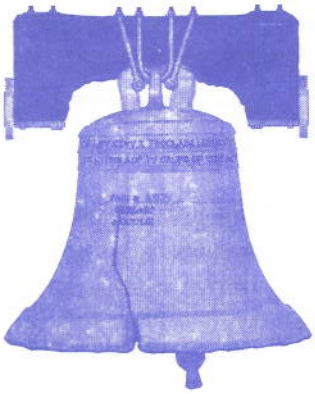
ACCE News

Vol. 8, No. 1 - January 1998

American College of Clinical Engineering



Philadelphia - Site of First ACCE Symposium

Mark your calendars now. May 30, 1998 is the date of the First ACCE Symposium devoted exclusively to the needs and concerns of our members. Be part of the brainstorming to develop effective strategies to excel in today's competitive environment. Engage fellow members in a think tank environment to create position statements on rightsourcing and future directions for clinical engineers. See page 16 to register.

URGENT: Input Needed on FDA Plans to Regulate Servicers of Devices

Recent rumblings from Washington gravely concern clinical engineers. See in depth analysis by Dr. Binseng Wang in this issue of the *News*, page 6. Wang heads ACCE effort to respond to Feds.

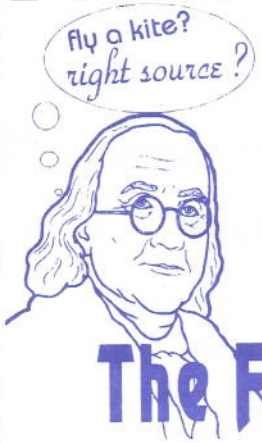
Shepherd Issues SMDA Tracking Alert

Marv Shepherd alerts clinical engineers to significant changes in Safe Medical Device Act (SMDA) tracking and reporting regulations. See inside *ACCE News* page 10 for details.

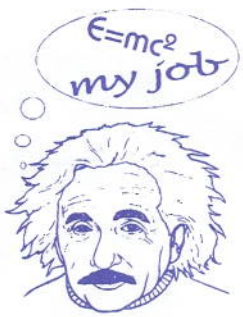
National Engineers Week

February 22-28, 1998 is National Engineers Week. Clinical engineering departments from coast to coast use this week as a way to heighten awareness of the critical role clinical engineers play in health care. For full details look to the internet at www.eweek.org.

First ACCE Symposium



Today's leaders in clinical engineering point the way to



The Future of Clinical Engineering

Saturday, May 30, 1998 Thomas Jefferson University Philadelphia

contact Jennifer Ott ottj@slucare1.sluh.edu 314-577-8018; 314-268-5178 fax
registration: Bryanne Patail bpatail.bio_med@beaumont.edu 248-551-0550

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

Frank R. Painter, frpainter@aol.com

In my part of the world, the last month of the year is marked by cold, dark days. My spirits, however, couldn't be higher. I just reviewed what 1997 brought ACCE: many new members, a successful Annual Meeting, plans for the First ACCE Symposium, plans for an Advanced Clinical Engineering Workshop, a solid financial picture, six well-written, timely newsletter issues, and a partridge in a pear tree.

Let's keep up the momentum. Make a New Year's resolution. ake one small step that will have a significant impact on the success f ACCE as an organization that benefits both you and the profession of clinical engineering. **Give a membership application to a colleague.** Explain the benefits of membership. It takes people to make an organization. If we all expend this small amount of effort, our membership will increase. We will be an even more powerful advocacy group for clinical engineering.

Mark your calendars now for clinical engineering brainstorming at its best, the First ACCE Symposium, to be held May 30, 1998, at Thomas Jefferson University in Philadelphia. See you all there.

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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My View of Year 2000

John Storch

ACCE News was among the first to alert the medical device community about the impending dangers of software disasters with the arrival of year 2000, **Future Shock - Millennium Clock Kills Medical Devices** (*ACCE News*, May 1997). Since then other articles have appeared, e.g., **FDA Assures House on Year 2000** (*ACCE News*, September 1997) and **Medical Devices and the Year 2000 Problem** (*Health Devices*, December 1997). I wish to share with readers of *ACCE News* several observations based upon personal experience as a medical device user as well as several years of software testing experience for a medical device manufacturer.

Some authors suggest that when contacting suppliers hospitals should request an exact description of (1) the method used to achieve compliance, (2) the testing process, and (3) the findings from the supplier's tests. This may not be a reasonable request. The procedures for software hazard analysis, verification and validation, and even clinical trials can be very lengthy documents. Each set of documents is unique to a specific model and software revision. Generally, only the FDA is interested in reviewing them prior to approval of a new or revised product for the marketplace. Even if a manufacturer is willing to share these documents, its collection may prove to be only another burden for the hospital without any real added benefit. In some cases, one just needs to know if the device is Year 2000 compliant or not, unless one plans on second guessing the FDA on whether or not a manufacturer's testing protocol is adequate.

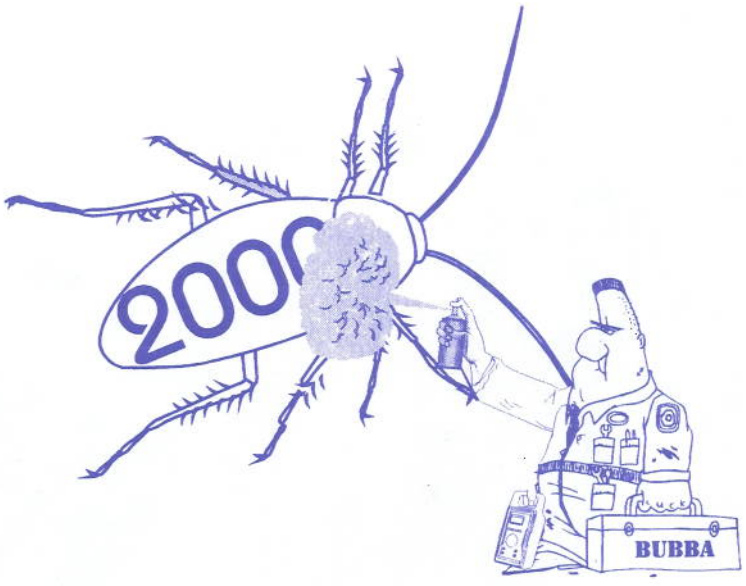
It has been suggested, should a response fail to come from a manufacturer, that a hospital itself may test the equipment. Extreme caution must be taken. Even ECRI states that its recommended testing is cursory and will detect only obvious problems. Software verification and validation, when done by the manufacturer, takes into account numerous interactions and may take days to perform. While *ad hoc* testing may give the impression that a particular device is safe to use, it is possible that a failure may still occur in a certain configuration or mode of operation, under specific patient conditions, with certain accessories attached, or any combination of these or other factors. Whenever possible, do not rely on *ad hoc* testing to give you your only sense of security.

ECRI has stated that a *"hospital should demand that the supplier remedy all Year 2000 problems."* Only the FDA can demand such a thing. Fortunately, FDA has already sent out a letter to manufacturers reminding them of their responsibilities under the law (See *ACCE News*, November 1997). However, you may still need to be somewhat flexible when requesting a manufacturer to respond by a certain date in your compliance letter. A hospital should not be so uncompromising and coldly look at the situation as "me against them." You must realize that each manufacturer must come up with a response for all of its customers and all of its product lines. Manufacturers will determine their own time line and prioritization for testing and resolution.

Pressing to have remedies implemented without charge may not be reasonable. Software changes involve a great cost for a manufacturer. The time spent in software development and testing, documentation for regulatory affairs, the production, distribution, and installation of software or firmware, and revenues lost due to delays in getting other product lines to market on schedule while addressing the Year 2000 problem all have an impact on the bottom line. For a company to simply write off a software upgrade to potentially thousands or tens of thousands of devices could cause a financial burden beyond its resources. Even the FDA letter to manufacturers does not specify change without charge. It simply states that the manufacturer must *"assist the device user in obtaining a remedy."* I have found that many of the companies that are currently non-compliant, but have fixes available, are offering them to their customers at a cost.

Finally, you must be cautious when trying to press a manufacturer for a free remedy. Can you realistically use the threat of going to a competitor's product? Do you have the freedom to go to another manufacturer? Are you not tied down by a purchasing group? Do you have the time for product evaluations, an installation, and user training? Most importantly, is there money in the budget? Before telling a manufacturer that you will begin contacting other suppliers for a replacement, make sure that you can answer all of the above questions in the affirmative.

Just because I am a medical device user, I cannot turn a blind eye to the realities facing the manufacturers and suppliers. Having worked on both sides of the fence, I can see the concerns of the device users, but I also have an understanding of the issues affecting the manufacturers. In addressing the Y2K problem, we need to work together toward a reasonable solution which will satisfy both parties in a timely fashion.



Bubba Battles Millennium Bug

Meetings

Brazil Forum Highlights Clinical Engineering

Lúcio Flavio de Magalhaes Brito
engenhariaclinica@nutecnet.com.br

The purpose of this message is to inform you of the efforts and success of Brazilian clinical engineering toward making clinical engineering one more profession involved in the delivery of health care in the future. We are working hard to improve clinical engineering in Brazil. We organized *Forum Internacional de Tecnologia em Saúde*, First International Forum on Health Technology, which took place in Sáo Paulo, Brazil, last November. This is the fourth and largest meeting we organized since we began promoting clinical engineering in my country several years ago. We owe much to the first ACCE Advanced Clinical Engineering Workshop (ACEW), which I attended in Washington, DC in 1991.

The purpose of the meeting was to introduce technology assessment concepts to health care professionals and to teach them how to use these concepts in practical areas. The Forum featured invited speakers from the United States, Drs. Seymour Perry, Yadin David and Binseng Wang. Many Brazilian clinical engineers and other health care professionals made presentations. A total of 218 participated in the Forum. I am pleased to report that the effort was successful in attracting a diverse group of healthcare workers. The distribution of attendees follows: system analysts (2), nurses (54), engineers (98), students (3), physicians (17), technicians (12), and others (32). To me, an important observation is that nurses and physicians represent 32% of the participants. I believe that the concept of clinical engineering is being accepted by health care professionals. The Exhibition attracted 10 medical device manufacturers and health product sales representatives. The number of exhibitors continues to increase with each meeting held.

Binseng Wang distributed the November 1997 issue of *ACCE News* to the clinical engineers in attendance. Wang, ACCE Board Member-at-Large and former ACCE Membership Committee Chairman, presented the benefits of ACCE membership to those attending the Forum. I look to an increase in the number of Brazilian members of ACCE.

During the time of the Forum, the newly constituted Brazilian Board of Examiners for Clinical Engineering of the International Certification Commission, administered its first exam to eight candidates.

Organizing conferences such as these is hard work, but after it is all done I believe that it is worth the effort. I hope that all my fellow ACCE Members are as happy as I am with the news of the success in the development of clinical engineering in Brazil.

New York Metropolitan Area Clinical Engineering Directors

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 October 28 and on December 16, 1997. In October a presentation was given by Jim Smith, President of EQ2 of Vermont. This was followed by member discussion which included JCAHO surveys including performance standards, hospital mergers and downsizing, and the upcoming anesthesiology post-graduate assembly (PGA). In December, Louis Costa, Senior Applications Engineer of Link Tech spoke on *The new healthcare standard IEEE 1073 Medical Information Bus (MIB).* Member discussion followed centered upon clinical engineering parameters which must be tracked for JCAHO, equipment which can be excluded from PM programs, and the inherent dangers of testing equipment attached to patients. Both meetings were hosted by ACCE member Mike Mirsky of St. Luke's Roosevelt. The next meeting will be held on February 3, 1998 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

People on the Move and in the News

Dickey Heads New Venture

Dave Dickey has formed left Fisher Consulting Services to start his own consulting company: Medical Technology Management. He is the President and CEO.

David M. Dickey

Morris Honored

The Dean of the School of Medicine at Oregon Health Sciences University has honored ACCE Founding Member, Bob

Robert L. Morris

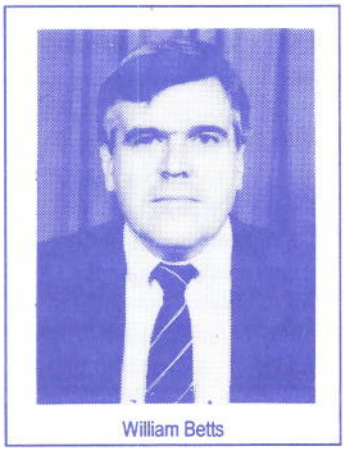
Morris, PE, CCE with an appointment as Emeritus Assistant Professor of Pathology. The honor is for his contributions to the education, research and patient care mission of the Oregon Health Sciences University and School of Medicine over the past 35 years. For more information about Bob, see **Profiles in Clinical Engineering** in this issue of *ACCE News*.

Hertzler Moves Up

Larry will join Dave Dickey at MTM next month as the Chief Operating Officer. Larry resigned from BJC Hospital System and is quite excited about the change.

Betts to Chair AAMI Board

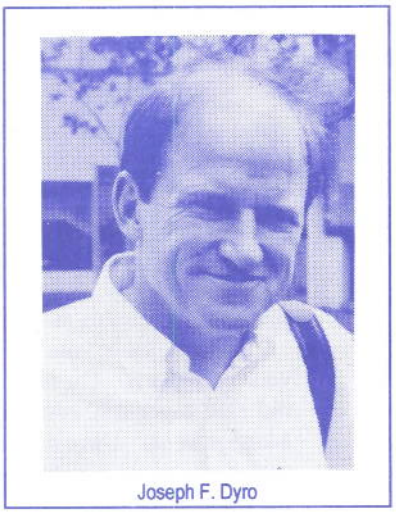
Bill Betts has been nominated Chair-Elect of the Association for the Advancement of Medical Instrumentation (AAMI). Bill looks forward to working with the ACCE leadership in his future role as AAMI Board Chair-Elect in 1998 and Chair in 2000. He anticipates building bridges between ACCE and AAMI that would be to the benefit of both organizations.



William Betts

Dyro Elected EMBS Rep

Joe Dyro was recently elected Region 1



Joseph F. Dyro

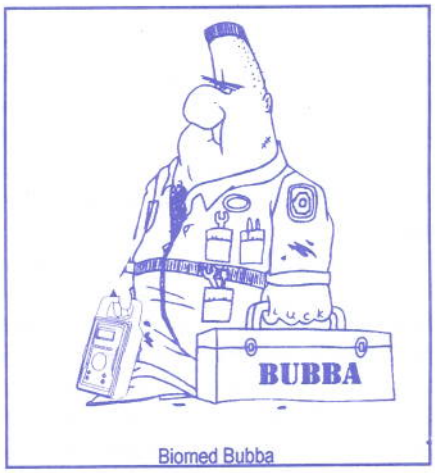
Representative on the Executive Committee of the Engineering in Medicine and Biology Society (EMBS) of The Institute of Electrical and Electronics Engineers (IEEE/).

Bronzino, Dyro, and Smith Elected to CED Board

The International Federation of Medicine in Engineering and Biology (IFMBE) announced that ACCE founding members, Drs. Joseph Bronzino, Joseph Dyro, and John Smith were elected to the board of the IFMBE Clinical Engineering Division (CED). The ACCE is a member society of the CED.

Biomed Bubba Debuts

Thanks to the collaborating efforts of ACCE members Mark Brody and Dave Dickey the rather pathetic character known by many as Biomed Bubba graces the pages of *ACCE News*. See the last issue where Bubba first appeared in connection with a report on Dave Dickey's presentation at the Northeastern Biomedical Symposium, October, 1997. Bubba's motto is *Electrical safety's my game; Biomed Bubba's my name.*



Biomed Bubba

What's A Clinical Engineer?

What's A Clinical Engineer Brochures are available from Jennifer Ott

3635 Vista Ave at Grand Blvd.
St. Louis, MO 63110-2520
JCOttSLU@aol.com;
(314)577-8018; (314)268-5178 Fax

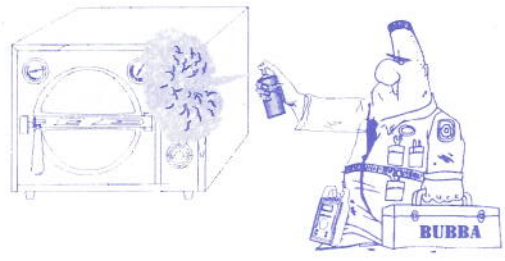
FDA Seeks User Comments on Servicers, Refurbishers, and Reconditioners

The FDA wants to determine the level of concern device users have concerning the lack of regulation for servicers, refurbishers, and reconditioners. A spokesman for the FDA said that FDA needs to receive comments on its Advance Notice of Proposed Rulemaking (ANPR) concerning medical device refurbishers and servicers published last month. Comments on the ANPR should result in FDA taking a coherent, regulatory approach to handling third-party servicers. There are several potential options for regulating servicers. One alternative involves requiring servicers, refurbishers, and reconditioners to register with FDA and comply with the GMP/Quality System regulation. FDA may also suggest that third-party servicers use labeling with such information as who refurbished a device and when it was refurbished.

The ANPR will contain general suggestions for regulation with the hope that comments will lead to further development of some of the suggestions. FDA seeks to create a regulatory approach for servicing industries that is more cost-efficient than those for original equipment manufacturers in the past because of declining agency funds.

Servicers, refurbishers, and reconditioners are being considered for regulation. Reprocessors and remanufacturers are already covered by the new GMP/Quality System regulation. A servicer is generally defined as an individual or company that repairs or performs preventive maintenance on medical devices at the request of the owners. Refurbishers inspect, functionally test, and perform preventive maintenance on devices without changing the performance of the devices from their original specs. Reconditioners are similar to refurbishers except they do not perform preventive maintenance.

ACCE member, Binseng Wang comments on the recent FDA action in the following article.



Bubba Refurbishing

FDA Rules Planned- In-House CEs Beware!

Binseng Wang
binseng@voicenet.com

Great news! Your holiday gift just arrived! The Center for Devices and Radiological Health/ Food and Drug Administration (CDRH/FDA) Office of Compliance in December 1997 published the Advance Notice of Proposed Rulemaking (ANPR) concerning medical device refurbishers and servicers. You can get a copy from the Federal Register's website or from CDRH/FDA's website. Do not get fooled by the title into thinking that this regulation would apply only to remarketing of used equipment. As usual, the definition of *servicer* is so loose that it will fit nicely on all in-house, contract, shared services, depot, and any imaginable combination thereof.

As most of you probably recall, Philip Frappaolo, Deputy Director of the CDRH/FDA's Office of Compliance, announced at the last AAMI Annual Meeting in Washington, DC, that the agency is considering regulating the medical equipment service industry. He stated that there are three basic options (see the Dec. 97 issue of *BIT*):

1. a regulation similar to that currently applicable to OEMs, i.e., the CGMP;
2. a *limited regulation*, in which the FDA would take part of the requirements of CGMP and apply them to servicers and refurbishers; and
3. a *voluntary program*, which would be a set of standards proposed by the industry to the FDA, which will use it to certify the industry.

Phil Frappaolo also made it clear that FDA has already ruled out the alternative of no regulation as *"very unlikely."*

In addition to the independent service organizations (ISOs) and refurbishers/reconditioners, FDA is clearly interested in including the in-house service departments. Phil Frappaolo mentioned that one of the FDA Deputy Commissioners had asked why these departments are not required to be registered with the agency and be inspected on a regular basis, after a fire in New York area hospital happened in 1994. In the AAMI '97 meeting this issue was discussed (or should I say heatedly debated) in several sessions and roundtables. It is very clear that the OEMs want to apply CGMP to all ISOs and used equipment remarketers. Some also want to include the in-house CE departments. The basic argument is to achieve a leveled playing field so the OEMs would not be the only ones bearing the high cost of compliance to the new regulations on servicing. It is unclear to me why they have not taken this issue to court or to the Federal Trade Commission, which is probably better qualified to deal with competitive issues than the FDA. I would not be surprised to see this as the next step.

Anyway, now you will have 90 days (including the holidays) to prepare your comments. Do not complain that I did not warn you before, because I did (see my guest editorial in the June 97 issue of *Healthcare Technology Management*). Have a nice and happy holiday season if you can! Please send comments to me for incorporation into an official ACCE response.

I may be reached at the following coordinates:

Binseng Wang, Sc.D., CCE
Senior Director, Clinical Engineering and Quality Assurance
MEDIQ PRN Life Support Services, Inc.
One MEDIQ Plaza
Pennsauken, NJ 08110 - USA
Telephone: (800)-222-4776 or (609)-662-3200, extension 5516.
Fax: (609)-661-1635 or (609)-661-0278

Dear ACCE Member:

I ask you to tell a colleague about the **only** organization dedicated **solely** to promoting the profession and interests of **clinical engineering**. Explain the membership categories and benefits which are detailed below. An application form is on the following page.

Individual A person demonstrating evidence of professional practice of engineering in a clinical environment for at least three years and meeting one or more of the following three conditions:

1. Possession of a baccalaureate degree in an engineering discipline or engineering technology from an accredited college or university;
2. Certification as a clinical engineer (CCE), by the International Certification Commission; or
3. By recommendation of the Membership Committee in recognition of exceptional contributions, consistent with criteria established by the Board, to the profession of clinical engineering.

Associate A person interested in the goals and objectives of the College and who does not qualify under other membership categories.

Candidate An individual interested in the purpose of the College and meeting one of the following two conditions:

1. Currently enrolled at least half-time in an accredited baccalaureate or graduate program in engineering, engineering technology, or related course of study; or
2. In the process of completing the three year clinical experience requirement for individual membership after having received a baccalaureate or graduate engineering degree.

Fellow An individual member may be advanced to Fellow status in recognition of distinguished service to the profession or achievement in the field of clinical engineering.

Membership Benefits

The ACCE is building a strong profession, a credible profession, a dynamic and a flexible profession. ACCE membership gives you advantages that will enhance your career now in this rapidly changing healthcare environment and for many years to come in the following ways:

- **Access to a network of clinical engineering experts and peers**
- **Representation of your interests to legislators, regulatory agencies, and health care professionals**
- **Instant access to critical information on the ACCE web page**
- **Up-to-date information in *ACCE News*, the only clinical engineering newsletter**
- **Special events and programs such as Advanced Clinical Engineering Workshops and audio-teleconference series**
- **Discounts on publications and meeting registrations**
- **Opportunities to share your expertise with other professionals**

Definition of Clinical Engineer

A clinical engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology.

Membership Application Form is on the other side. Give it to a Colleague today!

Sincerely,

Frank R. Painter, President

AMERICAN COLLEGE OF CLINICAL ENGINEERING

MEMBERSHIP APPLICATION FORM

Name: _____

Specialty: _____

Degree(s): _____

Certification/Registration: _____

BUSINESS ADDRESS:

Employer: _____

Department: _____

Street: _____

City, State, Zip: _____

Country: _____

Phone: (_____) _____ Fax: (_____) _____

E-mail address: _____

HOME ADDRESS:

Street: _____

City, State, Zip: _____

Country: _____

Phone: (_____) _____ Fax: (_____) _____

Send Correspondence to: [_] Office or [_]Home

Date: _____ Signature: _____

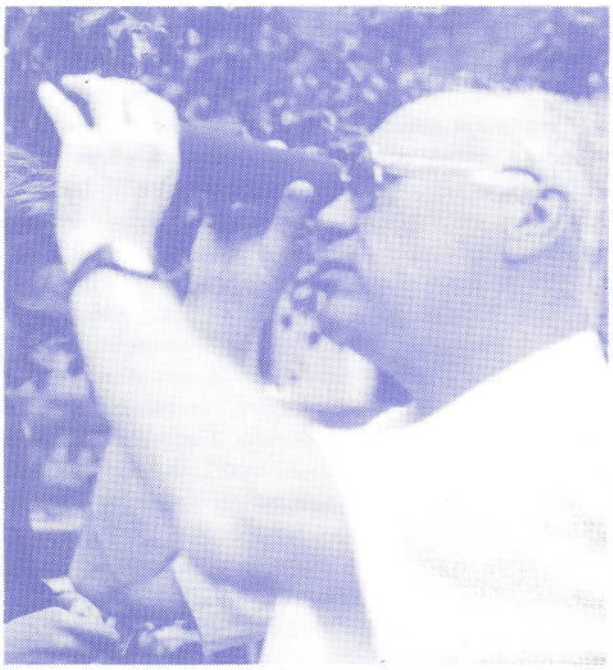
APPLICATION FEE: Individual and Associate Member - US $50; Candidate Member - $25

INSTRUCTIONS: Please return completed application and check to: ACCE, 5200 Butler Pike, Plymouth Meeting, PA 19462, USA. Attach curriculum vitae/resume to verify your professional credentials. Formal education, training, and clinical engineering experience will be reviewed by the Membership Committee for applicability to assure consistency with the mission of ACCE.

Clinical Engineering Profiles

Robert L. Morris, PE, CCE
Clinical Engineer, Humanitarian

Robert (Bob) L. Morris has been at the Oregon Health Sciences University in Portland, Oregon, for forty years. He considers Portland the best place in the world to live. He is currently Director of the Clinical Engineering Department. Up until last July he was also an assistant professor in the Department of Pathology and a tenured member of the primary faculty of the School of Medicine. In 1959 after a stint in the Air Force where he learned electronics and at a time when most electronic equipment utilized vacuum tubes, Bob began to work at University Hospital. He began as a technician, worked his way through college, and progressed through all of the positions of a modern clinical engineering department to become the director of the Clinical Engineering Department. A few side trip made life more interesting.



Bob inspecting kaleidoscope in Warsaw

After obtaining a degree in physics, Bob did his internship and residency under George Johnston, designing and building one-of-a-kind devices for basic and clinical research. He did analog and digital design work, using vacuum tubes, transistors, and integrated circuits. Many systems also involved optics, fluidics, glass and mechanical subsystems. Morris taught graduate courses in physiological instrumentation and electronics to students from physiology, biochemistry, medical psychology and other departments at the University.

After 10 years designing and repairing instruments, Bob moved to the clinical laboratory. For the next 10 years, he was instrumental in the computerization of the clinical laboratory, taught computer programming, system analysis and laboratory instrumentation courses to post-doctoral fellows, graduate and undergraduate students and medical technology students. He has taught electronics and instrumentation to medical technology students since 1967. In 1985, Bob was appointed Director of the Clinical Engineering Department in Hospitals & Clinics at Oregon Health Sciences University while still maintaining his position in the Department of Pathology.

Bob has been involved in professional activities (IEEE, AAMI, AAPT, ACCE, ISTAHC, etc.) since 1959. He is a founding member of ACCE. He is a licensed Professional Engineer (electrical) and is a member of the second group of clinical engineers to become certified. He served on the Clinical Engineering Board of Examiners for a record number of 11 years. He has actively participated in three of the four ACCE Advanced Clinical Engineering Workshops.

Bob likes to travel and has been actively involved in international activities since 1980. He has served as a consultant for various US governmental and international agencies and for many non-governmental organizations (NGOs) and charitable organizations. He has worked in over 28 countries as a consultant and teacher. Bob has taught courses on trouble-shooting and repair of US, European, Chinese and Russian medical equipment. Lately he has focused upon the establishment of equipment support systems and various aspects of technology management. He holds visiting faculty appointments at several foreign universities.

Bob Morris has a broad range of interests and views himself as a generalist in the field of clinical engineering. His hobbies are traveling and reading history, philosophy, poetry and historical travel biographies. Bob is a mediocre but hopeful poet, a person who loves music but has no musical ability, a repository of miscellaneous trivia only vaguely relevant to anything and a middling story teller. He is falsely reputed to have one of the slowest arms in the United States when it comes to picking up a bar tab.

Bob Morris officially retired from Oregon Health Sciences University last July, but continues doing clinical engineering and is busier than ever. He still serves on the Institutional Review Board Committee on Human Research. His lifetime goals have been to do work that he enjoys, to teach and mentor others and to travel. Those are still the goals that guide him.

FDA Modernization Act-97 Changes SMDA

Marvin Shepherd
Marvins523@aol.com

The Food and Drug Administration Modernization Act of 1997 makes some significant changes to the Safe Medical Devices Act of 1990 (SMDA). These changes affect both Medical Device Tracking (MDT) and Medical Device Reporting (MDR) regulations.

Marvin Shepherd

Medical Device Reporting

Under the new law, the FDA regulations are to limit user reporting to a representative sample of user facilities. This sample will constitute a representative profile of user reports for device deaths and serious illnesses or serious injuries. The FDA's plan is yet to be written, and until it is written and fully implemented, the present requirements will continue to apply. Not later than November 19, 1999 the FDA must report back to Congress on its plan and also on the progress toward implementation of the plan. One required change will become effective on February 19, 1998, *i.e.*, summary reports will be required on an annual rather than semi-annual basis. All the requirements for the new law are available on http://www.fda.gov. (See Sec. 213 for the changes in "Reporting".) This change to sample testing will probably delight all except those who are included in the sample. In addition, we might expect that the sample will periodically be changed. The addition of new technologies and changing healthcare patterns might be expected to modify the user facility samples over time.

Medical Device Tracking

Twenty-seven devices are presently on the list of those that must be tracked. Until spring of 1997, there were only 26. Then stents were added. It is now the FDA's plan (under the Modernization Act-97) to contact manufacturers of devices that have previously been identified as being tracked devices to indicate whether they should continue to track these devices or if tracking may be discontinued. Manufacturers currently required to track devices should not discontinue tracking prior to communication from FDA. This change becomes effective on February 19, 1998.

User facilities are not required to respond to this change in tracking requirements until notified by the manufacturer. Some user facilities are still not aware that the fundamental requirement for an effective device tracking program rests with the manufacturer. The manufacturer will tell the user facility if any one device needs to be tracked. At such a time, the user facility must then involve themselves in the tracking program. For additional information, see Sec. 211 of the FDA Mod Act of 1997.

ACCE Board Highlights

December 10, 1997

Jennifer C. Ott, Ottj@slucare1.sluh.edu

President Frank Painter reported on the lack of progress in resolving the copyright issue with the World Health Organization. He announced a 1998 membership campaign with the objective of equally and exceeding the phenomenal success of last year. Painter called for a Board meeting in May to be held during the 1998 Health Tech meeting which many ACCE Board Members will attend. Painter announced the resignation of Tom Judd as Member-at-Large. Bill Betts is stepping down in May as chairman of the Membership Committee to take the post of Chair-Elect of the Association for the Advancement of Medical Instrumentation (AAMI). **Secretary** Jennifer Ott reported no hitches in distributing membership directories, certificates and pins. **Treasurer** Bryanne Patail reported a sound financial balance sheet with adequate reserves. The 1998 Budget was presented and unanimously approved by the Board. The Board unanimously approved the recommendation, presented by Bill Betts, Chair of the **Membership Committee,** of four new members. Government Relations Committee Chair Francine Reibman, contacted several key insurance company executives who are influential in government policy making serving on advisory committees. Important contacts are forwarded to the *ACCE News* editor for complimentary copies. **Education Committee** Chair Jim Wear called for suggestions for speakers for 1998. Jennifer Ott, Program Director of the First ACCE Symposium detailed the progress made toward that seminal event. She announced Ira Tackel as Symposium Facilitator. Leading clinical engineers will comprise a panel which will interchange information with the attendees of the Symposium in a think-tank, brain-storming atmosphere. *The Future of Clinical Engineering* is the theme of the Symposium. Tom O'Dea as fund-raiser joins Joe Dyro, Ken Taylor, Ira Tackel, Jeff Secunda and Bryanne Patail on the Symposium Committee. **Newsletter Editor**, Joe Dyro presented his annual report. In 1997, six issues of the News were produced on schedule, advertising achieved desirable and predicted levels, circulation topped 900 on months when mailings were made to promote membership. Full text of the *News* is available to all ACCE Members on the ACCE Home Page. Non-members can access table of contents, highlights and excerpts. Dyro noted that items for publication continue to stream in at an ever increasing rate and thanked all ACCE members for their use of the newsletter as a communication medium. Dyro updated the Board on **Advanced Clinical Engineering Workshop** plans for November 1998 in Mexico. **Webmeister** BJ Morgan updated the Board on present and future server options. Member-at-Large Binseng Wang alerted the Board to recently announced FDA actions which could profoundly impact clinical engineering practice (see page 6 of this issue of the *News* for full details of this late-breaking development). The Board will meet next on February 11, 1998.

Welcome to ACCE!

The Board unanimously approved the following recommendations of the Membership Committee:

Individual Members

Timothy Adams
Paul Frisch
Stuart Meldrum
Jim Keller

Correction, Correction, Correction

In the last issue of ACCE News, Vol. 7, No. 6, William Hyman was incorrectly listed as Associate Member. Bill is an **Individual** Member.

Advocacy Awards Deadline Approaching

Tom O'Dea, Chairman of ACCE's Advocacy Committee wants to hear from you. Every year awards are made to the individuals who publish articles promoting clinical engineering. The pen is a powerful tool if properly wielded. Put pen to paper and tell your story.

The View from the Penalty Box

David Harrington, davesbt@kersur.net

It is not too often that the general press carries stories about problems with technology in healthcare. In the month of December, two such articles appeared in the *Boston Globe*, one of which was distributed by the Reuters New Service and may have appeared in other newspapers around the world.

The first article of note appeared on December 1, 1997 and was part of a series on problems in healthcare. While the article was very critical of the for-profit healthcare systems, several of the most critical findings were from the non-profit hospitals. In one incident, there were only 14 nurses caring for 56 patients in a neonatal intensive care unit. What is interesting here is that this particular unit is very well equipped with technology and the technology allowed the low level of nursing. But unfortunately even with all the technology the staffing level was 50% of the minimum state licensure requirements for an intensive care unit, *i.e.*, one nurse for every two patients. This may be the tip of the iceberg in which hospitals try to have technology replace nurses in the future. Does the book *"Coma"* by Robin Cook change from fiction to non-fiction? Also in this article was a report from another hospital, also a non-profit, where over 700 patients did not receive proper care because a blood gas machine was not properly calibrated and maintained. This was one of the few times that I have seen a device mentioned as a source of less that ideal patient care.

One of the above hospitals has a large and well known clinical engineering department and the other contracts out its services. Therefore, there is no direct connection, in these cases, between good healthcare and in-house clinical engineering programs. I had difficulty understanding why the administration's action consisted only of the firing of the person who publicly complained about the blood gas machine. As it has too often occurred in the past, administration went, "ready, fire, aim".

The second article, distributed by Reuters, on December 19, 1997, was based on the Sounding Board column in *The New England Journal of Medicine* of December 18, 1997. The column stated that old drugs and inappropriate devices were donated to Bosnia over the period of 1992 to 1996. Basically, almost 50% of the material donated was not appropriate for use. The cost of the donations was calculated as $25.5 million but the cost of disposal to get rid of the inappropriate material was listed as $34 million. The closing paragraphs of the *NEJM* article called for better co-ordination of donations, with strict guidelines and fines for dumping outdated drugs and inappropriate devices. The authors also criticized the World Health Organization (WHO) for not supplying such guidelines. In previous issues of this newsletter much has been said on the work that ACCE has done in developing donations guidelines and the battles with WHO on its use the ACCE guideline without proper acknowledgments. It appears that we still have a problem in getting information on what we have done out to the appropriate organizations, both nationally and internationally.

As a side comment on the donations to Bosnia, having seen what was shipped there over those years, I am surprised that **only** 50% was deemed as inappropriate. Some of the blame has to go to the governments that kept many containers of supplies in storage for years before distribution. These same governments also have to be faulted for the raiding of many of the containers by those who were looking for items to sell on the black market. This is a problem not only in Bosnia but in all countries where large volumes of donated material arrive after a disaster, natural or otherwise.

So from the **Penalty Box** I wish all a Happy New Year and the continued growth of our profession.

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Announcing AIMBE Annual Event

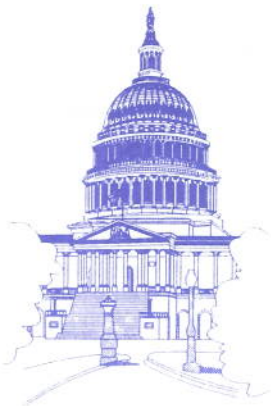
American Institute of Medical and Biological Engineering (AIMBE) announces its Seventh Annual Event, *From Gene to Function: Bioengineering's Role,* in Washington, DC, March 1-3, 1998. Immediately preceding the event on February 27-28, the National Institute of Health (NIH) Symposium, *Bioengineering: Building the Future of Biology and Medicine*, will be held at the Natcher Conference Center, National Institutes of Health, Bethesda, MD. Charting a vision for the future of bioengineering research is the goal of the two-day NIH symposium. The format will include plenary sessions, 16 panel discussions, scientific posters and exhibits related to research in biology and medicine. Plenary sessions and panels will delineate grand challenges, identify barriers to success and highlight important research themes. Posters and exhibits will provide a forum for showcasing NIH-funded bioengineering projects fostering future collaborations among investigators, industry, and small business.

On Sunday, March 1, meetings of the College of Fellows, Academic Council, and Council of Societies will precede three membership forums addressing important public policy issues facing the medical and biological community: academic-industrial relationships and technology transfer; undergraduate education curriculum; and pending congressional legislation addressing the role of bioengineering at NIH. The forums are designed to obtain maximum dialog and input from members of the AIMBE community. ACCE is a member of the Council of Societies.. Several ACCE members are members of the College of Fellows.

On March 2, the program moves to the National Academy of Sciences (NAS) for three sessions focusing on fundamental research, implications for NIH and industry, and regulating new technologies.

On March 3, the National Science Foundation and AIMBE will co-sponsor an all day program featuring presentations from Federal agencies funding bioengineering research. This is your opportunity to learn about the scope of Federal programs in medical and biological research, and to meet Federal program officers who manage these programs. This event will be held at the Washington Marriott Hotel.

For information on the above please call AIMBE at 202-496-9660.



Web Trappings

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

Visit the ACCE Home Page at the address below. Your feedback is always helpful.

http://info.lu.farmingdale.edu/~acce/

Calendar of Events

- AIMBE Seventh Annual Event, *"Bioengineering and Functional Genonomics,"* February 28 - March 3, 1998, Washington Marriott Hotel and National Academy of Sciences, Washington, DC. Contact AIMBE 202-496-9660.
- 24th IEEE Northeast Bioengineering Conference, Penn State Univ., April 9-10, 1998, Seth Wolpert: 717-948-6752, sxw33@psu.edu.
- 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, Ex: 203, 609-419-0530 fax, e-mail: swamy@nextgeninter.net.
- American Medical Informatics Association, 1998 Spring Congress, Philadelphia, PA. Contact AMIA 301-657-1291.
- ACCE: First ACCE Symposium, May 30, 1998, Plymouth Meeting, PA. Contact Jennifer Ott 314-577-8018; 314-268-5178 fax; ottj@slucare1.sluh.edu.
- AAMI 98: 33rd Annual Meeting and Exposition, May 30-June 3, 1998, Philadelphia, PA.
- ACCE Reception and Business Meeting, June 2, 1998, Philadelphia, PA. Contact Jennifer Ott 314-577-8018.
- Annual Meeting, American Society of Physicists in Medicine, Aug. 9-13, 1998, San Antonio, TX. Phone 301-209-3350.
- Beacon Biosensor Symposium, October 2, 1998, Trinity College, Hartford, CT. Laurie MacFarlane: laurie.macfarlane@trincoll.edu; 860-297-5364; 860-297-5300 fax.
- 20th Annual International Conference of IEEE Engineering in Medicine and Biology Society, October 29-November 1, 1998, Hong Kong, http//www.ee.cuhk.edu.hk/embs98.html.
- 18th Annual Northeastern Biomedical Symposium, Nov. 9-11, Albany, NY. Contact Ronald Hulin 518-525-1799; ibs98@aol.com

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Cath labs, C-arms, Special Procedure Rooms, and other fluoroscopic x-ray equipment need tubes replaced during their life. This newsletter offers technical tips helpful in the understanding and applications of camera tubes and CRTs used in this equipment. New industry developments, new tube types, and other helpful insights are discussed in this comprehensive collection of articles.

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First ACCE Symposium The Future of Clinical Engineering

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First ACCE Symposium

The Future of Clinical Engineering

On **Saturday, May 30, 1998**, a panel of distinguished leaders in clinical engineering will enlighten, provoke, stimulate, and incite you to chart your way into the future. Adequate time is planned to maximize audience participation for questions and answers, brain-storming, and alternate points of view. **Ira Tackel** is Host and Moderator. Panel members include **Malcolm Ridgway, Larry Hertzler, Tom Bauld, and Dave Dickey**. Formal program will run from 9 AM to 12:30 followed by free lunch. Optional tours, poster sessions, *ad hoc* discussions, and breakout sessions in the afternoon. Thomas Jefferson University is conveniently located in Center City Philadelphia.

For more information contact Symposium Committee Chair Jennifer Ott:
314-577-8018 phone; 314-268-5178 fax; ottj@slucare1.sluh.edu.

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