

# ACCE News

## *President's Message for the August 1993 ACCE Newsletter*

*Joseph F. Dyro, Ph.D., CCE*

August, 1993

Since the last newsletter, the Annual Meeting was held in Boston and your Board has met twice. The 85 members who packed the meeting were filled with enthusiasm and realism. Old acquaintances were renewed and many new faces were welcomed into the ranks. After a jovial, warm-hearted social hour, the meeting began with reports from the Officers. Membership is increasing and finances are sound. The Board announced a delay in annual elections. Tom Bauld, Ph.D., ACCE Vice President, discussed the preliminary results of the ACCE membership survey. Concerns over the need to promote advocacy were expressed. The participants in the ACCE Advanced Clinical Engineering Workshop were introduced.

Marvelous news has come out of Chicago! Ode Keil has informed me that the Joint Commission on the Accreditation of Health Care Organizations has adopted the ACCE definition of a Clinical Engineer and will include this definition in a soon-to-be published glossary of terms. JCAHO recognition of the definition should be wonderful news to those who labored so diligently to develop the definition. We can all breathe a sigh of relief in knowing that a universally acceptable definition has been successfully achieved and firmly established. JCAHO joins the IFMBE Clinical Engineering Division, the United States and the Canadian Board of Examiners of the ICC, and the Canadian Medical and Biological Engineering Society in accepting and promoting the ACCE definition of a clinical engineer. In a related action, the ACCE Clinical Engineer definition was printed in *Second Source Biomedical* (July/August 1993). In addition, in that article several members gave their perspectives on the future of clinical engineering. Thanks to Bob Morris, Ph.D., Ira Tackel, Tom Bauld, Ph.D., Yadin David, Ph.D., and Manny Furst, Ph.D. for promoting the profession in this way.

Tom Bauld's initiative and follow-through on the ACCE membership is remarkable. Thank you, Tom, for your efforts that show clearly the issues of greatest concern to the members of the College. The Board is

currently addressing the most important items: education; advocacy; communications; and future directions of clinical engineering. We plan to put programs into place this year to address all of the major concerns.

Dave Harrington did a splendid job in editing the ACCE News since the founding of the College. Thanks, Dave, for your selfless contribution of time, energy, and creativity. You recognized the News as the main instrument by which all members can feel a close part of the College. Dave Simmons has accepted the challenge of continuing the fine tradition of excellence. The new Dave will emphasize the role of the newsletter in getting people involved in an active way with the College and its many programs. Welcome, Dave Simmons. Just a suggestion—the best way for any member to acknowledge, support, and encourage the new Editor is to send material of interest to the editor. Dave wants to provide you with a vehicle for expression. Some helpful advice or commentary which has resulted from your experiences could benefit many if it is published for all the members to read.

A group of ACCE members attended the June 3, 1993, FDA meeting on MedWatch in Washington, DC. John Hughes, Tom Bauld, and Al Jakniunas attended the meeting. Their remarks from the floor

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clearly established the presence of clinical engineering and the ACCE at the meeting, and firmly underscored the importance of the clinical engineer in the process of medical device surveillance. The commentary appearing in this issue of ACCE News on MedWatch has resulted from the efforts of our members who attended the meeting. The ACCE Board has endorsed the concept of a committee to represent ACCE in Washington at meetings such as this. Members who live in the area are encouraged to get in touch with John Hughes who will coordinate this effort.

Thanks to the efforts of Ethan Hertz, timely revisions of the ACCE bylaws have been proposed. Members will be voting on the changes in the near future.

I thank Gailord Gordon for inviting the ACCE to have its annual meeting in connection with the meeting of the International Society for Technology Assessment, at his Kaiser Permanente Biomedical Engineering Center in California in 1996. As usual, Gailord has the big picture in sharp focus. The years ahead will require clinical engineers to contribute heavily to technology assessment in their respective institutions as just one more way to control health care costs. The Board is considering the offer and will report to the membership when a decision is made.

In a few days, I will be traveling to the International Clinical Engineering Workshop on Development, Assessment and Maintenance of Medical Instrumentation in Trieste, Italy, on September 16-17, 1993. There I will speak on the role of clinical engineering in economic conversion in the defense sector and departmental organization for effective medical device management. The workshop is endorsed by the ACCE, the Italian Association of Medical and Biological Engineering, the Center for Research and Study of Medical Devices, the Division of Strengthening of Health Services of the World Health Organization (WHO), and the Biomedical Equipment Assessment and Management (BEAM) - ECC Research Project. After the workshop I will spend two days at the IFMBE Clinical Engineering Division Board Meeting. At this meeting and workshop, the CED Board will present its International

Directory of Clinical Engineers. This useful resource, listing all clinical engineers worldwide, will be made available to all ACCE members.

I hope you all have had an enjoyable summer and were able to take some time to rest. I would encourage each of you to take a little time in the next few days and weeks to tell a clinical engineer you know who is not currently a member of ACCE about the College. Our membership is growing. As we join together in increasing numbers and act as a united body, each individual stands to gain in professional stature and quality of life.

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## *Vice President's Report* **FDA NEWS: The Federal Government Responds to ACCE Concerns**

ACCE President Joseph F. Dyro, Ph.D., sent a letter to Donna Shalala, Ph.D., Director of the Department of Health & Human Services describing ACCE's intent to participate in policy matters and its concern with the heavy FDA emphasis on enforcement activities. Phillip Frappaolo, the Deputy Director of the Office of Compliance and Surveillance in the Center for Devices and Radiological Health (CDRH), responded by thanking ACCE for the communication and inviting comment and collaboration on issues of mutual interest.

At the AAMI Meeting in Boston in a session on FDA Recalls, Chet Reynolds expressed his appreciation for the comments that the ACCE sent regarding the Draft Form for User Reporting of device problems. The content of ACCE's comments was described as valuable in the revision process.

Mr. Reynolds provided a detailed response to a personal letter I sent describing my concerns about the lack of FDA response to submitted comments, the severe impact of enforcement activities on companies such as Bunnel and Physio-Control, and the slowdown of 510(k) applications.

At the FDA Commissioner's Conference on the new FDA MedWatch Program, I expressed that ACCE was eager to assist and participate in supporting the FDA activity for voluntary device problem reporting.

### **Editorial Staff**

David Simmons, Sc.D., Editor	703-938-5227
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ACCE was invited to join as an official MedWatch Partner to help inform our members and motivate them to play a role in post-market surveillance. The ACCE Board has approved a motion that we become a MedWatch Partner.

We are making progress. The ACCE voice is being heard and considered in FDA activities. Our presence at the MedWatch Conference again demonstrated our commitment to understand, comment on, and support FDA programs. We must do more to ensure that our perspective is delivered and heard. Comments and suggestions to your Board and Officers are welcome.

### **FDA Civil Penalties for SMDA Infractions**

The FDA is developing regulations that deal with the process of appeal by healthcare facilities if and when the FDA imposes fines under the SMDA. Comments on these regulations were due July 26, 1993. ACCE chose not to submit a position. The decision about whether fines will be imposed will be determined after a study about the compliance in user reporting.

### **FDA Study Criticizes Data Presented in 510(k) Applications**

A recent report (referred to as The Temple Report) from the FDA described a study of the adequacy of the science and scientific methods found in applications for medical device approvals [510(k)s]. The conclusions were that many studies were poorly designed and implemented and that action will be required by the agency to improve the quality and content of the submissions.

While stating in the MedWatch Conference that methods would be introduced to speed up the 510(k) approval process, the implication from the Temple report is that better study design, increased detail, and improved supporting data may require longer time for the manufacturers to collect and longer time for the FDA to analyze than before.

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### **FDA's New MedWatch Program:**

*Reported by John Hughes and Thomas Bauld, Ph.D.*

On June 3, 1993, the FDA held a Commissioner's Conference in Rockville, Maryland, to announce the MedWatch program.

Upon receiving notice of the event in mid-May, Joe Dyro, Ph.D., ACCE President, requested participation from ACCE members in the Washington area. The ACCE was ably represented by John Hughes of the Washington Hospital Center, Al Jakniunas of Howard University Hospital, and Thomas Bauld, Ph.D., of the University of Michigan Hospitals.

MedWatch was created to consolidate reporting and to improve voluntary post-market surveillance of all medical devices, drugs, biologicals, and nutritional products. The new voluntary component replaces what used to be handled by the US Pharmacopoeia.

Dr. David Kessler, Commissioner of the FDA, emphasized the point that regardless of the extent of clinical trials, there are ongoing adverse events related to drugs and devices that only the users can identify to the FDA. For example, interactions with many medications cannot effectively be identified in trials, nor do trials reach all possible patient populations. Lack of reporting problems with breast implants contributed to their staying on the market well beyond when the auto-immune-like disorders had occurred. A 1992 study reported in Drugs Aging found that from 3% to 11% of hospital admissions in the elderly were due to adverse drug reactions.

The American Medical Association, the American Dental Association, the American Nurses Association, the American Society of Hospital Pharmacists, the Pharmaceutical Manufacturers Association, the JCAHO, the College of American Pathologists, and the Health Industry Manufacturer's Association (HIMA) were invited to participate in the conference. Notably absent from the program were the very organizations that would have contributed substance to the discussion -- AAMI, ACCE, the American Hospital Association, and ECRI. After concerns were expressed to FDA officials, ACCE was invited to become one of the professional organizations identified as a MedWatch Partner. Partners agree to promote the program to members. The ACCE Board has approved this initiative.

The FDA and speakers representing the professional organizations made strong arguments that participation in voluntary reporting efforts was vital to the well-being of current and future patients. The FDA wants users to report suspected problems and not wait for compelling evidence or direct connection of a device/

drug to the adverse event. Dianne Kennedy of the FDA is the Director of MedWatch.

Many professional journals will be carrying articles in the next few months by David Kessler, MD, the FDA Commissioner, on the MedWatch program. An article appeared in JAMA, June 2, 1993, Vol. 269, #21. The Physician's Desk Reference (PDR) will now include tear-out reporting forms.

To improve the process of reporting, the FDA combined six prior forms into one, Form 3500, single-sided for voluntary reporting. This was a major achievement. All forms will be sent to one address at the FDA for triage and handling. The FDA can now accept problem reports using a modem (800-332-7737) or by FAX (800-332-0178). In addition, there is a Hotline (800-332-1088) for discussing problems with an FDA staffer. A similar but two-sided version, Form 3500A, is now the designated form for mandatory reporting, but is not required until the Final Regulations are published.

For the first time, FDA officials stated and expressed in writing that they have gone to court to protect the confidentiality of device problem reporters and they have won every time. They have always kept patient identification confidential. They recognize that effective reporting will not occur unless confidentiality is preserved. An FDA representative indicated they may address confidentiality further in regulations to be proposed, especially in the area of information submitted to manufacturers. Note that the new form requests the name of the initial reporter of the problem as well as the institutional contact person.

For a copy of the Desk Guide for Adverse Events and Product Problem Reporting, which describes the MedWatch program, call (800) 332-1088. This valuable resource was distributed to the conference participants.

As part of the effort to improve communications, the FDA released in June an "Electronic Data Interchange Strawman Standard for Adverse Event and Problem Reporting." This preliminary document is designed to form the basis for improved use of computers to facilitate data transmission between the FDA and the medical device manufacturers and users. For more information, contact Isaac Hantman at FDA/CDRH FHZ-306, 1390 Piccard Drive, Rockville, MD 20850.

The FDA also indicated it would begin inspecting healthcare facilities to determine compliance with the mandatory reporting required by the SMDA. There is substantial concern in the FDA about under-reporting. Be prepared with your files of incidents, your program description, and the details of your staff educational program.

Part of the intent of the FDA is to improve feedback to manufacturers when problems are determined to require action. The FDA will pilot a rapid notification system for one year to inform manufacturers as reports are received.

The question of when the Final Regulations for User Device Problem Reporting will be available was raised by Allan Pacela of Quest Publishing and Tom Bauld. The response from Chet Reynolds is due in August or September 1993.

No discussion of the process of Device Tracking was held either, despite its implementation date of August 29, 1993.

## Unanswered Questions

How will the emphasis on voluntary reporting and the promotion by professional societies affect the mandatory reporting by healthcare institutions? Many clinical engineers are worried that the processes implemented to manage mandatory reporting and consolidate all information through one point of contact will be disrupted with voluntary reporting by staff using the self-mailer designed by the FDA. What are the consequences if voluntary reporting occurs, but the institution fails to make a mandatory report because the facts are not made known to the responsible staff in the hospital?

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## ECRI Health Technology Assessment Information Service (HTAIS)

A recently announced service from ECRI may be of interest to a number of ACCE members involved in Technology Assessment and Technology Management. I have contacted Dr. Jeff Lerner at ECRI (215-825-6000) and found out information summarized below. In addition, I have requested a completed information package and a sample report

on the topic of Home Uterine Activity Monitoring to evaluate the content and format of the reports.

This is a consulting service designed to provide institutions with comprehensive reports on all types of technology assessments, including drugs, devices, and procedures. Unlike the ECRI product comparison system "Select+", this HTAIS is designed to address the clinical value of a technology for specific procedures; e.g., a new laser application that is being proposed, or a new radiopharmaceutical. This is truly technology assessment information to assist clients in making acquisition/investment decisions of a large magnitude.

The \$15,000 cost entitles the subscriber to 50 points. Each major analysis ranges between 8 and 12 points. One could acquire roughly 5 full reports to use up the \$15,000. After that, you simply resubscribe. You have a full year to use the 50 points. It takes 45-60 days for the complete report, and that will be reduced as more baseline reports are prepared and require only to be updated with new research results.

The reports are comprehensive and prepared by doctoral level clinicians, life scientists, and biostatisticians and are reviewed by two to four outside non-paid clinical and biomedical expert consultants in the field. When requests are made, there is a telephone interview with your staff to establish the scope and details of your need.

Considering the expertise that ECRI has brought to the field of technology management and the fact that a comprehensive report would cost about \$3,000, it seems to be a good value. It is unlikely that most clinical engineers would have access to the resources that could yield a comprehensive analysis for that cost within those time frames. Also, the impact of such major decisions is very high, so money invested up front could have a large return.

Candidates for the Board of Scientific Reviewers are being solicited by ECRI. Reviewers are not compensated, but are eligible for an annual \$5,000 Best Review award.

*Fall seven times,  
stand up eight.*

*- Japanese Proverb*

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## ***Minutes of ACCE Board Meeting Held on May 11, 1993 at Boston, MA***

Called to order at 5:30 EDT by President Joseph F. Dyro, Ph.D.

### **Board Members Present:**

Joe Dyro, Ph.D. (*President*)  
Tom Bauld, Ph.D. (*Vice President*)  
Ira Tackel (*Treasurer*)  
Steve Grimes (*Secretary*)  
Ethan Hertz (*At-Large*)  
Phil Katz, Ph.D. (*At-Large*)  
Mike Carver (*At-Large*)

### **Committee Chairs Present:**

Frank Painter (*Membership*)  
Wayne Morse (*Public Affairs*)  
Denver Lodge (*Advocacy*)

### **Board Members Absent:**

Matt Baretich, Ph.D. (*Past President*)  
Gerald Goodman (*At-Large*)

### **Invited Guests:**

Didier Vallens (*IFMBE - France*)  
Diego Bravar (*IFMBE - Italy*)

### **Convened**

Meeting was convened at 5:30PM EDT by President Dyro.

### **Old Business**

Reading of minutes from previous Board Meeting was waived (April 12, 1993). Joe moved that those minutes be accepted as amended; Tom seconded; the motion was passed unanimously.

### **President's Report**

Joe reported that the ACCE Membership Survey had recently been completed and the results tallied. He indicated that membership response was very positive —74 responses to date out of approximately 140 members. The survey also included an individual member profile that was completed and returned by respondents, resulting in the most accurate ACCE member database to date. Joe announced that ACCE has become an affiliate society of the CE Division of the IFMBE and, as a result, has access to (and will be included in) the international directory of CEs.

## **Vice President's Report**

Tom Bauld, Ph.D., reported on ACCE communications with Dr. Shalala's office in response to her calls for more support from health care professionals. He discussed the latest Draft Form (Safe Medical Device Act of 1990) summarizing ACCE's official response commending FDA on improvements, format & information content that is easier to work with while expressing concern about the form's requirements for patient initials & medical records (discharge summary), since that could lead to patient identification. ACCE's response also questioned the real difference between FDA's Voluntary Incident Report and its Required Problem Report, as there does not appear to be much difference in content between the two forms.

Tom distributed and discussed the Summary Report of the ACCE Member Survey. The objective of the survey was to learn what members want and to update ACCE's database. Tom said that, based on survey results, ACCE needs to concentrate on such key areas as education, sharing of resources (e.g., sample policies & procedures), advocacy, and technology assessment. Phil Katz, Ph.D., suggested that the Board announce to membership (during the upcoming annual meeting) that the Board is analyzing results of survey and will subsequently report on its findings and the impact they will have on on-going and future programs.

Tom distributed a format for and sample of a clinical engineering effectiveness example or case study (i.e., productivity). He pointed out that this was one area in which the member survey demonstrated a strong interest. He said that, using this format, other case studies could be solicited from members which could then be distributed as a member benefit or sold as a subscription service.

## **Treasurer's Report**

Ira Tackel stated that ACCE had filed with the IRS for classification as a 501(c)(6) not-for-profit corp. Dues have been billed to the membership for the balance of 1993 on a pro-rated basis. Phil suggested that a policy be adopted whereby new members have their application fee applied to the first year's membership fee if they are accepted between January 1 and June 30 or applied to the following year's membership fee if accepted between July 1 and December 31 (there then being no membership charge for the July 1 through December 31 period in that case).

## **Secretary's Report**

Steve Grimes reported that the membership survey was successfully distributed, and the responses were collected and tabulated. The member database had undergone an extensive update, representing the most comprehensive listing of ACCE member information. That data is now available on request to any at ACCE having a legitimate need.

Steve said that copies of Bylaws were distributed by fax to all ACCE Board Members. He distributed a preliminary copy of the ballot for election to ACCE's Board as well as a second ballot with proposed ACCE Bylaws changes, including 1) the addition of one membership classification and 2) increasing terms of all board members to 2 years.

## **Summary of General Discussion**

### **Bylaws & Election of ACCE Board**

Joe presented a slate of candidates for election with the stipulation that the nominating committee had recently been re-organized because of an unexpected resignation. Phil observed that the composition of the newly constituted committee did not adhere to the Bylaws and that the proposed slate therefore was not valid. A discussion ensued.

Meeting was adjourned at 7:00 PM to attend General Membership Meeting. Re-convened 9:30 PM.

Joe proposed that a new nominating committee be formed and that it review and make changes as necessary to the proposed slate of candidates. Phil moved that Yadin David, Ph.D., be appointed as chair of the nominating committee; Joe seconded; the move was approved unanimously.

A discussion was held regarding the formation and development of clinical engineering organizations in France and Italy by representatives of their respective societies, Didier Vallens (France) and Diego Bravar (Italy), guests at the Board meeting.

Tom proposed that the Bylaw change issue be resolved prior to membership vote on nominees for office (i.e., make structural changes first, then do next elections). Steve suggested that if the Bylaws were modified to extend board member terms to two years, that this extension could be applied to the existing Board members. Phil agreed it was possible but that the Board

should consider making Bylaws changes independently. Joe appointed Ethan Hertz, with the affirmation of the Board, as Bylaws Committee Chair.

Phil related his experience with other organizations where newly elected presidents and other officers seem take at least 6 months to come up to speed and that one year terms are too short for a board member to become truly effective.

Ira noted that the Bylaws state that 3 of the 4 members of the nominating committee are not to be board members. He proposed that there be continuity in the nominating committee and that these committee members serve staggered terms of more than 1 year. He felt that such a committee should place one name in nomination for each position and he wants the nominating committee to put forward their "best" candidate. Ira suggested that in contemplating Bylaws, modification to nominating committee structure should be considered.

## Secretariat

Wayne Morse proposed that the corporation be relocated to a state other than Washington since Washington requires that a corporate Board member be a resident. He suggested the state where the secretariat is located. The corporation will remain in Washington State and Ethan will chair the Ad hoc committee to establish a permanent secretariat.

## Committee Reports

### Education

Joe presented the Education Committee Report prepared by James Wear, Ph.D.

### Finance

Joe presented a preliminary 1993-94 budget. This was prepared based on data previously supplied by the treasurer, secretary, and chairs of membership, advocacy, and education committees. Income (member dues, workshop, donations) totaled \$19,000. Expenses (secretariat, dues to other professional societies, committee expenses, newsletter, legal, and accounting) totaled slightly over \$15,000. Joe indicated this was preliminary and was being presented for review and feedback. Frank Painter noted that AAMI is trying to build up a reserve of 50% of their budget and that this might be something ACCE should consider. Ira and Joe will work to finalize the report.

## Advocacy

Denver Lodge discussed his committee's proposal for increasing *professional awareness*, making non-CE health professionals aware of clinical engineering by providing awards. Joe asked Denver to submit both a revenue and expense projection. Tom observed that Denver's proposals were in keeping with membership survey results.

## Newsletter

Wayne reported that Dave Harrington wishes to retire as editor. The Board will undertake the search for a new editor. Tom would review survey to determine who expressed an interest and would be qualified to serve as editor.

## Public Affairs

Wayne estimates brochure expense at \$2,000, but suggests that he be given direction from board as to where and to whom ACCE is to be marketed (i.e., he suggests ACCE needs explicit marketing goals) before he can put together a plan & associated budget. Phil further suggested that the board consider preparation of a business plan; from that plan Public Affairs could take its direction.

## Other Business

Annual meeting was held on 7:00 PM on May 11, 1993 with about 75-85 people in attendance.

Joe adjourned the meeting.

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## Second International Advanced Clinical Engineering Workshop Executive Summary

August 9, 1993

### 1. Workshop Organization

Global interactions in recent years have promoted the role of the World Health Organization (WHO) in prioritizing the problems faced by countries, particularly developing ones, for critical health care issues. Placed high on this problem list is the field of management, maintenance, and repair of health care equipment. The need of a workshop for training and updating the leading clinical engineers from Eastern Europe, the republics of the former Soviet Union, and Central and South America was perceived after

discussions between representatives of WHO's Division of Strengthening of Health Services and some US clinical engineers. Because of the successful experience in training Latin American clinical engineers in the first Advanced Clinical Engineering Workshop in 1991, the US clinical engineers involved in that effort felt that a second month-long Workshop would be beneficial and thus should be developed for May - June 1993.

The American College of Clinical Engineering (ACCE) lent its support through a number of its leaders and members who formed the Boston Organizing Committee (BOC), named for the location of the 1993 AAMI annual meeting and proposed site for the second Workshop's classroom training. The International Federation for Medical and Biological Engineering's (IFMBE) Clinical Engineering Division indicated that it would help co-organize the event alongside BOC and provide faculty members, assist in developing regionally relevant curriculum, and help find qualified participants.

WHO requested that, in addition to the Workshop's primary focus on Eastern European applicants, whose Ministers of Health would be contacted by their European regional office in Copenhagen, BOC should consider allowing some additional qualified Latin American engineers to attend. BOC would be assisted in making these contacts by WHO's regional office for the Americas, the Pan American Health Organization (PAHO) in Washington, DC.

The organizing committee was set up and a plan of action was drafted in the summer of 1992. BOC members included the following: Dr. Yadin David, President; Thomas Judd and Dr. Joe Dyro, Vice-Presidents; and Chairs and Vice-Chairs for four key subcommittees. These included (1) Selection: Bob Morris and Tom Bauld; (2) Finance/Logistics: David Harrington and Antonio Hernandez of PAHO; (3) Curriculum: Drs. Jim Wear and Binseng Wang; and (4) Practicum: Frank Painter and Mark Brody. Two advisors who provided region-specific assessment of training needs included Al Jakniunas for Eastern Europe and Adriana Velazquez for Latin America.

## 2. Participant Selection

Overall, there were 50 applicants from 25 countries in Eastern Europe and the former Soviet Union as well as 30 applicants from 10 countries in Latin

America and the Caribbean. Thirty-five participants, including four women, were selected from 20 Eastern European countries and 5 Latin American countries on the basis of a variety of factors. Acceptance criteria included their experience, credentials, their country's commitment to clinical engineering and their own personal commitment, ability, and access to assisting in policy development and implementing change in health technology management in the home country. All were degreed engineers, with good English communication skills, and had at least two years of clinical/technical experience.

## 3. Funding

Fundraising activities resulted in revenues of approximately \$83,000, which equaled expenses for the Workshop. Primary sponsorship came from the following sources:

- 10 Eastern European participants received full funding from the United Nations Industrial Development Organization (UNIDO), based in Vienna, Austria.
- 10 other Eastern European participants received funding from UNICEF, WHO, and the American International Health Alliance (AIHA). AIHA utilizes US Agency for International Development (US AID) grant money to partner US hospitals with those of the former Soviet Union.
- 6 participants from Latin America were funded by the Rockefeller Foundation and PAHO.

Other primary financial and in-kind support came from the following: (1) the US medical device industry: Bio-Tek, J&J/Critikon, SpaceLabs Medical, Physio-Control, Imed, RSTI, Replacement Parts Industries, Mediq/PRN, Siemens Medical, and Nellcor; and (2) other organizations such as DPG International, ECRI, Quest Publishing, and Second Source Publishing. Funds from these sources, other than those designated above, paid for the remaining 9 Eastern European participants' travel, food and lodging, as well as all other Workshop costs; i.e., participation in the AAMI meeting, ICC certification in clinical engineering candidacy examinations, and ACCE membership application fees.



## 4. Workshop Execution

The Workshop was scheduled to coincide with the AAMI annual meeting in Boston, allowing the participants to attend from May 8-11, 1993. Lodging during their stay in Boston was provided at Wentworth Institute, also the site of the classroom portion of the Workshop from May 12-22. The classroom time was aimed at providing the theoretical foundations for improving utilization of technology in healthcare delivery. Difficulties peculiar to developing countries and a few case studies of complex technologies were also discussed. Over 20 faculty members from ACCE, IFMBE, and WHO/PAHO were involved, each considered to be a leading expert in their particular subject matter. US-based faculty included the following, in addition to the BOC members named above: keynote-speaker Dr. Joel Nobel - President of ECRI, Tobey Clark, translator Leo Friedman, Ed Hines, Al Jakniunas, George Johnston, Jim Keller, Wayne Morse, Dr. David Simmons, Terry Speth, and Henry Stankiewicz. Many of these instructors made considerable sacrifices of time and money in order to participate in the program.

A practicum or hands-on technology management training was provided for the participants at over 20 sites around the US from May 23 to June 7. Clinical engineers who developed and hosted these experiences included the following: Ray Acosta, Shyue-Ling Chen, Tobey Clark, Steve Cunningham, Dr. Yadin David, Mark English, Gary Evans, Kelly Gallenopolis, Gary Geiger, Jerry Furnce, David Harrington, Tom Judd, Joseph Kane, Henry Montenegro, Nick Noyes, Frank Painter, Jim Pipenbrink, Ed Plante, Jeff Secunda, Henry Stankiewicz, Stan Trojanowski, David Wilder, and Bob Viccari.

Workshop participants each received a Certificate of Workshop Completion from the University of Arkansas for Medical Sciences. Each of them also took the ICC certification in clinical engineering candidacy examination as well as applied for ACCE membership.

## 5. Results & Follow-Up Activities

Participant evaluations indicated that they were very satisfied with the classes on healthcare technology management principles and with the opportunity to see these principles applied in hospitals. They felt confident of their ability to assist in development of policy for technology management as well as to

implement and direct programs aimed at helping their health care systems acquire the right equipment, use it appropriately, and maintain it in a reliable condition. Furthermore, they are now expected to act as trainers to teach and assist other technology management professionals in their countries.

Although similar Workshops for other regions of the world are contemplated in the future, BOC members have agreed to focus their collective energies for 1994 in providing technology management continuing education for US colleagues.

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## Need by October 15th: 20 Infant Incubators To be Shipped by the US State Department to Kyrgyzstan

Halfway around the world, the Republic of Kyrgyzstan is situated on the western spur of the Tien Shan Mountains. The best known of its border neighbors is the People's Republic of China. This country, which is slightly smaller than our state of Nebraska, has been pushed and shoved through changes not of its own choosing since 1850. It has witnessed the rise and fall of the USSR which forced upon this small land their politics and the name Kirghiz Soviet Socialist Republic. The once nomadic people, descendants of Genghis Khan, were forced to live on farms, raise products for the state, and adopt a new language. Mountains in sight of the capital city of Bishkek are taller than our own Mt. McKinley.

The population of 4.5 million is very young. Forty percent of the population is 14 years of age or younger, and only 7% is 65 years or older. Due to the break-up of the USSR, each republic has been largely left to fend for themselves. With respect to health care, Kyrgyzstan finds itself with a structure and facilities for delivery but little else. The deficiencies are almost too numerous to count. Its outstanding health care issues revolve around infectious disease and maternal/child care issues, particularly neonatal care.

The Kyrgyz Minister of Health has sought partnerships with some different entities in the United States both to better utilize his country's internal health care assets and to attract outside assistance. University of

Kansas Medical Center in Kansas City and a health care group of physicians, administrators, and other professionals operating out of Atlanta have been among those responding. After an invitation by the Minister of Health in 1992, the Atlanta group is sending a husband-wife family practice physician team this fall on a long-term assignment to Bishkek. Drs. Ken and Sheila Patterson will work alongside the Minister of Health, Kasiev Naken Kasievich, in optimizing best use of health care resources for the republic. An early focus for them and one for which they have been well prepared by their training in the US involves improving neonatal care. After discussions with the Kyrgyz ambassador to the US and the Minister, they believe that **20 infant incubators could make a real difference in saving the lives of many babies there.**

The Pattersons will be moving to Bishkek in early November. With the assistance of the Kyrgyz ambassador, the State Department has asked one of its affiliated organizations, the FUND FOR DEMOCRACY AND DEVELOPMENT of Washington, DC, to provide free shipping from Atlanta to Bishkek for several containers of medical supplies, journals, and equipment.

**The contact for the Atlanta group for this project is Thomas Judd, Assistant Administrator for Kaiser Permanente in Atlanta, telephone (404) 365-4240 and fax (404) 233-0485.**

American College of Clinical Engineering members who served as faculty in the Second International Advanced Clinical Engineering Workshop and sponsors will recall that two participants came from Kyrgyzstan - Migijas Rysculbekov, Ph.D., from Bishkek, and Ormonbek Kudaiberdiev, MSEE, from Osh, the second largest city. These two individuals run technology management operations for the Minister of Health in their areas of the country and will be available at the other end of the shipment to facilitate best use of this equipment. It is preferable that the incubators be donated and able to operate from 220 V. Shipping from the donor site to Atlanta can be worked out.

Thanks for your assistance.

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## ACCE Leads Efforts to Add Evidence of Continuing Practice to ICC Certification

ACCE conducted a continuing education feasibility study/survey among its members on behalf of the International Certification Commission (ICC) in early 1992. The survey had two purposes: 1) to determine member continuing education priorities; and 2) to ask certified and non-ICC certified members whether adding an “evidence of continuing practice” component—with heavy emphasis on continuing education—would add value to the existing ICC clinical engineering certification program in the United States.

Information from the survey was turned over to the ACCE Education Committee in the summer of 1992 to assist future planning efforts. The survey showed that members want ongoing training on current clinical engineering (CE) technology and management issues, as outlined in ACCE’s definition of CED practice areas.

Survey results were also utilized by a joint task force made up of representatives from ACCE and from the US Board of Examiners in Clinical Engineering. The task force was empowered by ICC to develop a proposal for adding a new component to the Certification Renewal Program. Because the US BMET Board of Examiners was also considering the addition of an “evidence of continuing practice” component, CE and BMET Board leadership decided to combine features of each other’s proposals into a combined version. This combined proposal was approved by their Boards and the ICC at the May, 1993 meetings in Boston.

Recently, ICC sent information to all currently certified individuals seeking feedback on the new Certification Renewal Program. The program will require evidence of continuing practice as a requirement for certification renewal. The program will be implemented January 1, 1994 with a three-year phase-in period. The following is quoted from the ICC’s new brochure concerning this program:

*“The purpose of the new requirement is to ensure that certificands maintain a level of*

*professional knowledge and skill which is consistent with the standards according to which certification was initially conferred. Program requirements are designed to be well within the reach of all active professionals.*

*The program is based on the accumulation of at least fifteen points over a three-year period, with a recommended average of five points per year. Points are awarded for participation in a wide variety of activities which contribute to the professional development of the certificand."*

A copy of ICC's listing of "Acceptable Activities and Point Scale" is located on page 12. Congratulations to ACCE for its leadership in adding value to the certification process. In this case, we have done this by fulfilling one of our organization's stated purposes, that is "to establish the standard of competence and to promote excellence in Clinical Engineering practice."

### **Acceptable Activities & Point Scale**

The activities considered acceptable as evidence of continuing practice, along with the points awarded for participation in each type of activity, are outlined on page 10. No more than ten points may be accumulated in any one category. The subject areas listed on the following page are intended to serve as a guideline when selecting activities with appropriate content. Other areas not listed may be acceptable as long as their relevance to the profession is clearly evident.

It is recommended that participation in the activities listed on the following page be related to the following subject areas:

- Construction and Renovation
- Consulting
- Design
- Equipment Management
- Equipment Service and Maintenance
- Management
- Manufacturing
- Research
- Safety in the Healthcare Facility
- Teaching

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## **ACCE Bulletin Board Available for Members**

A new benefit is now available for all ACCE members. With the cooperation of ECRI, ACCE members can access the ECRINet Bulletin Board. There are a number of special groups and conference areas available. Once you access ECRINet, you can join the ACCE Conference and leave messages.

The bulletin board software is easy to use and menu driven. The phone number is (215) 825-9284. When signing on, you will be prompted for your first and last name. The system will not have you listed and will say "The name you entered was not found in the user log." Then you will be prompted for your city and the type of terminal you are using. You will also be asked to supply your own password of up to eight characters. Each subsequent time you sign on, you will use your password.

When I first began to use it, I had a problem with their software recognizing my communications settings. After entering my password on the second call, I got a message that I had only 2 minutes left on my call. That message was the result of miscommunication between the two computers and the fact that I use a network modem at the University of Michigan. A call to Jeff Deboles at ECRI, (215) 825-6000, quickly resolved the problem.

The main limitation I see is the difficulty editing messages. Moving the cursor requires holding the CTRL key in addition to another non-obvious key. You obtain the list of editing commands by pressing CTRL /.

Mo Kastis is the ACCE member who will be actively involved with the management of the ACCE Bulletin Board, so leave him a message with your ideas.

There are many other services available on ECRINet, including Manufacturer Support Policies and other special conferences.

Good luck, do the networking thing, and contact your friends and colleagues!

Tom Bauld, Ph.D.

## *Technology Assessment*

Activity	Points	
	For Teaching	For Attending
<b>I. Courses</b>		
a. Academic course at a university or college	1.5 pts./credit	1 pt./credit
b. Vocational/technical course	3 pts./course	2 pts./course
c. Company course, short course, workshop	1 pt./day	1/2 pt./day
d. Correspondence course, teleconference	2 pts./course	1 pt./course
e. Other relevant professional & technical session	1/2 pt./day	1/2 pt./day
<b>II. Authoring Publications, Articles, Presentations</b>		
a. Books or monographs		5 points each
b. Publications, patents (national), book chapters		2 points each
c. Presentations made at national & international meetings		1 point each
d. Presentations made at local & regional meetings		1/2 point each
e. Articles published in trade or local newsletters		1 point each
<b>III. Professional Society Participation</b>		
a. Meeting attendance <i>(relevant professional/technical meetings at international, national, regional, or local level)</i>		1/2 point per day
b. Active participation in society <i>(committee assignment, offices held, etc.)</i>		1 point per activity per year
<b>IV. Other Professional Study</b>		
a. Self-Study <i>(relevant journal reading, audio tapes, &amp; other self-learning activities)</i>		1 point per 20 hours

### **Device Tracking Forms Included with New Devices**

As a result of activities undertaken by the Health Industry Manufacturer's Association (HIMA) and medical device manufacturers, Medical Device Tracking forms will soon be shipped with all new medical devices sold in the United States. This action has been taken by HIMA and device manufacturers in order to better facilitate incident reporting in compliance with the Safe Medical Devices Act. The forms will also be distributed by the American Hospital Association (AHA) as a result of AHA-HIMA agreement. For details or more information, call Dee Simons at HIMA, 202-437-7227, or Bret Berek at AHA, 312-280-5218.

### **ACCE**

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