

ACCE News

Vol. 8, No. 3 - May 1998

First ACCE Symposium

May 30, 1998 == Philadelphia 1998

Malcolm Ridgway, Tom Bauld, Greg Davis and Larry Hertzler will engage a clinical engineering full house at the First ACCE Symposium in Philadelphia, Pennsylvania at Thomas Jefferson University. Ira Tackel will host and moderate the proceedings. The afternoon **Hot Topics Poster Session** features *OR Fires, CAP Rule Changes, Consulting Tips, FDA and Y2K*. Brainstorm with speakers and attendees to develop effective strategies to excel in today's competitive environment! Where do you stand on rightsourcing and on future directions for clinical engineers? Find out! Join us! Enjoy facts, fellowship, and fine Philly food. You may register at the door, Room 101, Bluemle Life Science Building on 10th between Walnut and Locust. See this issue of *ACCE News*, page 16, for details and registration information.

ACCE 1998 Teleconference Series Announced

The series of eight lunchtime audio teleconferences for 1998 begins May 21 with Tom Bauld speaking on the rules and regulations of the FDA and how they affect you. See page 4 & 5 inside.

ACCE IN PHILADELPHIA

See page 15 for a schedule of ACCE events at the Annual Meeting: Symposium, Board Meeting, Reception, General Meeting.

Year 2000 -- Wang Warns

Dr. Binseng Wang expresses his concerns over inappropriate reaction to Year 2000 inadequacies of medical devices. See Editorial on page 3 inside this issue of *ACCE News*.

ACCE Annual General Membership Meeting and Reception



Come! Join Us!

American College of Clinical Engineering

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

The outstanding teamwork exhibited by ACCE members have made it a pleasure to serve as your President. I'll be handing over the controls in a couple of months but before doing so I will establish a tradition: the *Annual State of Clinical Engineering Address*. To be among the first to hear this assessment of where we stand you must attend the **ACCE Annual General Membership Meeting**, Tuesday evening, June 2 in Philadelphia at the Marriott Hotel. I have a lot of good things to say. Come early! Meet me at the Gala Reception! Don't miss it! A hint: clinical engineering is rock solid. I just returned from HealthTech '98 where ACCE members dominated the presentations. Wherever you turn, magazines, conferences, TV, radio, you will find the best of clinical engineering.

Thanks go to all of you who have renewed membership for 1998. Our ranks continue to swell with new members adding to a solid base of some of the finest clinical engineers in the world.

The star-studded 1998 Teleconference Series is a must for keeping current and continuing to grow in our profession. Thanks for Jim Wear's efforts in organizing this outstanding program.

First ACCE Symposium, May 30 at Thomas Jefferson University in Philadelphia promises to be a brainstorming session we will long remember. Don't miss the provocative, informative perspectives of clinical engineering's gurus, lively discussions and the poster sessions on this year's hot topics: FDA, Y2K, CAP, Fires, Consulting Opportunities.



Frank R. Painter

ACCE News

ACCE News is the official newsletter of the American College of Clinical Engineering (ACCE).

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Editor

Joseph F. Dyro, Ph.D., CCE
21 Bob's Lane, Setauket, NY 11733
jfdyro@aol.com; (516) 751-7244; -7802 Fax

Assistant Editor

Rachel Mercado, mercadr@cpmail-am.cis.columbia.edu

Advertising Manager

Caroline Campbell, cac1@mhg.edu; (202) 877-7151 (Rates and Deadlines)

Address corrections:

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

ACCE

5200 Butler Pike
Plymouth Meeting, PA 19462-1298
(610) 825-6067

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

ACCE on the Web

Editors Needed

The ACCE News needs editors and writers. If you would like to help to maintain and improve the quality of your newsletter, please contact its Editor, Joe Dyro. Call 516-751-7244 or jfdyro@aol.com.

Letters

ACCE News, 21 Bob's Lane, Setauket, NY 11733
516-751-7802 fax; jtdyro@aol.com

Other Estonians Aid Aid

Sir--Thank you very much for printing my message in the *ACCE News* (Vol. 7, No. 4, Sept. 1997), especially for editing it before printing and sending me a copy. It became much better after your editorial work. Your including the article in the *News* helps us in different ways. It is an endorsement from ACCE, the most powerful national organization of Clinical Engineers, that we in Estonia are headed in the right direction having established as the main goal of medical devices-related policy the strengthening of hospital-based clinical engineering groups. It helps me in my voluntary capacity as adviser to the Ministry of Social Affairs and at Tartu University and its Training Centre of Medical Equipment.

The only problem which diminishes a little bit the value of the paper is that it was based on my self-introduction and therefore it is somewhat excessively *AID-centered*. The efforts underway in Estonia are based more and more on the work of my colleagues from the Training Centre of Medical Equipment, from hospitals of Estonia, and from the Technological Bureau of the Ministry of Social Affairs.

Siim Aid

Tartu University Clinicum, Estonia
siim@cut.ee

Year 2000 Testing Concerns

Binseng Wang, binseng@voicenet.com

Recently I read messages on several bulletin boards and trade magazines on how to perform Y2K tests on medical equipment. I must say that I feel very uncomfortable about this discussion and would like to share my thoughts, hoping some wiser persons will prove me wrong.

First, I would like to say that I am not an expert on this issue, nor do I want to ignore serious patient safety problems. However, I do not believe it is the biomedical technician's or clinical engineer's duty or right to evaluate the Y2K risk on devices in whose design and manufacturing they were not involved. Since they do not have the detailed hardware descriptions, much less the software source programs, they cannot perform a comprehensive evaluation. The tests suggested by ECRI and other international experts only check for clock problems and do not necessarily uncover problems caused by the use of clock information for internal computations and data interchange with other devices such as remote alarms and central stations.

If the testers find anything wrong, the only thing they can do is to recommend that the clinicians discontinue using the device. The biggest dilemma they will face is what to do if a device fails the clock test, e.g., erroneous clock readout, but may not pose any safety problems. Unless the hospital has an alternative device, can buy a new one, or can rent one, discontinuing usage may cause more harm rather

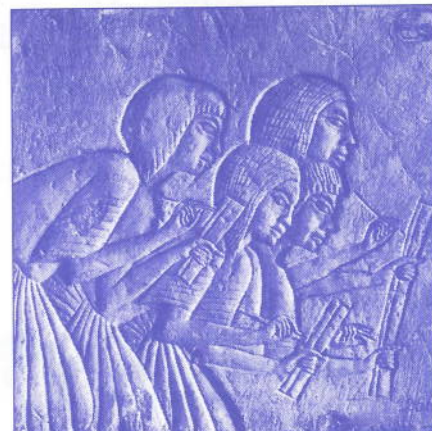
than reducing risk under certain conditions, e.g., not putting a patient on a ventilator that works fine but cannot keep an accurate date.

Even if the testers were able to perform a thorough evaluation, they cannot make appropriate modifications. They may violate the manufacturer's copyright or patent and, furthermore, be accused by the FDA of adulterating a device. Naturally, their hospital's legal counsel will hang them if the modification injures or harms a patient. On the other hand, plaintiff's lawyers would love to sue hospitals for incomplete tests that did not find problems which later caused patient injuries or death.

As most people know, the FDA is actively soliciting information from manufacturers and holding them responsible for safety problems caused by Y2K. Unfortunately, the FDA stated that it will not require the manufacturers to report the Y2K status on all of their products to the FDA because it "would be a time consuming and resource intensive process and would require the development of a new regulation." The FDA proposes to request that manufacturers voluntarily submit Y2K compliance information for posting on or linked to the FDA's Web site. The OEMs are required to perform a recall only when a safety risk exists.

I have the impression that a significant number of devices probably will not have their safety or efficacy affected by Y2K. However, that does not mean that they will function normally. Many will default to 1900 instead of 2000. Some will not even allow the user to set the clock beyond 1999. These inconveniences can, unfortunately, turn into more significant problems if the internal clock information is read and used by another system, e.g., through a data port. Unfortunately, many OEMs are likely to refuse to offer test results or solutions alleging that these devices are obsolete; so the user will have to assume full risk and liability for using equipment beyond 1/1/2000. I believe many OEMs are gleefully awaiting the largest sales windfall in the next two years using this argument. Hopefully, your hospital will be able to afford a huge capital budget.

So far, the only alternative I see is to write those legal letters to the manufacturers holding them responsible for any problems. I recommend that you do not perform any tests, much less any corrections, on your own! Just book yourself a nice, long cruise, preferably one out of telephone reach, and leave town a few days before 1/1/2000.



Write those letters!



Education Committee
5104 Randolph Road
N. Little Rock, AR 72116

ACCE 1998 EDUCATION PROGRAM

Founded in 1991, the American College of Clinical Engineering (ACCE) is committed to enhancing the profession of clinical engineering. With members in the United States and abroad, the ACCE is the only professional society for clinical engineers.

For 1998, ACCE will offer an exciting educational program at a low-cost. By participating in an audio-teleconference, you will be able to obtain up-to-date materials without incurring any travel expense or time away from office. There will be a 1-hour class once a month and a different topic will be covered in each class.

Recognized experts in the field are selected to make up the faculty and the topics are the ones requested by our members. In a class the lecture will last for 45 minutes followed by a 15-minute question and answer period.

Classes will be conducted on the third Thursday of each month at 12:00 noon, EST. Continuing education units will be issued by the University of Arkansas for Medical Sciences. For participating in the audio-teleconference you are required to use a phone with a mute button.

The ACCE audio-teleconference is an opportunity to get the clinical/biomedical engineering people in your area together. The teleconference can be a way to start a discussion with your colleagues. The cost can be shared by different institutions paying for each course or they can pool their funds for the series. A larger site might sponsor the course and charge single attendees from other sites.

For registration forms and more information, contact Educational Committee Chairman, James O. Wear at 501-370-6618.

1998 Program Schedule



THE BUSINESS OF CLINICAL ENGINEERING

MAY 21, 1998

FDA Issues

Tom Bauld, PhD
University of Michigan Hospitals
1500 E Medical Center Drive
Ann Arbor, MI 48109-0002

JUNE 18, 1998

Year 2000 Issues

Steve Wexler
VA Headquarters
810 Vermont Avenue NW
Washington, DC 20420

July 16, 1998

ACCE Symposium Recap

Ira Tackel
Thomas Jefferson Univ. Hospital
129 S. 9th Street
Philadelphia, PA 19107

AUGUST 20, 1998

ISO 9000

David Simmons, ScD
Health Care Engineering, Inc.
3114 Elmendorf Drive
Oakton, VA 22124

SEPTEMBER 17, 1998

Technology Assessment

Brian A. Porras, MSBE
Premier
4601 Charlotte Park Drive, Suite 300
Charlotte, NC 28217

OCTOBER 15, 1998

Consulting Services

Dave Dickey
Medical Technology Management
PO Box 808
Clarkston, MI 48346

NOVEMBER 19, 1998

Financial Management
of a Biomedical Service Business

Binseng Wang, ScD, CCE
MEDIQ/PRN
One MEDIQ Plaza
Pennsauken, NJ 08110-1460

DECEMBER 17, 1998

Non-profit to Profit

Jennifer C. Ott, MSBME
SLUCare
3635 Vista Avenue @ Grand Boulevard
St. Louis, MO 63110-0250

Meetings

EMBS Presentation: Engineering Neural Tissue

James A. Gilchrist

Clinical Engineering, Touro College School of Health Sciences

March 17, 1998 at Rockefeller University in New York City, the Engineering in Medicine and Biology Society sponsored a talk by Case Western Reserve University Biomedical Engineering researcher Ravi V. Bellamkonda, Ph.D. entitled *Engineering Neural Tissue*. Tissue engineering is a rapidly expanding field that encompasses many areas such as cellular and molecular biology, biomaterials, chemical, mechanical, and biomedical engineering, imaging, and medicine. The goal of tissue engineering is to augment, replace, or regenerate compromised tissue. Neural tissue engineering is a specialized branch of tissue engineering which focuses its attention on the central and peripheral nervous system and its support structures. In general it is recognized that peripheral nerve regeneration techniques have had more success than central nervous tissue regeneration techniques.

Dr. Bellamkonda's lab uses a three dimensional hydrogel scaffold arrangement coupled with support and growth factor proteins to enable nerve regeneration. His research is based on two main hypothesis: recreation of the permissive fetal environment at the site of the lesion is critical for the regeneration of adult nerves

and permissive three dimensional scaffolds and drug delivery vehicles can be used to tailor the environment at the site of the lesion to favor regeneration.

His technique involves the use of a hydrogel material to be used as a bridge which will support and encourage a cut axon to grow into, through, and out of the bridge so that it will reinnervate the end target tissue with which the nerve cell was originally in contact. The hydrogel material is engineered so that it can support nervous tissue *in vitro* and allow axons to grow or not grow through the material by careful regulation of the pore size and/or composition of the hydrogel. The axons that grow in the hydrogel are supported structurally by hydrogel adhesive proteins and axon growth is stimulated and directed proximal to distal from the nerve cell body by the positioning of nerve growth factor protein (NGF) concentration gradients released within the hydrogel by lipid microcylinders constructed for this purpose. The release of NGF from the lipid microcylinders can be varied so that the amount, rate, and direction of axonal growth can be adjusted. This three dimensional arrangement is preferred over the traditional two dimensional arrangement (on a slide for example) since it is a better representation of the *in vivo* environment. Dr. Bellamkonda has successfully identified and constructed a suitable hydrogel bridge with nerve growth factor components. One major obstacle remains. The axons grow into, through, but

not out of the distal portion of the bridge so that they cannot reinnervate the target tissue. If current efforts to solve the dead zone problem succeed, clinical applications will draw nearer.

New York Metropolitan Area Clinical Engineering Directors

Ira Soller

The New York City Metropolitan Area Clinical Engineering Directors Group met on March 24, 1998. A dynamic presentation on *Pulmonary Measurement* was given by Ted Tabor and Dave Glielmi of Novamatrix. Subsequent member discussion included sharing information relating to the Y2K problem, automated noninvasive blood pressure measurement during stress test, effects of HDTV and cellular phones on physiological monitoring, and new developments in CMMS software. The meeting was hosted by ACCE member Mike Mirsky of St. Luke's Roosevelt. Other ACCE members in attendance included Kelly Galanopoulos and Nicholas Pinto. The next meeting will be held on May 26, 1998. 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.

Stumped

Mary Ann Gore

Miss Wood made an emergency room visit last Friday evening for bronchial congestion and abdominal distention. The sweet, helpful, caring, paramedic-in-training, began attaching EKG electrodes. Chest electrodes in place and now for the right leg lead. He pawed, poked and pulled through a tangled cocoon of sheets and blankets enclosing Miss Wood's lower body. After several minutes and with a perplexed look, he looked up at me and said "Are her legs crossed or something? I can't find the right leg." I said it was amputated. He said, "Oh, I was really stumped!" It took the darling fellow a few moments to realize what he had said. In the meantime, I told him that I, Betsy and Miss Wood all got a kick out of his remark.

Editors Note: Miss Laura Wood is the 96-year-old aunt of my wife, Betsy, and currently resides at 21 Bob's Lane with the Editor and his family. A former student of Miss Wood when she was Head Mistress of the Knox School, Mary Ann Gore, often visits helping with her care.

People on the Move and in the News

Welcome to ACCE!

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

Individual Members

Tobey Clark

Carol Davis-Smith

Associate Members

Keith Deline

Michael Mastro

*Congratulations,
new members!*

Dyro to Senior Member in IEEE

Dr. Joseph F. Dyro has been elevated to the grade of Senior Member of IEEE. In his notification of Dyro, IEEE President Joseph Bordogna wrote, "Only 8% of the 320,000 members hold this grade which requires experience reflecting professional maturity and professional achievements."

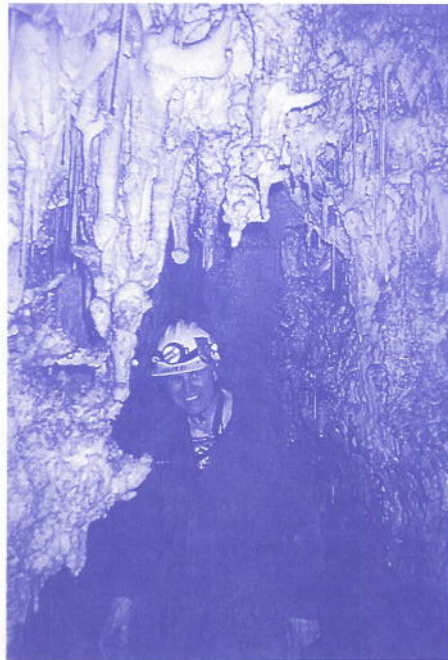
Bauld Descends to New Depths

Dr. Tom Bauld, Rock Lizards Explorer Post Advisor and Past President of ACCE, was recently published in *NNS News*, the official newsletter of the National Speleological Society. His article, *Michigan explorers perform service project in Carlsbad Caverns N.P.*, with accompanying photographs detailed the positive aspects of cave life.

Tom and his interest in caving was featured in *Profiles in Clinical Engineering* in last month's *ACCE News*. Tom lead the Post team in removing two old metal bridge

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sections which had been installed in the 1950's to protect small pools. The sharp edges of the bridges were wearing away the rock underneath.



Busman's holiday, Tom?

20/20 Eyes Bruley

Mark Bruley was featured on a recent nationally broadcast 20/20 program describing the all too frequent catastrophic occurrences of fires in the hospital environment. Mark described the dangers of enriched oxygen environments combined with lack of knowledge concerning the fire triangle. Mark's presentation and a Poster on *Surgical Fires Can Be Prevented* can be seen at the 1st ACCE Symposium, May 30, 1998 in Philadelphia.

Dickey Advocates In-House to Advocate

Advocate Health Care, Oak Brook, IL, announced consolidating the clinical engineering function across five member hospitals with the assistance of Medical Technology Management, Inc. ACCE Member, **David Dickey**, MTM's president

and CEO in noting that clinical engineering is on the upswing stated, "A clinical engineering program can have a direct effect on patient care, especially when you consider the negative impact of improperly operating equipment," says Dickey. "Establishing in-house service and support management is more cost effective and allows you to deal directly with service quality and regulatory issues." Advocate's Technology Manager, Joseph Dysko said that Advocate's new medical equipment service program will incorporate the best features of established in-house equipment programs, using a combination of internal resources and outside vendors to maximize equipment service options.



Dave Dickey

Remembrance of Frank Yip

Marv. Shepherd

Frank Yip of San Bruno, CA died recently. He was head of the Biomed Maintenance Department at the Cardiovascular Research Institute, University of California at San Francisco, before starting his own medical device marketing business about 1970. In achieving his substantial business success, he constantly visited hundreds of healthcare facilities...mainly on the West Coast. His visits will be remembered by Clinical Engineers and BMETs not only for his product knowledge but for his technical solutions and his frequent assistance in connecting one person with a problem to a second person with a solution. Over the past 25 years I received phone calls from various facilities and the voice on the other end frequently began with "Frank Yip suggested that I give you a call..." On other occasions, it was Frank who called and he might have said "...I was down at _____ hospital and they can't seem to understand the new standard on..." Frank was the communication glue that held many of us together. The internet is a remarkable tool for communication, but it won't replace the remarkable efforts of Frank Yip.

Reflections

George I. Johnston

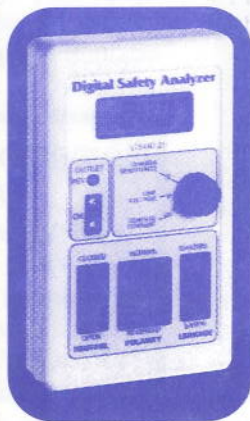
While attending night school to obtain my electrical engineering degree, I had what turns out to be the benefit of working seven years as a medical electronics technician (before the term BMET) at Johns Hopkins Hospital. Following graduation I lucked out again and spent three years as a design engineer in NIH's Instrument Section, now the much larger Bioengineering and Instrumentation Branch. All of this prepared me well for my ultimate goal, a career as a biomedical engineer in an academic research institution. As it turns out I was able to leave NIH to start a biomedical engineering support operation at the, then, University of Oregon Medical School, and, now, Oregon Health Sciences University where I spent thirty years before retiring to a second career of consulting on clinical engineering education and training and forensics work.

When I started at Hopkins in 1948, Drs. Helen Taussig and Alfred Blalock had just pioneered open, but not stopped, heart surgery with their famous *blue baby* operation to compensate, not correct, a septal defect in the heart. Without the heart-lung machine, which was to come a few years later, opening of the heart to suture closed the hole in the septum was not possible. Blalock and Taussig came up with a successful alternative, anastomosing the subclavian artery feeding the left arm back to the pulmonary artery, thus reoxygenating a portion of the arterial output. While not a 100% correction, this procedure allowed the baby a modest life. I never could fathom why that did not compromise oxygenation and nutrition to the left arm; but apparently it didn't.

It was only eight years later, while at NIH, that I saw my first heart-lung machine, a new device which would allow correction of those septal defects. This first machine, British made, was not of today's roller pump style, although one such device was being developed in our shop at that time. The British machine had rocker paddles that squeezed the tubing in a way that produced a pulsatile flow intended to mimic the body's natural flow characteristics. At that time no one knew if pulsatile flow was physiologically required. This machine, therefore, was to be compared against the roller pump version being fabricated in the Instrument Section's machine shop. Today we all know the results of that study. Roller pumps are standard. Surgeons no longer need to operate on a beating heart.

Dale

Products Rated No. 1 In Customer Satisfaction

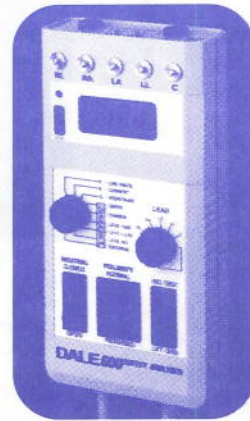


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8 Sizes
To Suit Any
Budget
And Power
Requirement

Dr. Stanley Sarnoff, director of one of the Heart Institute's research divisions, was one of my favorite clients. I designed and maintained numerous devices used in his cardiology research. One day while working on some of his equipment he remarked, "You know, I've never understood all that technology you have provided. Now, my brother... he understands all that stuff." It was days before it dawned on me that he was talking about David Sarnoff, head of RCA!

My three years there were great. My friends, though, refused to believe I would abandon a career with the U.S. Government for a university. "Ah, you will comfortably retire here after 30 years just like the rest of us." However, just three months short of three years, on April 30, 1958, I bade them goodbye and in my old 1948 Chrysler Traveler with the trunk, back seat and roof carrier loaded headed west to start my new 30-year career as founder and director of Research Instrument Service (eventually called University Hospital's Clinical Engineering Department) at Oregon Health Sciences University.



George Johnston

CLINICAL ENGINEERING PROFILES

Marvin Shepherd

Visionary, Gadfly and Technical Iconoclast #001

Looking backward in time, 40 years seems a blur of professional activity that sharpens markedly as the present approaches. As Marv. says *"Those 40 years are hard to count since I seemed to always jump from one interesting activity to another. It is only now that it is easy to trace (and have time to trace) the development of a Clinical Engineer who began his career in a University setting and over a 33 year period, spread his activities well beyond the University."*

Marv. was born in the northern California hamlet of Eureka (250 miles north of San Francisco) at a time when redwood trees and salmon were an unlimited commodity and the local economy thrived on just those two industries. While a freshman in high school, his family moved to "Brown's Camp", south of Eureka, cleared several acres, and built a home along the beautiful Eel River. After high school, the Air Force supported him for 4 years during the Korean war while he provided technical support to fighter planes in Okinawa and fighter and transport planes in Montana and South Carolina. In 1956 he joined the Ampex Corporation to help them assemble and test the first video recorders ever built for TV studios. After a year, the recorders were completed and he continued as a Junior Engineer in their Instrumentation Engineering Department.

In 1958, he joined the Physiology Department at the University of California Medical School in San Francisco (UCSF) to establish an electronic shop for the development and construction of research instrumentation and to support the equipment used in medical school classes. This was his introduction to the application of engineering principles to medical and research problems. After 10 years with the Physiology Department he transferred to the Proctor Eye Research Foundation where he worked on an electrical model for the physical properties of the eye.

In 1962, Marv.'s bachelorhood was interrupted when he met and married Patsy in San Francisco. They added two daughters to the family, Sana & Dina, and began to raise them in the free spirited, San Francisco environment.

Marv.'s hospital experience began in 1971, when he was recruited to solve the microshock problem that was allegedly killing UCSF hospital patients. He discovered that the solution to microshock was to make modifications in the design of facilities and devices, educate nurses and doctors, and assure an effective device maintenance program.

In 1975, Marv. assisted the Hospital Council of Northern California in their establishment of its shared engineering program, *Med-Equip*. It was while consulting with this program that Marv. began to develop his systems approach to analyzing device failure data. This led in 1983 to the AAMI monograph on medical device safety in hospitals and ultimately resulted in a paper (co-authored by Reynold Brown, MD) that was awarded Paper of the Year by *AAMI/BIT* for 1993. The paper emphasized the use of the systems safety approach for analyzing the *cause(s)* of device-related accidents and the importance of standardizing on the definitions for failures. With the passage of the Safe Medical Devices Act (SMDA) in 1990, Marv. incorporated systems safety concepts into a manual, *the Shepherd System for "Medical Device Incident Investigation & Reporting."* The manual with its updates is published by Lippincott/Raven Press. Since 1994, Marv. has converted the system's safety model into a risk management model, using this model to teach *Managing the Risks of Technology* seminars nationwide.

Recognizing the deficiencies in nursing education regarding technology, in 1980, with the help of clinical engineers like Joe Dyro and Steve Friedman he launched *Device Techniques*, a newsletter focusing on the nurse's role in assuring the safe use of medical devices. In 1986, the FDA,

Office of Training & Assistance asked Marv. to join a Steering Committee on Nursing and Technology. Working with June Abbey, RN, PhD, Marv. used the system safety principles to develop a **Abbey/Shepherd Device Education Model** for nursing, which aided nursing educators in identifying module content for nurse education/training in technology. About this time, Joe Dyro and Marv. collaborated on an audio/visual presentation entitled *The Whimsical Use of White Tape*, a product that identified the three reasons nurses use adhesive tape and ways by which its use could be avoided.

Under the auspices of the Society for Critical Care Medicine (SCCM) Marv. developed a technology assessment model applying it to pulse oximeters and closed-loop infusion devices. Marv. presented the model at a plenary session on Technology Assessment at the SCCM annual meeting. Another Marv. creation was the establishment of the highly coveted **Technical Iconoclast** title granted to those brave souls who defend a virtually indefensible position while suffering the slings and arrows of a brutally hostile crowd of naysayers.

In 1991, after 33 years, Marv. retired from UCSF, but a funny thing happened on his way to retirement. He enjoyed accident investigations so much that he continues to consult with hospitals and manufacturers on device-related incidents, as well as with lawyers as an expert witness. He currently provides seminars on investigation techniques, the SMDA, and the management of the risks of technology. He continues to develop computer-based training aids for groups such as AAMI (Electrical Safety Manual), Kaiser, the VA, and the Monterey Bay Aquarium Research Institute.

In 1996, Marv. became the second member of ACCE to achieve the distinction as an ACCE Fellow. Marv. says that *"bioengineering has been evolving since I joined the field in 1958 and there is little doubt that it will continue; however, the fun is in immersing yourself in 'the doing' and I intend to continue my active involvement 'in doing' for the foreseeable future."*



photo by Joe Dyro, TI #004

Shepherd whale watching at Mendocino

Editor's Note: we saw grey whales with pink polka dots and the wine was very good

ACCE News



ACCE products

- Guidelines for Medical Equipment Donations\$25
- 1997-98 Membership Directory\$25
- CE Study Guide:
 - Book.....\$70
 - Disk\$90
 - Book & Disk.....\$150
- CE Definition Plaque.....\$40
- Code of Ethics Plaque\$40
- Lapel Pin\$8

- Teleconference Audio Tapes (incl. handouts)\$30
 - Business Planning Simplified, Tom Zdon
 - Implementing CQI in a Cost-Conscious Environment - Lana Berry
 - Perspectives from a CE in Managed Care: Where is our Role in Healthcare Headed? - Tom Judd
 - Breakthrough Management - Gailord Gordon
 - Incident and Accident Investigations - Marvin Shepard
 - Benchmarking - Robert Stiefel
 - Cost of Ownership/Cost Effectiveness of Service Support - Denise M. Axelrod-Kahn
 - Tools for Technology Managers: Strategic Technology Planning - Yadin David, Ph.D.
 - Medical Equipment Service Contract Management - David Simmons



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CAP Abandons Ritual

Dave Francoeur

I was not happy with certain Questions contained in the Laboratory General Checklist used by the Accreditation Program of the College of American Pathologists. Specifically Questions 01.7135 and 01.7195 required that inspections be conducted on a yearly basis without any regard to an assessment of risks. I recommended changes to the College. Where 01.7135 asked that *electrical equipment be inspected annually for frayed power cords and intact plugs*, I recommended *patient care equipment be inspected prior to initial use, after repair or modification, and when a problem is suspected*. Where 01.7195 that checking for current leakage be performed *at least every 12 months*, I recommended *prior to initial use, after repair or modification, and when a problem is suspected*.

After discussions with CAP personnel, an exchange of correspondence, and deliberations by CAP, last week I received official notification of the implementation of my recommended changes. In his letter, Dr. Albert Rabinovitch, Checklist Commissioner of the Commission on Laboratory Accreditation, stated the following:

On behalf of the College of American Pathologists Laboratory Accreditation Program, I would like to thank you for your input to changes in the Laboratory General Checklist 1. Based upon your recommendations concerning electrical safety inspections, we have made changes to replace ritualistic checks with a more functional policy.

My success in affecting a change in overburdensome regulations should be an encouragement for all of us involved in medical device management. We should be involved in the creation and emendation of regulations and not merely confined to complying with them.

Editors Note: Dave didn't just sit around and complain about mindless procedures that consumed valuable time with little or no benefit. He did something about it. His conduct in this matter is admirable, an example of constructive professional involvement we should all strive to emulate.

Dave will have a Poster at the 1st ACCE Symposium in Philadelphia on May 30 where he will be available to discuss his work in affecting the above significant changes. We all owe Dave a vote of thanks.

The View from the Penalty Box

David Harrington, davesbt@kersur.net

I thank all who called and e-mailed on my last *View From The Penalty Box*. Your thoughts meant a lot to my wife and me. The good news is that she does not have to have chemo or radiation but has to be closely followed for the next five years. Hopefully nothing was missed during the surgery.

This past month has been a very strange one in the medical field. We saw one report stating that thousands of people are killed every year by drug reactions. The main question is how can this be blamed on the biomed? In the early 70's we got blamed for everything that went wrong in hospitals so it may be our turn again. We all know that the administrators won't take the hit. The nurses will simply say that they are over worked. The pharmacists will say they provided what the physicians called for. The insurance companies won't comment so I guess that just leaves us to take the hit again. What is really strange about this problem is that most hospitals have software that automatically checks for drug interactions and patient allergies in place. Since we are often responsible for the computers it must be our fault that the *professionals* don't use them.

There is a very real problem that we will have to respond to and that is the new high definition (HD) television systems that are starting to come into use. Many of you probably read about the problem at Baylor when a large majority of their patient telemetry channels were rendered useless when a local TV station started broadcasting HD images. [See FDA Advisory on page 12.] We all have been warned and it is up to us to contact the television stations in our area to find out when they will start the new broadcasting system and what frequencies will be used. Then we will have to rechannel the effected transmitters and receivers so the system will not crash and we will not look like dummies for not having prevented the problem. The best advice is to list all the telemetry frequencies that you have in use and determine which ones will be most likely effected by stations in your area. The engineers at the stations will be very helpful in answering your questions.

I must say that I am very impressed by the number of ACCE members that are doing presentations in Nashville and Philadelphia. I wish that more would write and publish what they are providing in the sessions. One major drawback that we have as a profession is the relative small amount of published material that is relevant to our day to day tasks. Please consider publishing your papers and sessions so more than the 20 or so attendees of the session can benefit from your knowledge. Our profession needs more of us to publish. I'm sure Joe Dyro, your *ACCE News* Editor would love to get material from you.

In closing, this past year has been a difficult one for many of us, with our jobs being outsourced, having to report to new administrators that have less of an idea of who we are and what our contributions are to modern healthcare, and our own self doubts that we are making a difference. But as someone that has seen what has been accomplished with the technology we support I can say we have and do make a difference. So don't be discouraged and keep on striving to be the best that you can be.



ACCE News

ACCE Board Highlights

April 8, 1998

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

President Frank Painter reported that the next Board Meeting and a general membership meeting will be held in Nashville, TN, during HealthTech '98. The ACCE Annual Meeting will be held on the evening of June 2 at the Marriott Hotel in Philadelphia. The usual gala reception will immediately precede the Meeting. Painter endorsed Marv. Shepherd's idea for a State of the Clinical Engineering Profession Address. He agreed to present this Address at the upcoming Annual Meeting. Mo Kasti, Marv. Shepherd and Tom Bauld will assist Painter in obtaining the pulse of the profession by means of questions targeted at the membership. Expect a report on this effort at the 1st ACCE Symposium on May 30 and at the Annual Meeting on June 2. **First Vice President** Jeff Secunda's report read by Jennifer Ott featured the following: internet options are being explored; past teleconference material is being reviewed; promotion of the 1998 teleconference series to begin; and FDA and Y2K are the leading topics. **Second Vice President** Mo Kasti highlighted the need to work on product development for members. He will seek standing discounts at such events as AAMI, HealthTech, AFSMI and ECRI and with companies that sell parts and test equipment. Kasti urged the creation of a task force to address quality standards for CE programs. He suggested ways by which the membership can register their opinions about services. **Secretary** Jennifer Ott is developing a plaque to award to ACCE Fellows. She described the first class nature of the gala reception immediately preceding the Annual Meeting on June 2. **Treasurer** Bryanne Patail reported a sound financial balance sheet with adequate reserves. The Board unanimously approved the recommendation, presented by Kelly Galanopoulos, Chair of the **Membership Committee**, of four new members. **Education Committee** Chair Jim Wear presented the topics for the 1998 teleconferences (see pages 4-5, this issue of *ACCE News*). Advertising plans were presented. **Advocacy Committee** Chairman Tom O'Dea voiced his concerns over the ebb in advocacy-based CE publications. Corporate sponsorship of upcoming events were discussed. **International Committee** Chairman Al Levenson announced his resignation. Jennifer Ott, General Secretary of the **First ACCE Symposium** confirmed that the Symposium is on track for May 30 (see advertisement on back cover of this newsletter). As expected, registrants are responding to advertising. Painter updated the Board on **Advanced Clinical Engineering Workshop** plans for November 1998 in Mexico City. Painter revealed that Joe Bronzino would like to host an ACEW at Trinity College in Hartford in the Spring of 99. Those interested in participating as faculty should contact Frank Painter. **Past President** Tom Bauld continues to incorporate committee comments on the Draft ACCE position, due in June, concerning the recently announced FDA ANPR. The ANPR contains provisions which could profoundly impact clinical engineering practice and adversely affect health care costs. The final draft will be sent to the membership and placed on the webpage. The Board unanimously approved funding **Web Meister** Bruce Morgan to move our present site to the new domain accenet.org. Jennifer Ott lead a brief discussion on clinical engineering distance learning by internet. **Member-at-Large** Dennis Minsent will work with Mo Kasti on developing technical teleconferences of benefit to BMETs. He assessed the AAMI SBET reengineering effort. The Board will meet next on May 5, 1998.



FDA Public Health Advisory

Interference Between Digital TV Transmissions and Medical Telemetry Systems

FDA has recently become aware of incidents involving digital television (DTV) transmissions interfering with medical telemetry systems that use TV channels. The purpose of this Advisory is to alert you to the potential for this problem and provide recommendations for your facility. In one case the telemetry system was operating on a TV channel which had been unused for many years but had been recently re-assigned by the Federal Communications Commission to a TV station in the vicinity of the hospital for DTV. The new TV signal interfered with the hospital's telemetry system and rendered it unusable. A second hospital in the same city was also affected.

Further information regarding this Advisory may be obtained by contacting Nancy Pressly, CDRH, Office of Surveillance and Biometrics, HFZ-510, 1350 Piccard Drive, Rockville, MD 20850, 301-594-2968 fax or nap@cdrh.fda.gov.

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Calendar of Events

- 1st ACCE Teleconference, *FDA Issues* presented by Tom Bauld, May 21, 1998. Contact James O. Wear, 501-370-6618.
- 5th Annual Diagnostic Imaging Technology Education Conference, DITEC '98, May 27-29, 1998, Cleveland, OH. Contact ditec@usa.net.
- ACCE: First ACCE Symposium, May 30, 1998, Philadelphia, PA. Jennifer Ott 314-577-8018 phone; 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. Jennifer Ott 314-577-8018.
- 2nd ACCE Teleconference, *Year 2000 Issues* presented by Steve Wexler, June 18, 1998. Contact James O. Wear, 501-370-6618.
- The Seventh Annual National Expert Witness and Litigation Seminar, June 18-19, 1998, Hyannis, MA. 508-457-1111 phone; 508-540-8304 fax.
- 3rd ACCE Teleconference, *ACCE Symposium Recap* presented by Ira Tackel, July 16, 1998. Contact James O. Wear, 501-370-6618.
- Technology Management in Health Care Systems, July 18-19, 1998, Bangalore, India. Dr. T.G. Krishnamurthy: clinic@aictb.emet.in.
- Annual Meeting, American Society of Physicists in Medicine, Aug. 9-13, 1998, San Antonio, TX. Phone 301-209-3350.
- 2nd Annual Orthopaedic Tissue Engineering, Aug. 10-12, 1998, Boston, MA. <http://www.biotech.nmhcc.org>; 888-670-8700 phone.
- 4th ACCE Teleconference, *ISO 9000* presented by David Simmons, August 20, 1998. Contact James O. Wear, 501-370-6618.
- Beacon Biosensor Symposium, October 2, 1998, Trinity College, Hartford, CT. Laurie MacFarlane: laurie.macfarlane@trincoll.edu; 860-297-5364.
- Biomedical Engineering Society Annual Meeting, Oct. 10-13, 1998, Cleveland, OH. Info: 216-444-5696 or 800-762-8173, 216-445-9406 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>.
- Advanced Clinical Engineering Workshop, Nov. 4-10, 1998, Mexico City. Joe Dyro 515-751-7244; jfdyro@aol.com.
- XXI National Biomedical Engineering Conference, Nov. 11-14, Mazatlán, Mexico. Info: Roberto Ayala at cmt@DNS.dsinet.com.
- IV International Conference on Clinical Engineering, Nov. 11-12, 1998 Mazatlán, Mexico. Adriana Velázquez at adrianavb@compuserve.com
- 18th Annual Northeastern Biomedical Symposium, Nov. 9-11, 1998 Albany, NY. Info: Ronald Hulin 518-525-1799; ibs98@aol.com.
- WSC '98, 1998 Winter Simulation Conference, Dec. 13-16, 1998, Washington, DC. <http://www.wintersim.org>.
- XXVth General Assembly of the International Union of Radio Science, Aug. 13-21, 1999, Toronto, Canada, 613-993-7271; ursi99@nrc.ca.
- BUDAMED '99, September 13-15, 1999, Budapest, Hungary. <http://www.fsz.bme.hu>; arato@fsz.bme.hu; (+361)463 2699 phone; 2204 fax.

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ACCE News

Don't forget!



ACCE Philadelphia Events

- ◇ May 30 9 AM - 2 PM **1st ACCE Symposium**
Thomas Jefferson University, Bluemle Life Science Bldg., Rm. 101
10th St. between Walnut and Locust
- ◇ June 1 6:00 PM **Board Meeting**
Philadelphia Marriott, 1201 Market Street
- ◇ June 2 6:30 PM **Gala Reception**
Philadelphia Marriott, 1201 Market Street
- ◇ June 2 7:30 PM **General Membership Meeting**
Philadelphia Marriott, 1201 Market Street



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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 Greg Davis**. 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.

Places are limited, so register **early** for this important event.

ACCE Members --- Before April 1: \$50; After April 1: \$60
Others --- Before April 1: \$60; After April 1: \$75; Students: \$30

Reserve your place! Complete and send above form! Register today!