. nurses in the ICU (several floors away) were also interviewed regarding default heart rate alarms. In the ICU, the cardiac monitors were new and default alarms were established when the monitor was powered "on." Several were not aware that the default alarms activated automatically on the ICU monitors. Since some of the ICU nurses "float" to the ER, this could present a similar problem.

One other fact that emerged from this investigation was that the computer clock was set one hour behind the actual time. This resulted in EKG recordings being improperly time-stamped and possibly date- stamped depending on the time of day.

Causes(s) ➡ The failure of the ER monitor to alarm was caused by operator error. The registry nurse thought that the default alarms would activate when power was applied to the monitor.

Recommendations ➡

1. Because the hospital had monitors some of which did and some of which didn't activate heart rate alarms automatically, those that did not activate automatically should be placarded to remind operators to activate the alarms. In addition, a note should be added to the operator manual explaining the need for an additional step to activate alarms.
2. In-service education should include the method for setting heart rate alarms and instructions that some monitors must be set while others are set automatically when they are powered "on." All device operators should be aware of this including regular ER staff, registry nurses and ICU-CCU nurses.
3. A person responsible for setting all of the date/time clocks on monitors, defibrillators and other devices, be it nurse or biomedical technician, should be identified. Resetting the clocks twice/year is required because of daylight savings time.
4. Older monitors should be phased out over time.

Berkovitz Solves Mystery

A six-pack of the world's only clinically engineered beer goes to Bob Berkovitz for successfully solving Bob Morris' puzzler *How Well Do You Know Electronics*? posed in the May issue of the *News*. Berkovitz is a student of Joe Dyro in Touro College's Clinical Engineering program. The beer is donated by Steve Friedman and Marv Shepherd who brew their unique suds in California (see story in last issue of *ACCE News*). Congratulations, Bob.

The view from the Penalty Box

Dave Harrington, davesbt@kersur.net

For anyone who has ever played ice hockey you know that the penalty box is a great place to observe the game and take in all the action. At recent meetings and conventions it was very easy to determine from whence clinical engineers come just by their conversations. Those from the U.S. were talking about managing contracts for the repair services of their equipment and were comparing notes on the outside research they on new equipment purchases. Those from outside the U.S. were talking about problems with their technology and how they were handling them. They were also discussing new applications for existing technology and the new equipment just coming onto the market.

The U.S. clinical engineers were more concerned about the new software programs that would produce more reports, track the activity of contracts and justify the outsourcing of the work. The international clinical engineers were concerned about spare parts, down time, training, and day-to-day operations.

From the penalty box is was very difficult to see which group was most in tune with the future of clinical engineering. Going out and visiting some of the locations it became clear, at least to me, that major changes are close at hand in our profession. Hospital administrators and health insurance companies are talking about equipment utilization, upgrading existing technology, without replacing it,. better utilization of existing resources and less on cost savings of contract management.

Which way are headed? Are our international colleagues pointing the way or are we? Only time will tell.

Web Trappings

B. J. Morgan, Webmaster, jmorgan@ibm.net

The ACCE web site is gaining interest as demonstrated by the increased number of visitors. In particular, the Message Center appears to be generating increased appeal, although it still falls far short of its potential as a communications medium for the clinical engineering community. Some of you may have noticed that the Message Center was down for a few days at the end of August. The System Administrator accidentally broke it and fixed it as soon as I brought it to his attention. Please continue to send me e-mail messages if there are any problems on the web site that I have not caught.

A suggestion was made to add a listserv to the ACCE internet presence so that members could automatically receive, in their e-mail, messages posted on a particular topic without having to log onto the ACCE web site and check the Message Center. This idea certainly has merit, although it is not necessary to run a separate listserv. To receive notification and text of all new Message Center messages click on the "Subscribe" link at the top of the Message Center page or simply scroll to the bottom of the page and fill in e-mail address in the Subscribe section. Removal from the list is just as easy.

Remember, the ACCE web site is a service for ACCE members. Comments and suggestions are welcome. Also, since the web site maintenance is a solitary effort, and prone to error, I appreciate being notified of any errors or corrections. Please contact me at.

FDA Assures House on Year 2000

In a June 26, 1997 statement before the House Subcommittee on Oversight and Investigations of the Committee on Veterans' Affairs, Acting Director of the FDA's Division of Electronics and Computer Science, Dr. Thomas Shope addressed the agency's approach to the Year 2000 issue. The following is excerpted from his report:

Any computer software that meets the legal definition of a medical device is subject to applicable FDA medical device regulations. Medical devices which use computers or software can take several forms including: embedded microchips which are part of, or components of, devices; or non-embedded software used with, or to control, devices or record data from devices; or individual software programs which use or process patient data to reach a diagnosis, aid in therapy or track donors and products. An issue that has been identified as warranting review is the impact of the "Year 2000" on some medical device computer systems and software applications. These products could be impacted by the "Year 2000" date problem only if they use a date in their algorithm or calculations, or in record keeping; and a two-digit year format was used in their design. Manufacturers of such products are the only reliable source of information as to the details of the methods used in the programming and whether these two conditions are met. While we are in the process of reviewing this issue, we do not currently believe that there will be any major impact on medical device safety.

Computer software frequently is embedded as a "component" of devices, i.e., software contained on a microchip to control device operation. Examples of such devices are: pacemakers, infusion pumps, ventilators, and many others. It is unlikely that most of these products would be impacted by the "Year 2000" problem. Almost none of these devices require knowledge of the current date to operate safely and effectively. For example, pacemakers do not use the current date in their operation.

Non-embedded software is intended to be operated on a separate computer, often a personal computer or work station. Such software devices may be used to enhance the operation of another device or devices and, further, may use the two-digit year format. It is possible that non-embedded software devices may rely on the current date for

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ACCE News
21 Bob's Lane Setauket, NY 11733

Calendar of Events

- First International Conference on Ethical Issues in Biomedical Engineering, Sept. 28-29, 1997, Clemson, SC. (864)656-7603; -4466fax; subrata.saha@ces.clemson.edu.
- IEEE/EMBS Society 19th Annual International Conference, October 30 - Nov. 2, 1997. Chicago, IL. (714)752-8205; -7444 fax; MeetingMgt@aol.com.
- International Scientific Meeting on Electromagnetics in Medicine, Nov. 3-5, 1997, Chicago, IL. Sponsored by URSI and IEEE. Information: http://www.eecs.uic.edu/~emmed.
- 17th Annual NorthEastern Biomedical Symposium, Nov. 3-5, 1997, Sturbridge, MA. NESCE, c/o David Riehl, 50 Ridgefield Ave., Bridgeport, CT 06610. dreihl@novamedcorp.com; 203-384-3037.
- Advanced Clinical Engineering Workshop, Orlando, FL. Nov. 11-12, 1997. (312)422-3807; -4571 fax.
- ASHE/ACCE Medical Technology Management Conference, Nov. 11-15, 1997. Orlando, FL. (312)422-3807; -4571 fax.
- American Society for Healthcare Engineering: 12th National Conference, Dec. 2-5, 1997, Chicago, IL. Contact: Patti Costello, One North Franklin, Chicago, IL 60606. Tel: 312-422-3807, fax: 312-422-4571.
- IEEE Engineering in Medicine and Biology Society,Information Technology Applications in Biomedicine (ITAB '98), A 'Special-Topic' Conference of the EMB Society, Washington DC, May 16-17, 1998, Swamy Laxminarayan 609-419-0531, Ext: 203, 609-419-0530 fax, e-mail: swamy@nextgeninter.net
- ACCE Clinical Engineering Conference, May 30, 1998, Plymouth Meeting, PA.