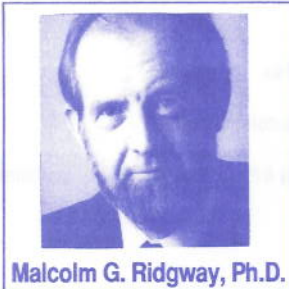


ACCE News

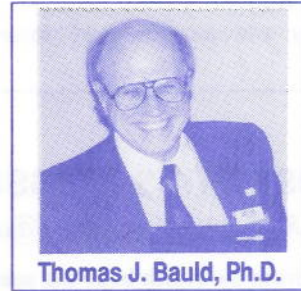
Vol. 8, No. 2 - March 1998

First ACCE Symposium — Philadelphia 1998



Malcolm G. Ridgway, Ph.D.

Malcolm Ridgway, Tom Bauld, Greg Davis and Larry Hertzler are featured speakers at the First ACCE Symposium on May 30, 1998, in Philadelphia, Pennsylvania at Thomas Jefferson University. Ira Tackel will host and moderate the proceedings. Be part of the brainstorming to develop effective strategies to excel in today's competitive environment. Engage fellow members in a think tank



Thomas J. Bauld, Ph.D.

environment to create position statements on rightsourcing and future directions for clinical engineers. Register today! See page 16 for registration information.

FDA Fact Sheet on Servicers of Devices

Tom Bauld presents details of impending regulations which if approved without emendation will have a profound effect on clinical engineering practice and will escalate the cost of healthcare. See inside page 7.

Vision 2000 Assessed

Mo Kasti presents a retrospective on the Vision 2000 project and points the way to continued success. See page 10 for details.

Clinical Engineers Week

Successful celebrations of Clinical Engineers Week were held across the country. Inside we feature two groups that accomplished much in promoting clinical engineering to their peers and to the general public. See inside page 4.

American College of Clinical Engineering

First ACCE Symposium

my career?
right source?



Today's leaders in
clinical engineering
point the way to

mergers?
my job



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

The bitter blasts from the North belie the season of new life about to burst forth. This issue of *ACCE News* gives evidence that ACCE is alive with many sound initiatives and its members are providing the kind of professional support and advocacy that we need.

Make sure you send in your 1998 dues if you have not already done so. A membership renewal statement is inserted in this copy of the *ACCE News*. Keep up your efforts to explain the benefits of ACCE membership to your colleagues. Give a membership application to a colleague today.

Plans are on track for the great First ACCE Symposium at Thomas Jefferson University in Philadelphia. This is a fine chance to hear Ridgway, Bauld, Hertzler, Davis and Tackel provoke us, inspire us and guide us through a brainstorming session which will result in a clearer vision of where you and I are going with our careers. We hope you will contribute to the lively discussions sure to take place. I look forward to meeting you all at the Symposium and the Annual Meeting in Philadelphia, May 30 and June 2, respectively. See you all there.



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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(206)236-0628 tel/fax; info@morsemed.com; www.morsemed.com

Letters

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

Slowest arm in the world

Sir--I should like to call your attention to an error in the January issue. The **Clinical Engineering Profiles** feature on **Bob Morris** contains an erroneous sentence that reads "He is falsely reputed to have one of the slowest arms in the United States when it comes to picking up a bar tab". Based on reports from around the WORLD, Bob has the absolutely slowest arm when it comes to picking up any tab, not just a bar tab. I am sure Bob would want that correction made.

Dave Harrington
SBT Technology, Inc.

Provocative appendages

Sir--In one of last year's issues of *ACCE News*, Marvin Shepherd suggested that engineers were more likely to respond to the ideas in articles if authors omit their credentials and add their e-mail addresses after their name.

This has to be provocative. Clinical engineers do not respond because, according to an AAMI survey, they only scan the journals and they don't write since they don't have the time.

With regard to the non-use of credentials, this would probably be well accepted by the less gifted, but bad at the professional level. Some scorn advanced academic degrees, claiming that experience is a better measure and that credentials have limited payoff with examinations that do not relate. Yet most professions rely on such credentials for setting up their exclusivity.

Also worth considering is the thought that an idea is more likely to be accepted if the presenter has a prestigious position or credentials that label him or her an expert in the field. Unfortunately our positions in the hierarchy are hardly prestigious, so we better hang on to our credentials; and if they do not relate, it is up to us to see that they do.

Michael Shaffer, NEMA
Boca Raton, Florida
(no e-mail address)

National Clinical Engineering Week

Sir--February 22-28, 1998 marked the third annual celebration of Clinical Engineering Week. Clinical engineers and biomedical equipment technicians are professionals dedicated to maintaining a safe and cost effective technical patient environment in healthcare institutions. They are qualified by education and experience to specify, test and maintain patient care equipment and can obtain voluntary certification in clinical engineering and biomedical equipment technology. Recently, these professionals have published on the effects of the building environment on patient outcome, the interaction of cell phones and other radio devices on patient devices such as pacemakers and implantable defibrillators, and human factors and the education of clinical equipment users. Healthcare institutions may obtain such

services internally, through the corporations through which they are managed, or from third-party vendors. In this era of shrinking capital and operational budgets, it is especially important for the patient that hospitals have access to clinical engineering professionals. In the face of a national trend of decreasing clinical engineering support, these dedicated professionals deserve the support of the healthcare community and the general public as they continue to minimize risk to patients from patient care systems.

Tom O'Dea
Chairman
ACCE Advocacy Committee

The Case for Clinical Engineering

Tom O'Dea, ACCE Advocacy Committee

Articles recently published in the *Journal of Clinical Engineering* emphasize the importance of clinical engineering¹⁻⁴. These articles include the following: interaction between building power quality and medical equipment and intensive care environments; the interaction of building ventilation systems and immunocompromised patient infections; and the evaluation of non-invasive detection of penetrations in protective gloves; improvement of operator performance through application of human factor engineering to medical device alarms. These articles demonstrate that the application of engineering principles to technical issues in the hospital environment can improve safety and performance, both operational and financial. Therefore, it would seem logical that hospitals and other health care institutions should insure access to clinical engineering and biomedical equipment expertise that is familiar with the operating environment of the specific institution(s). This expertise may be obtained in-house, in the corporate structure, or through third party contract, but should have a high residential presence, conversant with both the environment and staff of the particular institution. It would seem from recent impressions that the hospital trend is away from such familiarity from a mistaken impression that patient care is more cost effectively given without such resident expertise.

Fortunately, dedicated professionals exist in the clinical engineering and biomedical instrumentation fields. Proficiency gained by education and experience can be corroborated by voluntary certification programs in clinical engineering and biomedical equipment technology. Excellent publications and professional organizations exist to further these fields. At this period of National Clinical Engineering Week, Feb. 22-28, 1998, I urge readers to actively promote the value of the profession to institutions, legislators and the general public. We should not let internal distinctions distract us from the value of the profession as a whole. Healthcare needs our expertise and we need to be proud of past accomplishments and actively promote our future.

1. Bert, R. Power Quality Issues and the Effects on Medical Equipment, *Journal of Clinical Engineering* (1997) Vol. 22(1), pp.35-40.
2. O'Dea, T. Protecting the Immunocompromised Patient: the Role of the Hospital Clinical Engineer, *Journal of Clinical Engineering* (1996) Vol. 21(6); pp. 466-482.
3. Zeng, S. Berardinelli, S. New Method of On-Site Detection of Non-conductive and Conductive Penetrations of Protective Gloves, *Journal of Clinical Engineering* Vol. 22(5); pp.298-307.
4. Haas, E. The Design of Auditory Signals for ICU and OR Environments, *Journal of Clinical Engineering* (1998) Vol. 23(1); pp. 33-36.

National Clinical Engineering Week

Washington Hospital Center Clinical Engineering Week Festivities

Caroline Campbell, cac1@mhg.edu

Once again the Honorable Mayor Marion Barry recognized February 22-28 as Clinical Engineering Week. His declaration incorporated ACCE's definition of a clinical engineer, specified the benefit of utilizing clinical engineering skills to the patient population in the District, and identified that this week is celebrated in conjunction with the American College of Clinical Engineering.

The Biomedical Engineering Department at the Washington Hospital Center used the week to promote the profession within the walls of the institution, within the District, and throughout the greater metropolitan area. A traveling display of technology was circulated through the equipment-intensive areas of the hospital. Through the display, equipment users had the opportunity to test their troubleshooting skills and to learn about the purpose and functions of clinical engineering. The Hospital Center has a formal mentoring relationship with Roosevelt High School and visits to this school were made. Students with an interest in technology were targeted and were provided with an interactive technology display and information about clinical engineering.

The local BMET Society also met at the Washington Hospital Center at which Endocare presented the anatomy of an endoscope. The many visual displays provided by Endocare helped the group to understand how delicate and susceptible to damage the instruments are. Vendors showed their support of the recognition effort by sponsoring lunches and lectures for the Biomedical Engineering staff throughout the week. This third annual celebration of Clinical Engineering Week at the Washington Hospital Center was again successful in advocating the profession. We at the Hospital Center challenge all of our colleagues across the nation to sponsor their own events next year.



The Clinical Engineering Department of Washington Hospital Center

Michigan Celebrates

Thomas J. Bauld, III, Ph.D., bauld@umich.edu

The Southeastern Michigan area was again a major focal point for the celebration of Clinical Engineering and Biomedical Technology Week and National Engineers Week. The Michigan Society for Clinical Engineering (MSCE) continued its six-year tradition with several special meetings focusing on technology issues affecting hospital patients and staff.

The first event was a presentation on operating room fires by ACCE member, Mark Bruley of ECRI. The effects of oxygen enriched environments and ignition sources were detailed along with fine magic tricks. The meeting, held at the John H. Dingel Veteran's Hospital in Detroit, was hosted by ACCE member, Dr. Paul Ostrowski. Later in the week, Paul received the coveted Gold Award, the highest honor of the Michigan Society of Clinical Engineering. The presentation was made at the Annual Affiliate Society banquet of the Engineering Society of Detroit.

Dr. Thomas J. Bauld, III acknowledged the many contributions of clinical engineers and biomedical technicians on the University of Michigan's Public Radio station. The message was aired eight times on Wednesday, February 18th, the middle of Clinical Engineering Week. Several people who heard the message remarked later that they appreciated both the initiative and the content.

The final event of the week, a talk by Martina O'Brien of the University Medical Center, Tucson, Arizona, addressed the Year 2000 problem. Martina explained not only the subtle and direct issues with some medical devices, but the possible larger impact on hospitals and other facilities if key utilities and communications services are disrupted. Over sixty were in attendance including several information technology professionals from the University of Michigan Health System in Ann Arbor and local hospitals.

Thanks go to the MSCE planning committee for providing the leadership and resources to make the presentations possible and for selecting such highly qualified and informative speakers for Clinical Engineering Week 1998.

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

Dennis Vanderheyden

Paul Sherman

Philips Langland

Abdul S. Bukhari

Associate Members

Alexander Sensenbrenner

Ayaz Ahmed Malik

*Congratulations,
new members!*

Dyro is Fellow

Dr. Joseph F. Dyro has achieved ACCE Fellow Status. An S.B.E.E. from MIT and Ph.D. in Biomedical Engineering from the University of Pennsylvania, he has devoted over 25 years to advancing the field of clinical engineering. A Founding Member of ACCE he has served as President and currently is Editor of *ACCE News*.

ACCE Members at HealthTech '98

Many ACCE members will contribute substantially to the success of the upcoming HealthTech '98. **Dr. Yadin David** will do a workshop, *Real Telemedicine Applications and Issues*. **David Dickey** will present on *Documentation and Service Cost Analysis*. **Mark Bruley** will discuss *Medical Device Accidents: Investigative Considerations for Service Organizations*. **Scott Segalewitz** and **Ira Tackel** will join **Bruley** on a panel addressing *Everything You Always Wanted to Know About Sourcing Parts But Were*

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Afraid to Ask. **Dr. Tom Bauld**, **Elliot Sloan**, and **Dr. Binseng Wang** will lead the discussion on *Regulation of Biomedical Services*. President **Frank Painter** will reveal *An ISO for the Year 2000*.

Galanopoulos New Membership Chair

Kelly Galanopoulos has accepted the ACCE Membership Committee Chair position. Her appointment took effect immediately following the February ACCE Board meeting. Kelly has been a long-time ACCE member and has served on the Membership Committee for over six years. Her knowledge of committee responsibilities and procedures coupled with her enthusiasm and delight in helping ACCE in this capacity bodes well for an effective tenure.

Porras ACCE Member-at-Large

Brian Porras fills the position recently vacated by Tom Judd. Brian is active in the the ACCE Vision 2000 project and in workshops and teleconferences.

Betts to Premier

Bill Betts joins Premier in San Diego as Western Regional Director for Clinical Technology Services. He leaves Tucson where he was Director of Technology Management at Tucson Medical Center and, previously, Associate Director of Materials and Clinical Engineering at University Medical Center. He has an M.S. in Electrical Engineering and an MBA. He is a registered professional engineer and a certified clinical engineer. He has over twenty-four years of experience in clinical engineering and is a member of the AAMI Board of Directors and is currently the Treasurer/Secretary. He is also the immediate Past Chair of the International Certification Commission and is the incoming Chair-Elect of the AAMI Board of Directors. He has also served as

ACCE Membership Committee Chairman. Phone: (619) 481-2727, fax (619) 481-8919

Painter Speaks at AFSM International

ACCE President **Frank Painter** was invited speaker at the AFSM International's Fourth Annual Conference on Healthcare Services, March 14-17. His paper, *Reengineering the In-house Bio-Medical Service Organization*, showed how a hospital with a skilled biomedical service organization can convert from being exclusively in-house oriented to include other medical facilities in the same geographic area.



Frank Painter

Morris on the Move

Bob Morris writes, *I'm off to Ethiopia tomorrow, returning on 23 Feb. I will be in Singapore from 27 Feb. to 8 March and in Belize from 20 March to 2 April. Someone has to do it.*

Ostrowski Gets Gold

Dr. Paul Ostrowski received the coveted Gold Award, the highest honor bestowed by the Michigan Society of Clinical Engineering. The presentation was made at the Annual Affiliate Society banquet of the Engineering Society of Detroit.

Meetings

AIMBE Council of Societies

Caroline Campbell, cac1@mhg.edu

The Council of Societies of the American Institute of Medical and Biological Engineering (AIMBE) met on Sunday, March 1, 1998 in Washington, DC. ACCE is one of 15 member societies. AIMBE is considering making a national PBS series which follows a patient through the healthcare system. The objectives of the series will be to teach some principles of science and technology and to give a historical perspective of technology's impact on healthcare. This is a project which has been previously discussed among the ACCE membership. Given the projected costs of \$4000/minute or \$150,000/program, this effort is probably too expensive for any individual society and hence is a prime example of the benefit of a collective group of societies such as exists within the AIMBE. At next year's AIMBE Annual Event, a group will assemble to discuss themes, funding, and appropriate media groups. ACCE will be represented at this meeting as well.

A Summit meeting will be organized in the spring to discuss the contents of a consensus document supporting a Center for Bioengineering that serves as a repository of information regarding what is being supported by NIH. A draft of the proposed paper was distributed for review. Methods of technology transfer will also be discussed at the Summit meeting. For more information about AIMBE, visit the website which is linked to ACCE's website.

BECON Meeting at the NIH

William A. Hyman, Ph.D., w-hyman@tamu.edu

BECON, the Bioengineering Consortium, an inter-institute entity created at the National Institutes of Health, held its first formal symposium February 27-28 entitled *Bioengineering - Building the Future of Biology and Medicine*. The symposium was primarily oriented toward guiding the NIH's research agenda in bioengineering related topics, and thus had a relatively long-term perspective relative to what will emerge in the clinical setting. Projections of particular interest to clinical engineering include rapidly expanding amounts and types of data from diagnostic devices and the prospect of

future implants being partially comprised of living tissue. Thus, the next generation of such living devices will present very interesting challenges for on-site *maintenance* prior to use. For more information contact the BECON website at www.nih.gov/grants/becon/becon.htm.

AIMBE Annual Event From Gene to Function: Role of Bioengineering

Joseph F. Dyro, Ph.D., CCE, jfdyro@aol.com

This year's Event focused on the effort to move from newly discovered genes to expressed proteins and their function in normal function and disease. The Genes to Health Initiative and Functional Genomics, a.k.a. PhysioMe Project, is becoming a multinational scientific movement involving academics, industry and government agencies. The goal is to provide scientists, physicians, teachers, and industry functional descriptions that can be used to enhance design of experiments, aid the diagnosis of disease, plan appropriate medical/surgical interventions, and screen drugs. The first meeting session presented experimental studies of the translation of genes into function, integrative computational models, and databasing of fundamental observations. The second session dealt with the impact on industry and the potential role of NIH in carrying out the project. The final session, addressed ways in which FDA should prepare for the new technologies.

A forum, convened to discuss issues in academic-industrial relationships and technology transfer, featured speakers William Hende, Medical College of Wisconsin; Paul Citron, Medtronic; Douglas Lauffenburger, MIT; Dane Miller, Biomet; Al Potvin, MEECO; and Subrata Saha, Clemson University. All acknowledged the increased financial pressures upon academia and industry particularly exacerbated by managed care initiatives and rising cost of technology. The rising complexity of medical devices demands increased academic support. Academics are typically unfamiliar with issues of confidentiality, right to publish, indemnification and conflict of interest. Academia values federal support, e.g. NIH, more than industrial support because the former is peer-reviewed. Citron contrasted the

widely differing missions of academia and industry. The former expects to expand knowledge and to publish rapidly. The later needs to make profits and to reinvest in research and development. Industry support of academic research often yields intangible benefits. Academics in attendance were surprised to learn that the discovery/research phase consumes only 5% of the cost of bringing a medical device to market. Dr. Potvin revealed that when a company considers funding academic research its MBAs look not at the initial 5% cost outlay but rather the 95% required to later achieve a marketable product. Potvin stressed that personal relationships ultimately cement academic-industry agreements and aid in slicing through administrative and bureaucratic red tape. Lauffenburger stated that MIT prefers to deal with individual partners rather than with consortia comprised of companies. Individual companies as advisory board members pay no dues. Their participation leads to relations between researchers and the company.

New York Metropolitan Area Clinical Engineering Directors

Ira Soller

The New York City Metropolitan Area Clinical Engineering Directors Group met on February 3, 1998. A presentation on the Biophysics of Electro-surgery was given by Roger Odell Chairman of the Board of ElectroScope and Herb Etzold President of Armac. This was followed by member discussion which included Year 2000 and its effect on medical instrumentation, wireless LAN, recent JCAHO inspections, and possible FDA servicer regulation expansion beyond manufacturers. The meeting was hosted by ACCE member Mike Mirsky of St. Luke's Roosevelt. Other ACCE members in attendance included Nicholas Pinto and Michael Lauria. The next meeting will be held on March 24, 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.

ACCE Fact Sheet

Proposed FDA Regulation of Remarketers and Servicers

Thomas J. Bauld, Ph.D., bauld@umich.edu

Proposed Regulatory Issue

- ☞ The FDA is considering developing regulations to cover the business practices of remarketers and servicers. Either regulatory requirements similar to the Good Manufacturing Practices recently developed for manufacturers or a voluntary process are options the FDA will consider.
- ☞ They have issued an Advanced Notice of Proposed Rulemaking (ANPR) to inform the medical community of their intention to proceed with regulations. The FDA is requesting feedback from medical device users, remarketers, and servicers on whether regulation is needed.

FDA Justifications & the SMDA Experience

- ☞ The FDA has not presented any evidence of injuries or deaths to patients that would justify the imposition of any regulations. There are no examples to evaluate or upon which to comment. The FDA has over 600,000 Medical Device Reports (MDRs) from manufacturers that can be reviewed to find examples.
- ☞ The FDA ANPR document refers to “competitive and other issues” and “evolving industry practices and concerns raised by the GMP Advisory Committee.” These are not explained to allow comment or rebuttal. These vague and unspecified comments dealing with competitive activities should not form the basis for regulatory action.
- ☞ Phil Frappaolo, a Deputy Director of the FDA, has cited a 1994 fire in a NY hospital as a seminal event triggering the FDA to question why in-house servicers were not being inspected.
- ☞ Investigation of that fire revealed its cause had absolutely nothing to do with a device failure or improper servicing. The incident cited is absolutely irrelevant. From one source, we found there was one problem found in the fire investigation that was related to a facility deficiency.

Industry Segments:

Remarketers and servicers perform totally different functions and must be treated differently in any regulatory or voluntary compliance process.

- ☞ Remarketers acquire and sell medical devices. They take ownership and later transfer that ownership to others. Servicers perform repairs and maintenance for the current owners of equipment that is in active clinical use.
- ☞ Hospitals are not in the remarketing business except incidentally and then only as “as is remarketers.” They dispose of surplus equipment by sale or donation, often to assist other institutions locally or internationally or to recoup a small portion of their initial capital investment.

Why Regulation is Not Needed for Servicers

- ☞ There are voluntary standards developed by groups such as the JCAHO, CAP, AOA, and the National Commission on Quality Assurance (NCQA) for HMO's that healthcare institutions use as part of their quality processes. They are intended to assure quality care and continuously improve patient care and the management of the equipment used in patient care.
- ☞ There is little evidence that actions by servicers contribute to patient risk. Quite the contrary is true. Lack of appropriate service is likely to result in increased risk of device failure in clinical use. Many articles exist about incidents and accidents related to the lack of servicers in the early 1970-80.

JCAHO Impact on Servicers

- ☞ In-house and third-party servicers (ISOs) must conform to the hospital's Equipment Management Plan as part of the Environment of Care Standard.
- ☞ In-house and contract workers must show evidence of appropriate training and continuous education. Job descriptions must match the staff activities.
- ☞ If JCAHO accreditation is not achieved, hospitals face severe financial penalties. They will not be reimbursed for services provided to Medicare and Medicaid patients. Insurance payers will strongly reconsider their contracts for care to their insured patients.

Liability Issues:

- ☞ Hospitals face extreme financial and public relations impacts if patients are found to be injured due to negligence in device servicing. Lawsuits are a continual threat. Malpractice awards are often in the multi-million dollar range.

Other Influential Factors:

- ☞ State licensure of healthcare institutions are in place in California, Arizona, New York and Georgia. These states represent 20 % of the U.S. healthcare system. Their inspectors typically direct their focus upon maintenance issues.
- ☞ Certification of service professionals by the International Certification Commission is a major form of self regulation that a large percentage of biomedical/clinical engineers and biomedical technicians pursue to demonstrate their professional skill and knowledge of the field.

Suggested Actions:

- ☞ The FDA should regulate any remarketers that perform maintenance, refurbishment, or reconditioning of medical devices. Some portion of the GMP regulations seem needed.
- ☞ There is no need nor benefit to impose FDA regulation on servicers. The current JCAHO voluntary accreditation process is adequate for this group.
- ☞ For institutions not accredited, perhaps their servicers could be listed with the FDA.

Clinical Engineering Week Some Ideas

Tom O'Dea, odeat@msn.com

National Engineering Week, February 22-28, 1998, has just passed. Celebrations of clinical engineering were organized by many of our ACCE members. The activities served to advocate clinical engineering. While special events may have been scheduled for this Engineering Week, our efforts to advocate should continue throughout the year. The following is a list of suggestions that will help you in your advocacy efforts.

- * If National Engineering Week doesn't work out as your Clinical Engineering Week (CEW), do another week
- * Have fun. Whatever change this celebration engenders will take a while. Use CEW to cement relationships.
- * Allow all involved in clinical engineering and biomedical equipment technology to participate as equals. Actively seek out and encourage facilities management and information services to join CEW. This is not the time to be provincial.
- * Stress that both CEs and BMETs have helped patients by enhancing safety and service and have resulted in better cost/benefit ratio for the hospital. These facts could be stressed to both the health care community and the public.
- * It is entirely appropriate to mention that there has been a trend toward diminished CE/BMET presence in healthcare institutions and that this trend is not in the best interests of the healthcare institution or the public.
- * The source of CE/BMET support, whether from in-house, corporate structures or third-party organizations, is not the issue. From wherever the source, CE/BMET support must know the facility, equipment, systems, staff and patients of the specific institution. CE/BMET expertise is not generic.
- * Certification is voluntary but not a requirement. However, CE/BMET expertise is gathered by education and experience and certification is one way of verifying that expertise.
- * Write about your unique experiences. Publish, speak, discuss. You have much to offer the profession.
- * Have fun, be proud, and strive to advance the profession in your own unique way.

TSM Achieves ISO 9002

John O'Donnell, odonnj@holycrosshealth.org

Technology Services Management (TSM) of Holy Cross Hospital of Silver Spring, Maryland has achieved the stringent level of quality assurance certification - ISO 9002. This level of certification combined with the effort of the strong technical and management team committed to quality and a highly trained work force, ensures the highest standards of quality achieved.

TSM received ISO 9002 certification from TUV Germany on December 22, 1997. TSM is the first in-house healthcare service team to receive this certification. This is an industry standard which defines a quality management system in which all processes that affect quality are required to be repeatable and performed with a controlled, documented procedure.

ACCE member, **John O'Donnell**, Director of TSM, selected this approach as the way to demonstrate the quality of his service team to outside organizations. The approach also insures that the customer will get the same quality service independent of the technician or engineer providing the service. Some key highlights of the TSM approach to ISO include computerization of the documentation and a quality monitoring system. The system was a collaborative effort involving all the employees of TSM. The team members, not the Director, defined the processes. For questions and further information, call John O'Donnell at 301-754-7300.

The Seventh Annual National Expert Witness and Litigation Seminar

June 18 and 19, 1998

*The program for Experts, Trial Attorneys and
those who employ them*

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- Persuasive courtroom graphics and multimedia
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CLINICAL ENGINEERING PROFILES

Thomas J. Bauld, Ph.D.

Extraordinary Clinical Engineer and a Good Scout

Tom received the BS in Electrical Engineering and Ph.D. in Biomedical Engineering from the University of Pennsylvania in Philadelphia. While a Junior at Penn he was honored with the Junior Merit Award from the Engineer's Club of Philadelphia. As a Senior, he was President of the Penn Chapter of Eta Kappa Nu, the electrical engineering honor society. He was inspired to pursue a career in biomedical engineering by a professor, David Geselowitz, who taught a senior introduction to bioengineering course. His Ph.D. thesis research involved ultrasound measurements of the lung. One of his other achievements at Penn, was that he was 9 and 0 as pitcher in the engineering graduate school softball league in the summer of 1970. The Biomedical Engineers were undefeated that year. One of his team mates at third base was his best friend, Joe Dyro.

His first professional position was at Sinai Hospital of Detroit over twenty years ago where he started a department which grew to a staff of nine serving that 550-bed hospital. While at Sinai, he developed a strong student internship program with its next door neighbor, the A. Philip Randolph Vocational High School, providing career opportunities for many of their students.

In 1976, Tom was one of the founders and the first President of the Michigan Society for Clinical Engineers. The MSCE continues as a vital, active organization that co-sponsored three Midyear Meetings in collaboration with the Association for the Advancement of Medical Instrumentation. He co-chaired each of the Regional Meetings, in Detroit 1983, in Dearborn 1990, and again in Dearborn in October, 1990. After many years where membership in the MSCE was limited to engineers and department directors, Tom led the effort to expand the organization to serve all those interested in the field including biomedical technicians as well as engineers. The organization also changed its name to the Michigan Society for Clinical Engineering.

He has been active in AAMI ever since he graduated from Penn. In 1985, he received the AAMI Clinical Engineering Achievement award. At that time it was granted only once every five years. He was a member and then chair of the AAMI Education Committee, served as a Board Member, and as the Vice President for Clinical Engineering. In 1989, he and Lloyd Marks co-chaired the AAMI Annual Meeting in St. Louis. He also served as chair of the AAMI Foundation Awards Committee for three years.

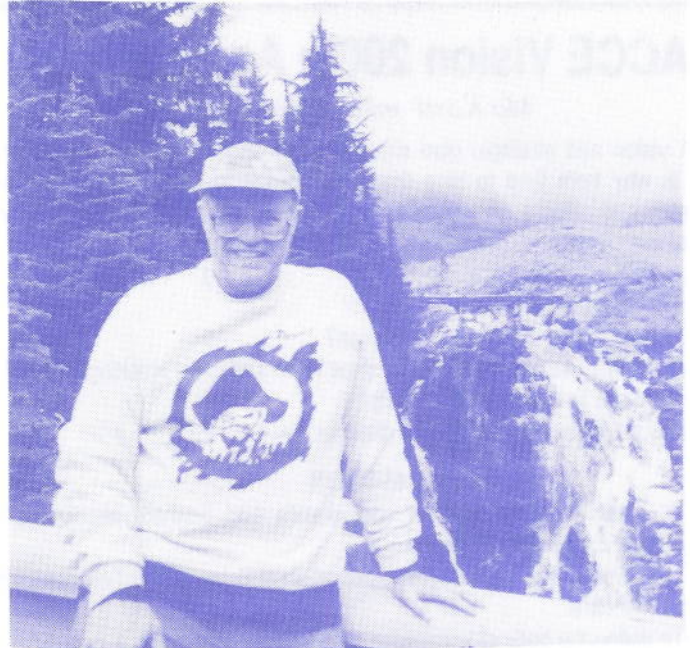
Tom has been a collaborator with many physicians over the years. He has participated in medical research on non-invasive measurements of the His-Purkinje electrical conduction system of the heart, measurements of the fontanel pressures of infants, and quantifying the dynamic response of blood pressure monitoring systems used in operating rooms and intensive care units.

Tom has produced a diverse range of writings including a monograph on developing in-service education programs for nursing and a description of the measurement of productivity in biomedical engineering departments.

In support of the education of BMETs, he helped secure the donation of a complete intensive care bedside monitoring system from Spacelabs Medical for use in the laboratories of Schoolcraft Community College, the local college in Southeastern Michigan training biomedical equipment technicians. Recently a similar equipment donation was arranged by Tom for the Biomedical Engineering Instrumentation Lab at the University of Michigan.

As part of an effort to promote the profession of clinical engineering, Tom was active in the inception of and a founding member of the American College of Clinical Engineering in 1990. He was on the Board for three years and then served two terms as the ACCE President. He led the committee which developed the Definition of a Clinical Engineer which has been accepted by all major organizations in the field, both in this country and abroad.

Because of the efforts of a Quality Improvement Team in his department



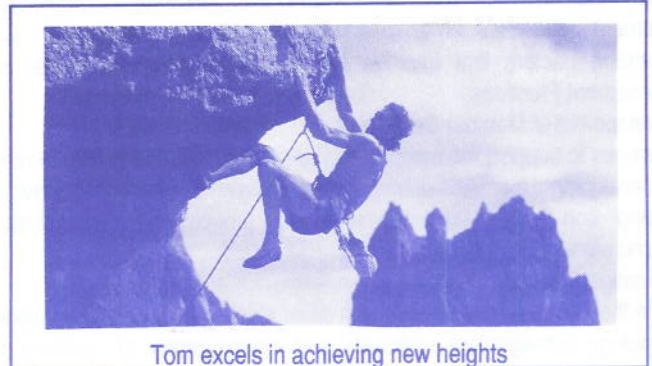
at the University of Michigan Health System, Tom was deeply involved with the development of a new BS Degree in Engineering Technology at Eastern Michigan University. There are now two degree programs, Biomedical Computer Engineering Technology and Radiology Imaging Technology available to professionals working in the field.

He has been the ACCE liaison to the American Institute for Medical and Biological Engineering (AIMBE) Council of Societies for several years. AIMBE is the umbrella organization that encompasses all aspects of the bioengineering field including the academic institutions, industrial concerns, and professional societies. In 1996, Tom was honored by being elected to the College of Fellows of the AIMBE. He joined an elite group of clinical engineers represented in that organization.

For the last ten years, Tom has been an adult leader with the Boy Scouts of America. He began with Cub Scouts with his son, Patrick, then moved into Boy Scouts, serving as a Scoutmaster for two years. For the last four years, has been a founder and Advisor for a High Adventure Explorer Post involved with rock climbing and caving. The adventures of the Post are exciting, slightly hazardous and have involved travel to at least fifteen states, and the rewards are terrific. Some of the nicest and most generous people Tom has met are cavers and rock climbers.

Tom has been married to his childhood sweetheart, Diane for over thirty-five years. It is amazing what a brief encounter on the boardwalk in Wildwood, NJ can lead to. "Say there! Do you have the time?"

Tom has demonstrated an exemplary dedication to the profession of clinical engineering and to the professional growth of all of its members.



Tom excels in achieving new heights

ACCE News

ACCE Vision 2000: Assessment

Mo Kasti, mkasti@aol.com

A vision and strategic plan should be an ongoing working document. That is why from time to time the board needs to take time and review progress and refocus resources and priorities. The following questions are part of such review we need to ask ourselves at ACCE:

1. Are we meeting our mission?
2. Are we getting closer to the Vision?
3. Are we accomplishing our initiatives?
4. Any major changes in the market since Vision statement requiring refocus?
5. What are the obstacles? Threats?
6. Any projects requiring priority changes?

MISSION

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

VISION

The American College of Clinical Engineering will actively promote and foster the role of Clinical Engineering in the business-oriented technology management process as an essential and integrated part of the healthcare system's core competency that enables cost containment and enhances quality and patient outcomes.

STRATEGIC INITIATIVES

I. Marketing/Public Relations

- a) Develop a public relations and an aggressive marketing strategy to demonstrate the use of technology as an enabler for change in healthcare.
- b) Assess the changing needs in the healthcare environment, identify new opportunities, and promote the skills and services of the membership.
- c) Coordinate grass roots efforts. It is the responsibility of every member to promote technology management.

II. Education

- a) The focus will be on providing tools for the membership that will elevate the expertise baseline and to enable them to play an active role in delivering technology management services in the changing healthcare environment.
- b) Activities will seek to improve the skills of the membership to appropriately manage technology.
- c) Areas that will be stressed include the following: Technology Management Business Practices; Benchmarking; Healthcare Cost Containment; Factors that Improve Quality and Patient Outcomes; and Reimbursement Practices.

III. Development of Member Services

New services to support the membership are to be developed. These range from developing business-oriented technology management models, developing and coordinating benchmarking processes, to coordinating efforts and eliminating duplicative work.

IV. Unification/Strategic Alliances

Integrate the efforts and resources with other existing organizations involved in technology management nationally and internationally to achieve the vision.

ACCOMPLISHMENTS

1. Marketing and Public Relations

- Development of the "What is a Clinical Engineer" Brochure
- Development of Materials for CE week.
- National CE Week Activities
- Publishing Abstract in AFSMI on Clinical Engineering as professional Services
- Presentation at AFSMI Meeting to OEM on the value of clinical Engineering under the Name ACCE. (Mo Kasti)
- Approximate growth in Membership of 10%

2. Strategic Alliances

- Government - Strong Government Relations group underway
- ASHE- Collaboration on conferences = Discount to members and ACCE exposure
- AAMI - cosponsoring meetings = ACCE exposure
- HealthTech -Cosponsoring meeting in San Diego = Discount and exposure
- AFSMI- Presentation to OEM on clinical Engineering Negotiation underway for collaboration and discounts
- FDA- Collaboration underway

3. Education

- A very successful Advanced Clinical Engineering workshop
- Audioteleconference
- A new Symposium

4. Member Services

- Newsletter
- Home page n Internet
- Grass Roots

Major Changes Since Original Plans

- SBET dissolved
- Market outsourcing booming
- Membership growth/decrease?

RECOMMENDATIONS

Refocus on the following projects for 1998

1. Membership:

- Corporate
- BMET Membership
- International

2. Marketing

- Conferences
- More Marketing- Advertising / display booth for conferences/
- Sponsor Speakers
- Incentives for publication
- PR to Corporate

3. Alliances

- FDA; AFSMI; International

4. New product developments -- *This is the key point: without new services, no value is or will be perceived by membership or new membership.*

- Certification
 - ⇒ individuals
 - ⇒ departments, programs
- Quality Standards
 - ⇒ Quality measures
 - ⇒ Benchmarking
- Discounts to Services / Products / Conferences

The View from the Penalty Box

David Harrington, davesbt@kersur.net

The Olympics are over and we saw that a group of highly paid professionals, great individual players, could not play and win as a team. Yet the women's hockey team, a group of dedicated players whom very few people ever heard of before, showed what team work can do. This is a lot like our profession, we have the high-paid superstars that get the publicity along with a lot of unsung heroes that do their job day after day to the best of their ability making health care better for all.

Several weeks ago a very nasty six-letter word, cancer, came into our household. For those of you that have never heard this word directed at you or a member of your family it is very difficult to express what that six-letter word can do to you. Those six letters change how you look at almost everything in life as we passed through the original diagnosis to the point of what and how do we tell the children and their spouses to what are the steps that need to be taken to beat these six letters. While I was playing hockey there could be 16,000 people screaming for someone to punch me out. No problem. In all my time in hospitals where administrators and everyone else was on me to perform another miracle with equipment that should have been replaced years before, nothing bothered me like those six letters. So what do you do? Being an engineer has certain drawbacks in situations like this. First you do the reading to see what the latest is on the treatment of the cancer, then you start calling all the people you have met over the years that may have additional information, compiling a data base of information that is vast and often contradictory.

As you sit talking with the physicians as they go over the treatment plan, your mind starts checking off all the points that you found during the research. You press the physicians on small points and totally forget the major points. In your mind all you can remember are all the bad things that can happen. You have to work to think positively, especially when talking with your spouse and family members.

After spending so many years in hospitals your mind zeroes in on the operating room. What ESU will be used? Will they put the dispersive electrode on right? When was the anesthesia machine last serviced? Are there problems with the lights? Will the blood be warmed? Are the IV pumps really checked or was a "pencil whip" PM done just to get the stickers done before JCAHO arrived? I have to admit that I talked with the biomed department before the procedure just to get a good sense on how they did their work. Then the mind goes to all the other departments and their equipment that will be involved. Who are these people? How well are they trained? Are they over worked and prone to mistakes? Sometimes being a clinical engineer can mean that you know too much about what can go wrong.

Then it hits you that there might be radiation involved. I was hired to run clinical engineering after a major accident in radiation therapy where a patient was killed by a botched repair/modification. Now I am really getting nervous.

Well, the day of the operation arrived, my wife was very nervous. I was jumpy but the OR door closed. Now our lives are in the hands

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and on the machines that neither of us can control. So now I have to find something to do to keep my mind occupied until the operation is over. Some 6 hours later I finally get to see my wife. There she lies, a groggy and hurting person who is not sure how she feels; but the insurance company says must go home in no more than 3 days. To make matters worse the pathology report will not be complete for at least 2 weeks, so the ordeal is not over yet. But she has received good care, all the equipment worked and now all we can do is wait.

As I look back at the events, it is a little like an out-of-body experience. There have been countless times that I explained to patients, family and friends who were having operations or treatments what each device did and why it was used. Now all those devices were used on someone with whom I have spent the last 34 years of my life. It sure is a strange feeling. Maybe we know too much and those who are not as knowledgeable as we accept that equipment in hospitals always works correctly. Have you ever seen a biomed or CE on a medical show? That must mean that the equipment never fails; right?

While nothing in life is certain, I am looking forward to another 34 years with Dottie and it is through the efforts of all of you, whether superstar or team player, that have healthcare technology has been pushed to a level where that will be possible. To all of you we say thank you and keep pushing that technology envelope so you and your loved ones can benefit as my wife and I have.



Advocacy Awards Applications Being Accepted

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.

ACCE News

Web Trappings

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

By the time you read this, there will have been over six thousand visits to the ACCE Web Site! Current issues of *ACCE News* are no longer being posted on the Web although archival issues will continue to be available. If you want the current issue, be sure your membership is paid.

A number of enhancements are planned over the next several months to better serve the members. First, a private **Members Only** section will be created, requiring a username and password for access. The membership list, and other items that the Board and members consider appropriate, will be included. Second, the site should have its own domain name (tentatively accenet.org) in the near future.

Also, a number of requests have been made for a **chat room**. This can be implemented. The only problem I see is that the members chatting must be on-line at the same time. It seems that separate **Message Centers** on specific topics would be more appropriate. These could be in either the public and/or private sections. If you have an opinion on this, please e-mail me at jmorgan@ibm.net.



ACCE Board Highlights

February 11, 1998

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

President Frank Painter reported a favorable resolution of the copyright issue with the World Health Organization permitting WHO to incorporate ACCE's *Guidelines for Donating Medical Equipment* into its publications. Letters have been sent to prominent clinical engineers inviting their application to ACCE. Painter reported that HealthTech is pleased that ACCE will attend HealthTech '98 in force. ASHE will host their MTM meeting in conjunction with HealthTech '98. Many ACCE members will speak at the May meeting in Nashville, Tennessee. Kelly Galanopoulos accepted the chair of the Membership Committee. Brian Porras has been appointed to fill the vacant Member-at-Large position. **Second Vice President** Mo Kasti reviewed the Strategic Plan document with the Board. See *ACCE Vision 2000 Assessment* on page 10. **Secretary** Jennifer Ott mailed directories to all 1997 members. **Treasurer** Bryanne Patail reported a sound financial balance sheet with adequate reserves. The Board unanimously approved the recommendation, presented by Bill Betts, Chair of the **Membership Committee**, of six new members and the elevation of Dr. Joseph F. Dyro to Fellow status. **Education Committee** Chair Jim Wear presented topics for future teleconferences. These include *FDA Issues; Future of Clinical Engineering; Year 2000; ISO 9000; Technology Assessment; Consulting Services; How to Start a Shared Services; and Organizational Shift from Non-Profit to For-Profit*. Jennifer Ott, General Secretary of the **First ACCE Symposium** detailed the progress made toward that seminal event to be held at Thomas Jefferson University in Philadelphia May 30. Panel members include Larry Hertzler, Malcolm Ridgway, Greg Davis, and Tom Bauld. Ira Tackel will moderate. **Advocacy Committee** Chairman Tom O'Dea sent articles to the *Journal of Clinical Engineering* and the American Society of Hospital Engineers outlining the ACCE advocacy program. International Committee Chairman Al Levenson is working on an Advanced Clinical Engineering Workshop in China. He discussed a brochure drafted to tout ACCE's ability to provide resources for third world countries. **Newsletter Editor**, Joe Dyro thanked the Board and members for timely contribution of material enabling issues to be mailed on schedule to members every two months. Dyro updated the Board on *Advanced Clinical Engineering Workshop* plans for November 1998 in Mexico City. **Past President** Tom Bauld presented a draft of the ACCE position concerning the recently announced FDA ANPR (see page 7, this issue). The ANPR contains provisions which would profoundly impact clinical engineering practice and adversely affect health care costs. The *ad hoc* Committee drafting the reply includes Greg Davis, Ethan Hertz, Jim Keller, Marvin Shepherd, Bob Morris, and Binseng Wang. The Board unanimously approved co-sponsorship of the forthcoming FDA Conference on the ANPR. **Member-at-Large** Dennis Minsent reported on the status of the reengineering of SBET. The Board will meet next on April 8, 1998.



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Calendar of Events

- 24th IEEE Northeast Bioengineering Conference, Penn State Univ., April 9-10, 1998, Seth Wolpert: 717-948-6752, sxw33@psu.edu.
- HealthTech '98, Nashville, TN, May 4-6, 1998, Information: 401-766-4142 phone; 401-765-6677 fax.
- National Conference on Medical Technology Management, Nashville, TN, May 4-6, 1998, Information: 312-422-3811.
- 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.
- 5th Annual Diagnostic Imaging Technology Education Conference, DITEC '98, May 27-29, 1998, Cleveland, OH. Contact ditech@usa.net.
- ACCE: First ACCE Symposium, May 30, 1998, Philadelphia, PA. Contact 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. 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.
- 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. Contact 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.
- XXVIth General Assembly of the International Union of Radio Science, Aug. 13-21, 1999, Toronto, Canada, 613-993-7271; ursi99@nrc.ca.

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For more information contact Symposium Committee Chair Jennifer Ott:
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