ACCE PRESIDENT’S MESSAGE

Clearly the ground is moving beneath us as healthcare is being revamped and rethought nationally. For some of us the changes are occurring immediately, for others, the changes are still on the horizon, but there is no room for complacency. We will all need a keen awareness of the new competitive environment and the best tools that are available for improving our management skills. ACCE is responding by making Vision 2000 the key priority for the coming year. Task Teams are being set up and we look forward to a definitive set of strategic recommendations and practical guidelines.

To address the other highly ranked issues of Advocacy and Organizational Collaboration, I have charged the Advocacy Chair, George Johnston with the assignment to develop a multifaceted promotion plan for the First Annual Clinical Engineering Week. This should provide many opportunities for each of us to celebrate and promote the activities and achievements that represent the best in clinical engineering. Our goal is to accomplish this celebration in conjunction with AAMI, ASHE, and the IEEE-EMBS.

I am also pleased to report that the ACCE is now a member of the American Institute of Medical and Biological Engineering (AIMBE) Council of Societies. AIMBE is aggressively lobbying at the federal level to maintain funding in medical device technology and biomedical engineering research. Such efforts are aimed at preserving America’s dominance in medical device research and development and its leadership in export of medical devices.

One of the best received ACCE activities of 1995 was the teleconference series. Members have attended the courses simultaneously from all over the country. Special thanks goes to Jim Wear and his committee for putting together the talent and the technology for these programs. The next series is scheduled to begin in January 1996 with topics based on the surveys done during the first six presentations. Look for more information soon about the new offerings and how you will be able to obtain tapes and handouts from the earlier courses.

We had a nice turn out for the ACCE get-together and Annual Business Meeting in May in Anaheim. The highlight of the business meeting was the presentation of Advocacy Awards to Wayne Morse, Monique Frize & Michael Shaffer, Enrico Nunziata, and Awa Diouf. Vice President Tom Judd reported the success of the Grass Roots Teams program which now facilitates rapid communication within ACCE. Binseng

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Wang presented the procedures for nominations for ACCE Fellow status and reported an increase in membership applications. Plans for a clinical engineering reference library were also discussed. Joe Dyro announced the availability of ACCE Guidelines for Donating Medical Equipment (which is free for ACCE members and $25 for others). Yadin David was named ACCE representative to the IEEE Healthcare Technology Policy Committee. Based upon the answers to the survey, you were overwhelming in selecting the AAMI Annual Meeting in Philadelphia in June 1996 as the site for the next ACCE Annual Meeting, so we will go forward with that intent.

I am very excited about the pilot 2 + 3 BS degree program in Biomedical-Computer Engineering Technology which has been implemented with courses this fall semester at Eastern Michigan University (EMU) in Ypsilanti, Michigan. It was developed by members of a Quality Team on BMET Training at the University of Michigan Hospital and faculty members from EMU. The program is designed for working Biomedical Technicians to obtain a BS degree on a part time basis and is intended to address the ever growing use of information technology in the biomedical field and to prepare technicians for a greater role in healthcare. The initial cohort group has 22 students. Our plans include expanding the program to other areas of the country by using distance learning technologies.

EDITORIAL: BALANCE
Mark S. Brody, CCE

Each of us has a few of those conversations in our lives that, no matter when it occurred, the content stays with us forever. Often, we can not fully appreciate its significance until sometime later even though we may recognize that the conversation has touched us at a deep level while it is happening. Typically, some future event triggers the playback of the earlier conversation in our mind. All of this is true in the scenario that I am about to describe.

One afternoon, five or six year’s ago, I was having a generally benign conversation with a technician in my office. I believe that the conversation occurred shortly after this technician had been promoted to a BMET III specialist during a period of major expansion in our department. At some point in the conversation the technician remarked about how much further I was with my life compared to where he was in his. Although the remainder of the conversation may have lasted less than fifteen minutes as we compared our status, I have replayed it in my mind many times since then. Ironically, the same facts have not always netted to the same conclusion.

What my colleague was superficially pointing out was that we were both in our late twenties (about 4 months apart), both married, both home owners working for the same hospital; but, I was a recently certified clinical engineer department head with a Master’s degree who was active in several professional organizations and he was only a staff technician. His inference was that my life was better. While I may have verbally agreed with him and even offered suggestions as to how he could professionally excel, something bothered me about the conversation even then.

It is important, as I describe my uneasiness for you, to understand that I was always impressed by the charismatic quality of this person. He openly enjoyed life and served as a strong informal leader within the department almost from the day that I hired him. While I was focused on my professional development; writing articles, presenting papers, participating on this committee or that to gain professional stature, he was enjoying a nice afternoon on the golf course and interacting with his peers over a beer or he was home enjoying his infant son.

This latter event is the one that has recently triggered my brain to remember our original conversation. For you see, I now have an infant son to spend time with and my DINK (Double Income, No Kids) paradigm has been irreparably shattered. I enjoy the time I spend

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with my son. However, as any of you with small children already know, keeping up with a toddler may be fun, but it isn’t easy. When he plays, you play and when he sleeps you must get some sleep; especially when he really wants you to play at 2am and 4am and... and you now start your day a 5:30am so that you can be home from work to see him before he goes “night-night.”

In case you are wondering where this is going let me tie it up for you with these three points. 1) In our lives we all make choices. Some choices are active and dependent on our immediate environment and some are passive acceptances of prior choices. Although I haven’t spoken with the a-fore mentioned technician is over a year, I know that he is now a manager in a position of considerable authority within the clinical engineering department. I suspect that he now has less time for other things that he enjoys. 2) To those of you who provided me with material for this newsletter expecting to see it published in the early fall, I apologize for the delay. The promotion of clinical engineering and related professional activities remains a strong value in my life. But, for the first time there wasn’t enough room in the envelope for me to balance it with all the other active priorities. This newsletter is published now and hopefully the quality of the material in this issue will offset its lack of timeliness. Finally, 3) for those of you who are reading this newsletter late in the day at the office - go home and spend some quality time with your family. The work will still be there for you tomorrow. Yet, for those of you who are enjoying the hard work of others described here-in after the kids are in bed and your day has quieted down - spend this time tomorrow night studying for certification, preparing an article for publication, reviewing a standard, or teleconferencing with a colleague to complete committee business.

Hey, the title of this editorial is balance, not acquiescence!
ACCE News

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utilized for advocacy awards. Nominations must now be submitted by December 31. The current composition of this committee is G. Johnston (Chair) and members, J. Hughes, D. Dickey, F. Wainwright, P. Lynch, and Dennis Auto.

- The Advocacy Committee is also looking into the possibility of producing a video to be used in an advocacy role. Because this could be expensive, more information is needed before being submitted to the Board for approval.
- George Johnston presented the idea of setting up a professional library of papers and documents available on the Internet. He will follow up in discussions with Joel Nobel, ECRI.
- There was a motion made by the Membership Committee that the ACCE membership list be placed on the Internet (ECRINet Bullet Board). The Board passed this motion 3 to 2.
- The Board voted unanimously in favor of continuing the audio teleconferences for another year since they have, in general, been breaking even financially and provide a tremendous benefit to the profession. Changes for the next series include spending $400-500 on flyers; using ads in journals (such as Journal of Clinical Engineering); and researching the possibility of credit card sign-up. Tapes of previous courses are to be made available on demand, at $25/course.
- ACCE member Adriana Velazquez announced the First Annual EXPOTECNOMED MEXICO 95 from October 18-21 in Queretaro City, Mexico. This event is sponsored by the Mexican Society of Biomedical Engineering and the Universidad del Valle de Mexico. For additional information, fax # (52429) 4-04-91 or e-mail: ibiomed@xanum. uam.mx
- The IFMBE International Clinical Engineering Directory is available through Joe Dyro.
- Ballots for ACCE officers and Board were handed out at the meeting. No new nominations were made.
- Ethan Hertz was named as ACCE member for AAMI's CE Department Standards Committee.
- An IEEE Healthcare Technology Policy Committee is being formed and Yadin David has been named ACCE representative.

- A task force was named to promote National Clinical Engineering Week (schedules for June 11-17, 1996).

Summary of August 2, 1995 ACCE Board Meeting
- Promotion of ACCE/ASHE MTM Chicago meeting continues; John Hughes & Tom O'Dea are the ACCE representatives on the Coordinating Committee.
- A member survey was sent out with ballots; results should be available in late August.
- The Pan American Health Organization (PAHO) would like to translate the Guidelines for Donation of Used Equipment into Latin American and Caribbean languages for distribution there. Tom Judd and Joe Dyro will discuss the issue with them.
- Membership Directory should be available late September.
- Ira Tackel and Tom Bauld are working on budget for next year.
- Vision 2000 Task Forces are being developed around four strategic initiatives; 1) Public Relations/Marketing, 2) Education, 3) Development of New Member Services, and 4) Unification of Efforts. Task force members identified so far are Tom Judd, Phil Katz, Ira Tackel, Bryan Patali, Fran Reibman, and Yadin David.
- Wayne Morse presented the idea of ACCE having a marketing agent for products related to ACCE activities. The Used Equipment Guidelines, CE Study Guidelines, audio tapes, etc., would be marketed with ACCE receiving a percentage of the proceeds. The Board asked Wayne to provide a written proposal for consideration.
- Joe Dyro proposed that a strategic alliance (in the form of a working agreement) be formed with the Journal of Clinical Engineering. The Board voted unanimously in favor of having Dr. Dyro prepare a document describing the relationship for further review.
ELECTION RESULTS

Joseph F. Dyro, Ph.D., CCE
Chairman, Nominating Committee

Thanks to all who voted in the 1995 election and completed the survey on activities that are important for the ACCE. The new officers are:

President: Thomas J. Bauld, Ph.D.
Vice President: Thomas M. Judd, CCE
Treasurer: Ira Tackel
Secretary: Marv Shepherd
Board Members: Ethan Hertz, CCE
Greg Davis
Gaylord Gordon, CCE
Phil Katz, Ph.D.

Congratulations to all those elected and a special welcome to our newest Board member, Greg Davis. The Nominating Committee now invites members to suggest candidates for future elections.

TREASURER’S REPORT

Ira S. Tackel

As of August 1, 1995, the ACCE checking account balance was $12,770.54. The vast majority of recent financial activity was due to teleconference fees and expenses. Expenses included: telephone costs, honorarium fees paid, duplication of materials, mailing and certificate costs. Jim Wear is putting together a final analysis to determine the financial success of this program.

SURVEY RESULTS

As part of the College’s ongoing member feedback process, a survey was conducted to determine where ACCE Leadership should concentrate resources. Members were asked to rate each of 10 items on a scale of 1 to 5. A rating of 5 noted that the item was of "vital importance to the profession and of continued professional growth of the member". Almost 50% of the active membership replied to the survey. The survey showed a high degree of support for the following activities. In order, the highest ranking items were:

1. ACCE Newsletter, at least 4 times per year (Avg. Rating 3.9)
3. Advocacy of the Profession (Avg. Rating 3.6)
4. Collaboration with Other Organizations (Avg. Rating 3.3)
   • Audio Conference Courses on Healthcare Changes
   • Audio Conference Courses on Outsourcing Clinical Engineering Services

The membership also confirmed that the venue for the next ACCE Meeting should be in conjunction with the 31st Annual AAMI Meeting in Philadelphia, PA from June 1 - 4, 1996.

NEW FDA GMP REGULATIONS

In July, the FDA released a draft of the GMP Regulations for manufacturers of medical devices that for the first time requires hospitals and other third party servicers to SEND COPIES OF ALL SERVICE REPORTS TO MANUFACTURERS and to ensure that following a repair, the devices meet all safety and performance specifications. On August 23, 1995 the FDA’s Office of Compliance held an open meeting to discuss these proposed changes. About 20 industry leaders made presentations to the capacity crowd.

According to ACCE President Tom Bauld, The new regulations would impose an enormous burden on hospitals when there is no evidence that the safety of patients is being adversely affected by “inappropriate” service support. ACCE member Mike Argenteri was one of those who provided feedback to the FDA Panel at the August meeting. Mike cited statistics from the SMDA 90 showed that less than 1/10 of 1 percent of the serious injuries or deaths relating to medical equipment stemmed from service errors.

Despite this information, Jack Spears reported in Biomedical Technology Today that “When asked why servicers should be regulated as manufacturers, an FDA panelist replied that servicers have a significant impact on a device’s continued safety and should therefore fall under the control of the FDA. Further elaborating, the panelist went on to say that the FDA must level the playing field between independent service organizations (in-house departments, ISOs, etc.) and their manufacturing counterparts.” In his article, Mr. Spears points out that independent

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GMP Regulation Letter #1—ACCE Responds

Thomas J. Bauld, Ph.D.
September 7, 1995
Dockets Management Branch (HFA-305)
Food & Drug Administration, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857
Re: Docket Number 90 N-0172

Dear Sirs,
The American College of Clinical Engineering (ACCE) appreciates the opportunity to comment on the working draft of the Current Good Manufacturing Practices Final Rule, dated July 1995.

Our organization consists of many of the most highly experienced clinical and biomedical engineers in the United States and around the world. These individuals have established and managed many of the largest hospital based clinical engineering/biomedical engineering departments in leading community hospitals and academic health care systems. Many of the members also have experience in the third party service area and have served as consultants in many areas of medical device management. They have led efforts in the area of device technology management, the development and application of computerized maintenance management systems, device safety standards, and education of engineers, technicians, and clinicians in the biomedical community. Their roles in their respective institutions include management of the Safe Medical Device Act processes, device recall management, investigation of device related incidents, service on Safety Committees, management of the biomedical equipment technicians, and acting as chief technology officers.

Our organization and its members have as one of their major priorities the promotion and safe application of medical devices in healthcare institutions and we support efforts that demonstrate a positive and cost-effective contribution to that goal. Unfortunately, the proposed inclusion of hospital based service providers as part of the CGMP for manufacturers of medical devices is not justified by the level or severity of patient injuries or patient deaths that can be documented as related to service activities. Studies by staff at ECRI have shown that an insignificant number of MDRs are related to maintenance activities.

The proposed regulations will add to the already significant burden imposed on hospitals by the FDA for User Problem Reporting and Device Tracking. Activities that have not yet been demonstrated to be either effective or beneficial to the healthcare of our patients.

It does not seem that those in the FDA preparing the regulation have an understanding or awareness of the realities of device service support or the resources necessary to accomplish the activities required by these regulations.

The level of administrative activity that will be required to comply with the proposed CGMP will add considerable expense to the provision of patient care when the healthcare industry is under dramatic pressures everywhere to reduce costs while maintaining the highest quality of service. Within the regulation, there is no provision to prioritize classes of devices where significant risks or problems may be shown to exist and hence where an effort of this type would be worthwhile. Also, there is no method to test the validity of the assumption that inadequate service leads to significant risks to patients.

Hospitals are already evaluated on their processes and procedures for safe and effective equipment programs by Joint Commission for the Accreditation of Healthcare Organizations (JCAHO). Most clinical engineers are members of ACCE, AAMI, or ASHE, professional organizations which educate their members and promote effective equipment management.

The following is an example of the expenses we expect to be incurred, for an institution of 500 beds where a typical annual number of corrective service requests for medical devices is approximately 10,000. A simple calculation of costs is as follows:

<table>
<thead>
<tr>
<th>Task</th>
<th>Labor</th>
<th>Materials</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorting and Distribution of Service Requests</td>
<td>$0.05</td>
<td>$0.05</td>
<td>$0.15</td>
</tr>
<tr>
<td>Duplication of Service Requests</td>
<td>$0.10</td>
<td>$0.05</td>
<td>$0.15</td>
</tr>
<tr>
<td>Mailing Service Requests</td>
<td>$0.10</td>
<td>$0.32</td>
<td>$0.42</td>
</tr>
<tr>
<td>Total</td>
<td>$0.25</td>
<td>$0.37</td>
<td>$0.62</td>
</tr>
</tbody>
</table>

For 10,000 reports, the cost will be $6,200 per year.
This represents a cost of $12.40 per year per bed!
GMP Regulation Letter #1—ACCE Responds

Totaling over the 1,000,000 hospital beds in the United States, the cost would be $12,400,000.00. This does not include other healthcare facilities such as outpatient surgical centers, sub-acute facilities, rehabilitation centers, or nursing homes.

Considering that there is no substantial evidence that a significant problem exists with in-house service providers, this level of expense cannot be justified in any cost-benefit analysis.

Specific language of the working draft that we are opposed to includes:
I Subpart -N, 820.200 (a) which includes language that states that "the finished device serviced meets the manufacturer’s safety and performance specifications. A copy of all service reports shall be forwarded to the original manufacturer."

We object because the language states that at the conclusion of service, it must be demonstrated that the device "meets the manufacturer safety and performance specifications." This will impose an impossible labor requirement because it requires a full and in-depth verification procedure of the device performance that is a waste of personnel time. While it is standard practice to verify basic device operation and safety when a repair is completed, it is absolutely not recommended practice to demonstrate total and complete compliance to performance and safety specifications. Such a demonstration is only justified and done at Incoming Inspection when a device is received into a facility or when a complete overhaul is completed. In addition, the manufacturers' service representatives do not currently ensure that a device performs to all its specifications when they do repairs.

We object to having to forward copies of all service reports to the original manufacturer because of the expense as listed above, and because there is no standardization of forms and terminology. Manufacturers may not be able to interpret or translate the reports sent to them into their standard data elements for analysis. If there are questions from the manufacturer, then there will be additional labor costs to the hospital and the manufacturer to discuss those questions. Manufacturers expend substantial resources to train their own service staff to complete their service reports accurately. They shouldn't need to train in-house service providers as well.

II Subpart -N, 820.200: The provision by which manufacturers will analyze hospital service reports "to properly assess whether there is an early wearout failure for a particular component or subassembly, to any misuse by users, and to detect any design flaws, among other things." Manufacturers cannot be expected to determine if there is "misuse by users" based on information provided in service reports since the reports are not sufficiently complete or detailed for such an assessment. Hospitals must not be subjected to having manufacturers make determinations of user error and the possible legal consequences that could arise from such allegations.

The time wasted by service staff complying with these requirements will, in fact, be counter-productive to good device service management, since less time will be available to attend to real corrective service activities, scheduled device inspections, and operator training. Managers of hospital service organizations are continuously evaluating the services they provide to ensure the services are adequate, sufficient, meet their customers needs and regulatory requirements, and add value.

In summary, we feel that the FDA has not demonstrated a need to include hospital based service activities in the CGMP for medical device manufacturers, there is no evidence to show an improvement in patient safety will occur and the economic burden imposed on hospitals is not in any way commensurate with any limited benefits that may accrue.

We strongly recommend that hospital and other healthcare system service providers be specifically excluded from complying with the CGMP regulations regarding service reports. We hope that our comments are seriously considered as the final regulation is formulated. We welcome the opportunity to meet and discuss further with your staff, any issues relating to medical device management and safety.
GMP Regulation Letter #2 - CALL TO ARMS!

Elliott B. Sloane

I spent two aggravating days in Gaithersburg, MD last week (September 13-14, 1995) watching our government at work, and it was not a pretty picture. Given the benefit of the doubt, perhaps the intent was well meant. From my vantage point, however, the process and outcome were grim. In a nutshell, the public Good Manufacturing Practices (GMP) Advisory Committee which the FDA had convened gave the FDA the apparent green light to move into regulation of the biomedical service industry, including service performed by in-hospital engineers and technicians. 

I say "apparent" because the 5-4 votes on the various aspects of the topic discussed were, in the words of the committee chairman, "less than a consensus," and included many reservations and concerns. Nonetheless, the FDA leader, Kimberly Trautman appeared to interpret their response as a "yes" vote to regulate all aspects of biomedical services, from repair and maintenance through refurbishment. I can only hope that the public comment that the FDA receives between now and October 23 will cause them to drop non-manufacturer service from their GMP regulation and defer taking any further action until a consensus can be reached through much more thorough, careful, and reasoned discussion takes place.

I believe that the Advisory Committee was trying their level best as public and business citizens to fulfill their role in addressing this issue, but was not given enough information to do so. Although several committee members asked what data there was to support this new regulatory role requested by the FDA, they were repeatedly only told that the data analysis presented earlier by ECRI, which contradicted the FDA’s position, was invalid and they were instead offered these two anecdotal rationalizations to justify the change:

1) Previously used implants (pacemakers & heart valves) and single-use disposables (angioplasty catheters) are being "reprocessed" and resold for clinical use without FDA oversight. Since the FDA’s newly revised definition of "service" now included various processes including "refurbishing and reprocessing," processes of restoring a device to its original specifications and/or performance, the Committee was told the FDA needed the committee’s mandate to regulate "service" in order to protect the public.

2) Under the new GMP, manufacturers were going to have to evaluate and integrate problems found in their own field and bench service activities into their overall quality assurance and reporting programs, so a "level playing field" needed to be created, with additional staffing and reporting costs forced on third-party repair companies to ensure fair competition.

As a Clinical Engineer who has devoted over 20 years in this industry to help improve the quality, safety, efficacy, efficiency, and cost-effectiveness of health care technology, I found the inadequacy of this "proof by intimidation" logic appalling. While I agree that the examples the FDA used deserve discussion and resolution, they beg the question. Where, exactly, is the problem? Good science and engineering demands that good solutions start with good problem analysis. Where is the logic? Does regulating the inspection, maintenance, or repair of an oxygen flowmeter have anything at all to do with reprocessing angioplasty balloon catheters. Furthermore, when was the FDA’s mandate expanded to management of “fair competition”? Even supposing that was a legitimate role, how does wholesaling force extra costs on the broad market segment of third party service make sense. Without accurate data to defend the concept, that is irresponsible, especially in a market desperately trying to conserve resources wherever possible so that the entire American public can get the most value out of each health care dollar spent!

Unfortunately, the other “logical” outcome that emerged from the committee was the recognition by the committee that since they accepted there was an urgent and significant public health risk that justified regulating “service” of all medical devices, effective management of that risk must, by definition, extend to all service providers, including in-house hospital service staff. Since there isn’t any overall technician certification or licensing that provides unbiased assurance of competence and training, and since JCAHO and other accreditation programs are voluntary, infrequent, and do not even attempt to get into levels of details like parts selection and service procedure validation and verification, the mission of safety embodied in the Good Manufacturing Practices cannot be met. Thus, a logical conclusion was drawn, but from a faulty initial premise.

After my fifteen years with ECRI, and my recent half dozen years managing the repair and management of one of the countries largest and most diverse medical equipment fleets, I could not honestly say that service mistakes have never happened, nor would I say that the quality and productivity of service activities cannot be improved. Quite the opposite: at the recent AAMI Annual Convention I delivered a talk advocating more aggressive technician licensing akin to FAA licensing for airplane airframe and power plant licensing, together with industry standards for repair quality and common procedures. That talk was based on a desire to start discussing how we can incrementally improve the skills and results on behalf of efficiency and safety, however, not on any clear pattern of patient injuries and deaths. No doubt such unfortunate incidents may have occurred, but in my experience most medical devices are remarkably well designed to withstand occasional servicing mistakes. Those patterns of failures that occur most
commonly are usually device and/or component limitations that should be readily evident from the manufacturers’ own service files, which is exactly why the GMP regulations need to include the manufacturers’ service activities. I sincerely doubt that dumping all of the third party and hospitals’ anecdotal service records, in all their varied content and format, will do anything but muddy the waters and will eliminate any hope of accurate analysis.

In my humble opinion, despite the countless hours volunteered to the FDA by professionals, various societies, and companies themselves, and despite the agencies best efforts by their best and brightest staff, the agency is still far from mastering the medical device business. Why they cannot effectively and clearly separate reprocessing of single-use disposables from electromechanical repair in a document they have labored over for years is beyond explanation. And then, why they cannot draw the following parallel for themselves is another issue: If an FAA-licensed airplane mechanic is able to repair a 50-year old Stearman biplane WWII trainer so that it can safely be used to give rides to American citizens, why can’t similar repair strategies be applied to most medical electromedical devices? Maybe the FDA feels they must reinvent each and every wheel, but that’s not what they are paid or asked to do! The repair and maintenance business has many exemplary training and quality programs in industry and the military that have existed for decades. Why not use them? Maybe their staff does not get out into diverse industries in the real world enough, or maybe they promote too much from within instead of hiring experienced people from industry. Why wasn’t there an experienced professional from the electromechanical repair/service industry on the Advisory Committee that the FDA selected? At least the committee would have had the benefit of that person’s wisdom to help them do the job correctly. Whatever the problem, I believe this country is not getting the results it deserves and needs in the medical device area.

I suggest that all of you warm up your word processors and fire a line to the FDA and your representative in the Senate and Congress. Even if you never, ever wrote a letter, this is the time to do so. Senator Oren Hatch of Utah has also been keenly interested in the vitality of the medical technology sector, and Vice President Al Gore has clearly been tasked with revitalizing the government and eliminating such wasteful endeavors. I suggest that you clearly and simply explain that non-manufacturer service is not and should not be part of the FDA’s mandate, especially under the Good Manufacturing Practices regulations. Remember to emphasize that any artificial distinction between hospital and third-party service is not an acceptable solution; technicians and engineers in either setting are working under similar technical and economic constraints, and adding useless extra costs to one industry will not only force smaller providers out of business, some of whom are single experts trying their best to serve small rural pockets of hospitals, nursing homes, and home health care technologies, but will drive everyone’s labor and parts costs up by reducing competition on top of the increased overhead to comply with GMP-style systems.

Comments for the FDA can be addressed as follows:
Kimberly A. Trautman
Office of Compliance, Center for Devices and Radiological Health (HFZ-341)
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850
ph: (301) 594-4648
For the public record, a copy of your comments must be sent to:
Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

If you feel so inclined, you might also like to offer your professional insight and experience to a later, more complete and effective discussion of how the efficiency and consistency of biomedical equipment service might be improved. If you feel so inclined, you might also express your thoughts about whether more comprehensive industry self-regulation, professional certification, or even federal service licensing might be useful or destructive, based on your own vantage point.

At least give the FDA and the government the benefit of the decades of our applied experience to guide them instead of letting them be driven by good intentions that have been distorted by fear and illogical thinking. While letting the FDA decide to regulate “service” may be good for your individual job security, and maybe even good for your paycheck, in the end you and I will pay dearly for the waste. There is still time for the FDA to choose to interpret their Advisory Committee’s self-stated lack of consensus in a constructive manner without any loss of face, which is the right thing for the industry and the American public.
servicers simply return the equipment to its original design specifications and typically do not perform warranty service—"where most of the design problems occur."

The FDA accepted public comment on the proposed regulation until October 23, 1995. The ACCE, AAMI, ECRI, SBET and several hospitals and corporations sent official letters to the FDA voicing their concerns about the proposed regulations. President Tom Bauld's letter, on behalf of the ACCE, and an open letter from ACCE member Elliott Sloane are reprinted in this issue.

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**MEMBERSHIP COMMITTEE ACTIVITIES**

**Binseng Wang, ScD, CCE**

This report covers the period from May 1995 through July 1995. In this period of time 15 invitations for interested parties to join ACCE were sent out and four applications were received and processed. Congratulations are extended to the following new ACCE members:

**Individual Members:**
- Ruben Dario Gonzalez (Cuba)
- Michael Berman
- Arpan K. Limdi

**Associate Members:**
- Banji A. Akinsola (Nigeria)

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**FELLOW MEMBERSHIP APPLICATION PROCEDURE**

**Binseng Wang, ScD, CCE**

**I. INSTRUCTIONS**

- Attach a check for the $25 filing fee. This fee covers the evaluation expenses and is non-refundable. An award fee of $50 (to cover the diploma cost) will be required if the application is approved.
- Mail the application to ACCE, 5200 Butler Pike, Plymouth Meeting, PA 19462.

The application will be reviewed by the Membership Committee using the criteria described in Section II, and then forwarded to the Board with the Committee's recommendation. The Board will make the final decision, which will be communicated to the applicant by the President.

**II. ADVANCEMENT CRITERIA**

The following criteria will be used by the Membership Committee for evaluating the candidates for fellow membership. These criteria are guidelines rather than detailed rules. They may also help potential candidates in determining their eligibility for advancement.

- **PROFESSIONAL SERVICE AND ACHIEVEMENTS:** At least fifteen years of professional experience, of which six years must be as a clinical engineer having the following activities:
  - making decisions which have significant direct clinical impact;
  - supervising and managing people, equipment, and budgets;
  - applying standards and regulations;
  - conducting technology assessments, evaluations, and device acquisitions; and
  - participating in patient safety and quality assurance/improvement.
  - achievements such as continuing education, awards received, and other notable accomplishments

- **DISTINGUISHED SERVICES TO THE PROFESSION:**
  **As an educator and/or researcher:**
  Scholarly and learned presentations and publications of the following types:
  - lectures presented in an academic setting; or
  - technical papers presented in a professional setting; or

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- short courses taught at professional meetings or accredited institutions; or
- articles published in peer-reviewed journals; or
- books and/or book chapters published for educational or research reporting purposes; or
- internal reports; or
- patents and innovative ideas.

As a leader:
Must have held at least two leadership positions (officer, committee chairperson, committee member, and other significant roles) in ACCE or other professional organizations with significant role in healthcare technology management.

As an advocate of the profession:
Presentations and publications made to professionals outside of clinical engineering.

III. APPLICATION OUTLINE

- PROFESSIONAL SERVICE AND ACHIEVEMENTS
  - Work Experience (supply the following information for each job held)
  - Organization, Employment Period, Job Title, Job Description (present)
  - Organization, Employment Period, Job Title, Job Description (previous)
  - Continuing Education (beyond those required for ACCE individual membership)
  - Institution, Study Period, Degree Obtained, Courses Completed
  - Others
  - Awards and Other Types of Peer Recognition
  - Awards (provide details)
  - Other Types of Peer Recognition (attach proof)
  - Other Accomplishments (not in the categories listed above)

- DISTINGUISHED SERVICES TO THE PROFESSION
  Educational and Research Activities
  - Lectures (Institution or Organization, Length, Audience)
  - Technical Papers Presented at Invited and Peer-Reviewed Meetings
  - Short Courses (Institution or Organization, Length, Audience)
  - Articles Published in Peer-Reviewed Journals
  - Books & Chapters Published
  - Internal Reports (attach abstract if possible)
  - Patents and Innovative Ideas (provide details)
  - Leadership/Organizational Activities
  - Organization, Office Title, Duration (ACCE)
  - Organization, Office Title, Duration (other organizations)
  - Advocacy of the Profession (to non-Clinical Engineering audiences)
  - Printed Material (articles, interviews, etc.—provide details)
  - Oral Presentations (organization, location, significance)
  - Other Activities (type, location, organization, significance)
  - Other Services (not in the categories listed above)

ASHE MEDICAL TECHNOLOGY MANAGEMENT MEETING

The ASHE Clinical Engineering Section Medical Technology Management meeting was held in conjunction with the annual Radiological Society of North America (RSNA) meeting in Chicago from November 29 - December 1, 1995. John Hughes and Tom O’Dea were part of the organizing committee. This meeting has been emphasized in prior newsletters as another avenue to receive quality training, and to foster the intra-organizational collaboration you have felt to be very important. The content of the meeting was strong and it provided a good opportunity for networking with others who you may not have met before, and it’s centrally located in Chicago.

Coordination of the MTM meeting with the RSNA was the idea of Joe McClain, an ACCE member who is also a major leader in the ASHE Clinical Engineering Section. Yadin David and Tom Bauld did a course on Benchmarking. Yadin also taught the course on Technology Management, and Scott Segalowitz taught about BMET Competency Training, a major JCAHO issue. All ACCE members received the ASHE member registration discount, a significant savings. The opportunity to attend RSNA and this meeting was very worthwhile, especially for those who are or should be involved in imaging technology. Don’t miss it next year.
CALL FOR ACCE ADVOCACY AWARDS NOMINATIONS!

George L. Johnston

Now is the time to prepare your nominations for the 1996 Professional Achievement and Professional Development awards. There are many members who have made outstanding contributions to the profession and recognition of clinical engineering. But we can’t recognize them and reward them unless we hear from you - via the nomination process. Those of you who attended the 1995 AAMI meeting at Anaheim had an opportunity to attend the ACCE meeting and applaud that year’s winners at the presentation ceremony. Now we encourage you to be thinking about other deserving clinical engineers you wish to nominate for 1996 awards. Discuss prospects with your colleagues and then fill out your nominations and collect the required documentation.

REMEMBER: YOUR NOMINATIONS MUST BE IN BY MARCH 1, 1996! AND IT COMES QUICKER THAN YOU THINK! USE THE NOMINATION FORM INCLUDED IN THIS ISSUE OF ACCE NEWS.

You may nominate more than one person for an award. But, please use separate forms for different awards. Also remember that these awards are advocacy awards, not merit awards. Their purpose is to encourage all of us to pursue advocacy activities on behalf of the clinical engineering profession.

For your information the awards descriptions follow:

• ACCE PROFESSIONAL DEVELOPMENT AWARD
  The Professional Development Award recognizes those accomplishments of professional advocacy which promote awareness and appreciation of clinical engineering within other healthcare professions. These actions are mainly through publications and presentations in a distinctly non-engineering, health related publication or conference. Publications and presentations must incorporate the word clinical engineer or clinical engineering in the title. Terms used must be consistent with the ACCE definition of clinical engineer.

• ACCE PROFESSIONAL ACHIEVEMENT AWARD
  The Professional Achievement Award recognizes accomplishments in defining the exclusive limits for the practice of clinical engineering, i.e. identifying unique functions, roles, activities, duties and responsibilities of clinical engineers. The work should either be published in a journal of professional standing or at a conference of a professionally recognized health related organization. Publications and presentations must incorporate the word clinical engineer or clinical engineering in the title. Terms used must be consistent with the ACCE definition of clinical engineer.

Eligibility Criteria
If the nominee is a clinical engineer, then he or she must also be a member-in-good-standing of ACCE. The ACCE Secretary will verify the standing of all clinical engineer nominees. (Dues must be current!) Those nominated who are not clinical engineers are not required to be ACCE members.

Award Description
Awards will consist of cash (amount to be established annually by the ACCE Board), and a plaque identifying the awarded and the title of the publication or presentation for which he or she is being recognized. The number of awards will also be set annually by the Board. Multiple awards for a given award will each receive a plaque, but will split the cash.

GRASS ROOTS TEAMS
  Thomas M. Judd, CCE

Last October the ACCE introduced a new program designed to increase communications between members and increase everyone's participation in the ACCE. Under this Grass Roots effort all members became part of a geographically proximal team. A team leader was appointed and charged with convening their team at regular intervals to discuss issues and possible solutions relevant to clinical engineering. The hope in creating these teams was to spawn local discussion of national issues and feed the ACCE Board with local issues of national significance. Current or recent Grass Roots activities:

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- soliciting ACCE member response to FDA’s anticipated GMP legislation changes;
- recruiting task force members for Vision2000; and
- efforts to enhance accountability by regional and local team leaders to ensure good 2-way communications flow throughout the membership.

Future activities suggested for this winter:
- discuss ways ACCE can assist local societies;
- become an information channel for communicating with FDA concerning certain key procedural changes;
- examine means to create national equipment database containing risk factor information to assist in equipment planning and replacement decision-making; and
- publish guidelines on how to extend local CE department budgets through hosting of on-site OEM equipment service training schools.

Please call or email me your suggestions for ongoing use of this communications channel. Voicemail: 404-364-7140 or Internet: judd104w@wonder.em.cdc.gov

VISION2000 - NEXT STEPS
Mo Kasti & Thomas M. Judd, CCE

Significant organizational energy was evidenced around the Vision2000 presentation made at the ACCE annual meeting in May in Anaheim by initiative Co-Chair Mo Kasti. Additionally, the project was voted as ACCE’s second highest priority activity by the recent membership survey. This strategic planning effort, outlined in the May, 1995 ACCE Newsletter, has now resulted in a formal vision statement. This vision will be pursued through the development and implementation of four strategic initiatives.

The Vision Statement adopted is the following: 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.

Supporting definitions for the vision statement include the following:
- Technology Management Process: This process encompasses a wide spectrum of technologies and activities. Technologies might include but are not limited to biotechnology, information systems, medical devices and software, imaging, and medical/surgical procedures. Activities might include but are not limited to traditional activities such as technology assessment, strategic technology planning, technology acquisition, technology management, and non-traditional activities such as organizational quality improvement, case management, clinical practice guidelines, and clinical pathways development.
- Business-orientation: Technology management activities are modeled and implemented in a business approach that demonstrates and quantifies value of its services in cost containment, generation of revenues, improvement of patient care, and achievement of quality outcomes. These activities will be conducted in a manner that continuously benchmarks, competes in the marketplace, and through investing in human assets.
- Healthcare System: This system covers a wide spectrum including but not limited to the following entities: provider institutions, physician organizations, health maintenance organizations, home healthcare organizations, suppliers, and manufacturers.

The four initiatives are the following:

1. PUBLIC RELATIONS / MARKETING
   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.

2. 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

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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.

3. DEVELOPMENT OF NEW 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.

4. UNIFICATION OF EFFORTS

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

The next step will be to form task forces to explore each initiative. The task forces are envisioned to include 4-6 individuals, of which one will be a team facilitator. As a coordinating activity, Project Chairman Mo Kasti will work with the four task force facilitators to keep team activities on track.

The ACCE Board has suggested the following timetable: (1) finalize task force volunteers and name facilitators in November, 1995; (2) empower the task forces to take 90 days to develop action plans around each initiative, including specific projects with personnel accountabilities, timetable, and budget required (through January, 1996); (3) the Board will conduct a special meeting in March, 1996, to consider task force results and how to optimally begin implementation; and (4) Implementation Teams will be named to begin designated activities.

ACCE members are invited to contact one of the following to volunteer for a task force position:

- Mo Kasti VM: 800-807-8955 X5750
  BEEPER: 800-SKYPAGE, PIN # 1252429
- Tom Bauld VM: 313-936-7893
  INTERNET: bauld@umich.edu
- Tom Judd VM: 404-364-7140
  INTERNET: judd104w@wonder.em.cdc.gov

Some members already indicated their interest to Mo at the annual meeting. It is envisioned that task forces will meet by telephone conference at least twice monthly over the 90-day period to complete their assignments. This is a significant opportunity to influence the future of the profession and ACCE. Please consider how you might become involved.

VISION2000 - PROPOSED GLOBAL INITIATIVES

Phil Katz, Ph.D. & Ira Tackel

The PACE initiatives, developed by Tom Bauld and printed in the May, 1995 ACCE Newsletter, are designed to improve clinical engineering cost effectiveness and are to be considered by the Vision2000 task forces as appropriate. We propose six other “global initiatives” for consideration by the task forces, as well.

- Develop models for revenue generating activities to offset cost of Clinical Engineering programs and or contribute to financial bottom line (PC support, Shared Services models, etc.)
- Broaden Technology base of Clinical Engineering activities to enhance value of technology management services (e.g., Imaging Support, IS, PC’s, LAN’s, Communications (data, video, voice), Clinical Laboratory).
- Address critical need for effective integration of Technology Management in optimizing outcome quality and cost containment for the institution.
- Develop core competencies to enhance the value of Clinical Engineering participation in diverse and non-traditional areas (e.g., statistical analysis, engineering principles, etc.)
- Develop of innovative human resource programs to augment satisfaction of technology management personnel.
- Identify educational resources which will increase the knowledge and awareness of Clinical Engineers about key political, economic, and patient care trends affecting organizational success.

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ACCE TELECONFERENCE SERIES

James O. Wear, Ph.D.
Education Chairman

The 1995 ACCE Teleconference Series was concluded on August 17th with a presentation by Dr. Warren Grundfest on “The Role of Technology in Determining Patient Outcomes”. This presentation was rescheduled after Dr. Grundfest did not make the July date. The site coordinators were notified of the reschedule and all but two sites were on line. On the August date there were some problems with dialing in because a fiber optic cable had been cut and the bridge had to call some sites.

The 1995 series had as many as 13 sites on line for Ode Keil and an average of 10 sites for other presentations. There were 40-50 participants for each call.

The 1996 series scheduled courses include:

- February 15  Breakthrough Management
  Gailord Gordon

- March 21  Incident Investigation
  Marv Shepherd

- April 18  Maintenance Insurance
  Dee Kahn

- May 16  Benchmarking
  Robert Stiefler

- June 20  Outsourcing
  Malcolm Ridgway

- August 15  Contract Management
  Dave Simmons

- September 19  Quality Improvement
  Lana Berry

- October 17  CE Involvement in Managed Care QI
  Tom Judd

- November 21  New Opportunities for CEs
  Ira Tackel

The cost for up to three ACCE members at a single site is $100 per course or $850 for the series. Additional attendees will be charged $25 per course. ACCE will accept checks, credit cards, and purchase orders. P.Os can be FAXed to Jim Wear at 501-771-1775 or call him at 501-370-6618 to make other reservations.

REPORT ON: IFMBE CLINICAL ENGINEERING DIVISION MEETING IN MERANO, ITALY

Joseph F. Dyro, Ph.D., CCE

The south Tyrolian village of Merano, Italy, was the site of the meeting of the Board of the Clinical Engineering Division (CED) of the International Federation of Medical and Biological Engineering, October 19-21, 1995. Chairman Nicolas Pallikarakis welcomed Treasurer John Smith, Secretary Joseph Dyro, and Board Members Myoung Ho Lee, Ulf Bostrom, Otto Anna, Peter Heimann, Diego Bravar and Pekka Karp. The board meeting coincided with the International Clinical Engineering Conference held in Merano. Several members of the board also participated in the Conference as members of the Scientific Committee, Session Chairs, and presenters. The Conference drew 237 registrants from 24 countries and addressed all aspects of clinical engineering in well prepared papers.

The Chairman's report included a report on the IFMBE Administrative Council meeting in Netanya, Israel, where unanimous support was received to continue the efforts of CED to promote Clinical Engineering worldwide. The Bioingeniera y Fisica Medica95 Conference, held in April in Havana, Cuba, received financial support from the CED and was graced by the participation of board member, Adriana Velasquez. Endorsement of the Advanced Clinical Engineering Workshop in Mombassa, Kenya, November 1996, and the BUDAMED96 Conference in Budapest, August 1996 was affirmed. The board has contributed to the continued progress on BEAM II. INBITs work on BEAM II received exposure. Strong financial support by the Administrative Council together with earned income from publication sales will enable CED to undertake initiatives in electronic publishing and the Internet, a Who's Who resource guide for clinical engineers, and educational programs in developing countries with particular emphasis on Asia. From the United States, Secretary Dyro reported on the American College of Clinical Engineering (ACCE); highlighting its teleconferencing program, grass roots team development, Vision2000 project, advocacy efforts and advanced clinical engineering workshops (Mombassa

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and Beijing). He reported on his participation in II SEC, the second clinical engineering symposium in Sao Paulo, Brazil, August, 1995.

Treasurer Smith reported a healthy account balance going into the next year. Turning attention to Canada, he remarked on his country’s efforts at harmonization of IEC and CSA standards over the next five years; the development of standards of practice for clinical engineering; success with educational programs through Telemedicine Canada; and venture into benchmarking efforts in the face of significant staff reductions. The IEEE/EMBS Annual Conference held this year in conjunction with the Canadian Medical and Biological Engineering Society annual meeting featured the themes of standards of practice, certification requirements, downsizing, continuing education, and health technology assessment.

Otto Anna reported on the situation in Germany. After a brief report on the Wurzburg meeting in September on ISO 9000 he outlined the clinical engineering realities of the unified East and West Germany’s discussing typical educational preparation and staffing levels. Anna heads a five-member Clinical Engineering Certification Committee that has certified 50 individuals in its first five years. Upgrading of educational programs will include the integration of medical with technical courses. A 1996 Cost Control Law will throw into sharp focus the issues of financial management, sampling costs, networks and computers in clinical engineering. A discussion on user-related medical device problems revolved around a recent paper pointing to a 70% figure due largely to the increased sophistication of medical devices and the lag in user understanding of device operation and application.

According to Karp, Finnish health care in the 90’s has been characterized by an adaptation to shrinking public economy. The consequences of the recession have been health care reorganization, privatization of support services, downsizing, and hospital closings. Two specific developments were mentioned. First, the Finnish Office for Health Care Technology Assessment (FinOHTA), headed by Karp, was established on January 1, 1995, to promote the effectiveness and efficiency of the Finnish health care system. The Office will concentrate on the commissioning of assessment studies, the dissemination of information to decision makers, and fostering international cooperation. Second, the three largest health care organizations, the hospital districts of Helsinki and Uusimaa and the Helsinki University Central Hospital (responsible for the hospital care of one-fifth of the Finnish population), have finalized a plan to merge their medical equipment maintenance units into a jointly owned company. In the case of the University Hospital, the plan would strip the hospital’s CE department of its maintenance function, leaving only the clinical engineers in the hospital with the task of technology management and R&D in biomedical engineering. This development in the Helsinki area does not, however, reflect the general situation in Finland. The 450 communities responsible for health care and the 21 hospital districts in which they belong are independent in their decisions and their own ways of solving problems.

From a second Nordic country, Bostrom (Sweden) began with a description of a voluntary certification system requiring two years of experience that lists 50 certified at the Master’s level and 100 certified at the lower levels. Many CE departments are downsizing, but some are expanding. Joining in on the user abuse/misuse issue, he offered that an 80% user error figure was recently reported compared to a 20% figure just 10 years ago. Using the critical incident method 90-95% of unreported incidents are user related. Reflecting his heavy involvement in the standard process, Bostrom discussed the slow (18 years in the works) advance of IEC 601.1, various extant equipment standards, and the five technical reports on medical device usage, i.e., defibrillators, electro-surgical units, defibrillator maintenance, ESU maintenance, and the development of instructional and educational material. Documents in progress include ergonomics and technology management.

On the other side of the world, Lee reported that Korea has 700 in its BME and CE society. Semiannual meetings typically draw 500 with 200 active presenters and result in four volumes of publications annually. The organization is actively involved with the national government in health care projects planning. Echoing others, Lee concurred with the major problem of mishandling. The lack of a certification program and the duty to harmonize the level of CE
support across the spectrum of hospitals are in need of attention. Lee encouraged continued discourse on realizing advanced clinical engineering workshops and international meetings in Korea as well as other parts of Asia.

Getting back to home, Bravar enumerated the Italian associations and described an expansion in educational programs across the country. Clinical engineers currently cover only 10% of the beds nationally. Hospital engineering has traditionally been dominated by civil engineers with mechanical and electrical engineers making in-roads over the last 15 years. Manufacturers are increasingly offering clinical engineering services. Technology assessment exists on a regional as opposed to a national level.

Peter Heimann presented the African Federation for Technology in Health Care, of which he is Secretary-General. The AFTH addresses all points in the technology management cycle: research, development, manufacturing, marketing, assessment, evaluation, procurement, and utilization. Of vital importance is the establishment and upgrading of communications in Africa and the integration of clinical engineering within the health care system. The fifteen member nations of AFTH comprise 100 million population. As one example not untypical of the African situation, he pointed to the Cameroon situation where 50% of devices are out of use and 80% are non-functional.

The second edition of the International Clinical Engineering Directory will be managed under the direction of a five-man committee consisting of Dyro, Lee, Smith, Heimann, and Bravar. Plans call for a Who’s Who in clinical engineering including a comprehensive database to aid in networking and resource management. The electronic information exchange committee was constituted with Smith, Lee, Pallikarakis, Bostrom and Karp members. Future meetings were discussed. It was agreed that CED support the upcoming Nordic/Baltic Conference, June 9-13, 1996, in Tampere, Finland, the Advanced Clinical Engineering Workshops in Sub-Saharan Africa, November 1996, and Beijing, November 1995, and BUDAMED, the August 1996 conference in Budapest. The CED will examine the possibilities for an International Conference in Clinical Engineering, probably in Budapest. Coincidentally, the CED unanimously approved the application of the Hungarian Clinical Engineering Society to become a member of the CED. Division presence at the 1997 IFMBE conference in Nice was agreed upon. It was further agreed that special emphasis be placed in fostering CED activities in Asia. The first CED sponsored program will be the Advanced Clinical Engineering Workshop sponsored by Orbis International and presented by a faculty from the ACCE and the CED. The Workshop is presented by The Chinese Society of Biomedical Engineering and SubSociety of Clinical Engineering and takes place November 6-10, 1995, in Beijing, PRC.

Bostrom invited members to suggest future editors for Clinical Engineering Update, the newsletter of the CED, and renewed his request for material to publish. An electronic magazine committee was constituted with members Bronzino, Velasquez, Lee, Pallikarakis and Bostrom. The meeting adjourned at 19:35, October 21, 1995.

REPORT ON: II SIMPOSIO DE ENGENHARIA CLINICA
Clinical Engineering Symposium II, Sao Paulo, Brazil

Joseph F. Dyro, Ph.D., CCE
Innovation, advocacy, enthusiasm, professionalism and vitality characterized the Second Clinical Engineering Symposium, II SEC, in Sao Paulo, Brazil, August 25-27, 1995. Creative planning by conference chairman, Lucio Flavio Brito and his staff set the stage for the key addresses on each of the three days of the symposium to be presented by a physician, an administrator and a clinical engineer. The strategy of bringing three professions together succeeded in promoting interaction and understanding across professional borders. The symposium attracted nurses, physicians and health care administrators from across Brazil. Reporters from the leading Brazilian trade journals, Suprimentos & Servicos Hospitalares and Guia de Fornecedores Hospitalares covered the symposium.

Brito, joining other dignitaries in the opening ceremonies, spoke on the crucial role ACCE has played
in fostering the growth and maturation of clinical engineering in Brazil. Paul Vegoda (Administrator), Chief Information Officer at North Shore Health Systems, Manhasset, New York, Physician, Steve Barker (Physician), MD, Chairman of Anesthesia, University of Arizona, Tucson, and Joseph Dyro (Clinical Engineer), spoke and were joined by ACCE member Frank Painter, Novamed, Bridgeport, CT, who through the support of the Pan American Health Organization was able to lecture at the conference and to assist in giving ICC certification examinations. Pedro Tonarelli of Uruguay rounded out the field of international speakers whose addresses combined with the many fine presentations by Brazilian clinical engineers, nurses, physicians and administrators to result in an informative and stimulating conference. The speakers all emphasized the critical role clinical engineering plays in the management of medical device technology. The various ways to provide clinical engineering support, e.g., in-house, third party, manufacturer, were discussed.

The Symposium was held at SENAC, the principal network of major technical colleges of Brazil. Other supporters included the companies, Baumler Hospitalar, Dixtal, Fanem LTDA, and Takaoka, RealPrev, and MMTK-Trade. The Scientific Review Committee was comprised of Clinical Engineering Consultants and Commerce, Ltd, the Federal School of Engineering of Itajuba, and the Federal University of Sao Paulo. An exhibit hall featured a wide range of medical products and services. Thirty technical courses were presented on such subjects as imaging systems, anesthesia machines, infection control, materials management, hemodialysis, and in-service education. The facilities, support, and hospitality were exceptional. The coffee was terrific.

Dyro and Painter administered ICC Clinical Engineering certification examinations to a dozen candidates. Brazil, as a result of new programs in four academic institutions, has educated a hundred clinical engineers over the past few years. The development of an ICC Brazilian Board of Examiners is well underway. Plans are in progress to repeat the event next year with the possibility of broadening participation to include other South American countries.

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REPORT ON: CLINICAL ENGINEERING AT CHILD HEALTH 2000,
2nd World Congress & Exposition, Vancouver, Canada, May 30-June 3, 1995

Elliott B. Sloane

Immediately after the AAMI convention in Anaheim, I headed up to the Child Health 2000 which was sponsored by UNICEF, WHO, and many other international agencies. The meeting turned out to be overwhelming, with thousands of scientists, engineers, physicians, and politicians from around the world, including many distinguished presenters, not the least of whom was Dr. Jonas Salk, in what turned out to be his last major public appearance.

The focus of the dozens of simultaneous tracks running through the day was wide-ranging: covering everything from education and prenatal care to advanced genetic research. Thanks to the hard work of Mr. George Eisler and his fine colleagues and staff from the British Columbia Institute of Technology, there was a three-day track titled "Global Approach to Appropriate Technology For Maternal and Child Health," in which I had the privilege to present and participate. Attendees and presenters came from the four corners of the world, including virtually every continent, and the breadth of discussion was astounding and immensely valuable to all. For myself, I came away with a hugely expanded sense of the definition of "technology" as seen from the poorest to the richest countries on the planet.

For example, one agency presented a case study from India in which they developed and marketed a birthing kit that was marketed alongside groceries in local stores. Inside this single-serving cereal-box-sized kit were the following: a clean plastic sheet to place under the mother, a piece of string, a razor blade, a couple of square inches of hard plastic block, a bar of soap, and an instruction sheet. While most of the items made immediate sense, the plastic block was an enigma until explained: most poor women gave birth on dirt floors where animals had also lived, and the infant death rate from tetanus was immense. The plastic block was to protect the plastic sheet from the razor blade while the umbilical cord was cut! This simple
example was one of many that drove home the point of how simple technical solutions could make a major difference in child and maternal health.

Dr. Joel Nobel presented a comprehensive update on ECRI’s available multilingual services, publications, and databases to help the attendees understand how to access them for their own country’s needs. He also reviewed ECRI’s international and historical experiences that underscore the need for careful planning and implementation of even the simplest of technologies.

For my part, I presented an explanation (on behalf of Tom Judd and Yadin David) about ACCE and how its members have been providing international education to clinical engineers through the Clinical Engineering Workshops since 1991, and discussed the future sites being planned. I also described the beneficial results produced by some of those 1991 trainees that I witnessed in cities I visited in Eastern Europe this past spring. I described the process of strategic technology planning being used by our colleagues to ensure that all life-cycle costs and considerations are included and budgeted prior to purchasing and using technology to help prevent buying products that can’t be effectively supported afterwards. All participants had their own horror stories of medical devices brought to their countries that only worked for the first few weeks or months, or in some cases never worked at all. They were especially impressed with, and appreciative of, the Medical Equipment Donation Guidelines that ACCE has created, and felt that such guidelines could go a long way to prevent well-meant intentions from causing more harm than good. Finally, I explained my experience and opinion that good, safe, tested used medical equipment that was available in the US could be effectively supported in other countries as long as the appropriate parts and test equipment were readily available at affordable prices and how this can truly help extend the limited health technology budgets available.

At the conclusion of the meeting, George Eisler convened a roundtable discussion of all of the attendees and agreed to organize some formal recommendations and guidance’s from the three day conference to assist the sponsoring agencies in their future programs. Hopefully, such a document will encourage future funding for the ACCE international initiatives, as well as help other related projects. Thanks and congratulations to George Eisler, et al for creating such a fine program and for inviting us to present ACCE’s activities.

NATIONAL CLINICAL ENGINEERING WEEK,
February 1996

George M. Johnston

Clinical engineers: unsung heroes or unnecessary baggage? Most of us in the trenches identify with the unsung heroes image. Yet, many of our more successful clinical engineering leaders who’s positions were suddenly changed to independent consultants may feel more like excess baggage. All of us recognize the need for vigorous promotion of our clinical engineering profession; the reality that a valuable service is often only missed when it is gone and the inability to rebuild once it has been abandoned. Hence the need to take vigorous action to educate those with whom we have professional relations or upon whom we are dependent.

The ACCE Board, in advocating recognition and support for clinical engineers and the profession, has approved the initiation of a National Clinical Engineering Week. This week-long celebration will provide a focus for a nationwide effort to promote the profession and the accomplishments of clinical engineers and their departments. Originally, the proposed dates for this activity were June 10-16, 1996. However, after reviewing the proposal, the Committee and Board decided to launch the program with the celebration of National Engineering Week in February 1996.

The National Clinical Engineering Week Task Force, headed by George Johnston, will be developing promotional materials to be distributed through our Grass Roots Teams. It is important that we reach all of our members in order that they may participate in developing an awareness of clinical engineering by our colleagues in other facets of health care during the months leading up to the celebration week.

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To be effective this must be a "Grass Roots" effort with maximum participation at the local level. Besides the obvious benefit of raising people's awareness of our profession, other benefits include: building pride in your staff, increasing recognition for your department, encouraging customer feedback by enhancing the informal interaction with your customers and departments with whom you collaborate, adding customers by demonstrating the range of services, capabilities and the devices supportable, inspiring high school, college students and faculty to further our profession, and by building vendor relationships.

Minimally, everyone is encouraged to follow the model developed last year by Washington Hospital Center (See ACCE Newsletter May 1995, Page 13).

The following is a list of additional local tasks to perform:
• Develop State, local, community, in-house events, meetings, workshops, displays, bulletin boards that highlight clinical engineering activities, services, values, etc.
• Send event notices and press releases to all community colleges and colleges with clinical or biomedical engineering programs. Provide brochures and/or speakers to explain the clinical engineering profession.
• Send event notices, press releases and letters to the editor of major journals and local newspapers.
• Send event notices to all local health care facilities, providers and suppliers.
• Request participation of all State, regional and local biomedical/clinical engineering societies as well as other engineering societies such as ASME and ISA (they often have biomedical interest). Develop local biomedical interest professional meetings with their joint sponsorship.
• Invite local CEO's, CFO's, CIO's and other healthcare organization senior administrators as well as State and local legislators and other prominent dignitaries to celebration events.
• Petition the governor of your State to officially declare NATIONAL CLINICAL ENGINEERING WEEK in February. Our goal is to have declarations in all 50 States!

PROFESSIONALLY CORRECT ADVERTISING

George M. Johnston

A goal of the ACCE Advocacy Committee is to assure that clinical engineering job descriptions and employment ads, properly reflect the credentials (particularly education and experience) that define a qualified clinical engineer. Towards that end, we have been encouraging members to maintain a sharp eye for inappropriate employment ads, job descriptions or other references and bring them to our attention.

Alert reader, Eben Kermit, CCE has reported just such an ad in the San Jose Mercury News. The heading is for a "BIO-MEDICAL (sic) FACILITY SUPERVISOR". In the opening sentence the ad reads "If you have an Associate degree or equivalent experience with five years in the medical equipment service industry, an excellent opportunity awaits you at our facility". At the close of the paragraph it goes on with: "You must possess substantial knowledge of electronics, human anatomy, physiology and medical terminology. Hospital experience, AAMI or CE certification is preferred".

Eben submitted this ad with the comment: "Associate Degree, Facility Supervisor, CE Certification? It doesn't add up!" The ACCE maintains that the person in charge of biomedical engineering at a healthcare facility should be a clinical engineer. Eben, who is a member of the ICC US Board of Examiners for Clinical Engineering Certification, also comments:

1. AAMI doesn't certify clinical engineers - the International Certification Commission does. AAMI only serves as the secretariat for the ICC, much the same as ECRI now serves as the secretariat for the ACCE.

2. To apply for CE certification one must have either a bachelor's degree in engineering or an appropriate science and three years clinical engineering work experience or be a registered professional engineer with three years clinical engineering work experience. Or, in lieu of either of those requirements, one must have fifteen years clinical engineering work experience with at least six years in a position of demonstrated responsibility.

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To educate the author(s) of this inappropriate ad, the ACCE Advocacy Committee will be forwarding an official letter to the number given in the employment listing.

Every ACCE member is encouraged to keep a sharp eye out for more such ads and report them either to the Advocacy Committee or a member of the ACCE Board. By forwarding your observations, you will then be helping us meet an important goal of our organization. We will use them as opportunities to educate health care professionals still in need of understanding of what constitutes a clinical engineer.

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ADVANCED CLINICAL ENGINEERING WORKSHOP III

The planned Third International Advanced Clinical Engineering Workshop was scheduled for August 14 - August 25, 1995 at the Mombasa Technical Institute, but had to be postponed at the eleventh hour due to United Nations-related worldwide funding cutbacks. The UNITO funds were needed to provide travel for the students from the Sub-Saharan African countries.

ACCE is an event co-organizer and a key contributor to the workshop’s faculty, although no ACCE funds are involved. Tom Judd and Yadin David have been leading this effort and will continue to work toward its realization next summer. Needless to say, the postponement was a major disappointment for the United States faculty, the international faculty, and of course, the African students. The US faculty included, Mike Gullikson, Frank Painter, Bob Morris, Tom Bauld, Tom Judd, and Mark Brody.

Like the previous two workshops for Latin America and Eastern Europe, it is envisioned that this program will strengthen technology management activities in an area of the world with critical healthcare needs. Clinical Engineers are being invited from approximately 50 countries and an Internet communications network is being established with these countries.

Buyers and Sellers of Multivendor Services Meet to Discuss Critical Issues and Find Common Ground

AFSM International, the association for the worldwide services and support industry, sponsored the First International Conference on Multivendor Services in Health Care. The three-and-a-half-day conference, December 4-7, 1995, was at the Fontainebleau Hilton Resort and Towers in Miami Beach, Florida.

Speakers addressed the new role of multivendor services in the hospital and medical center environment, including the impact of managed care, hospital systems integration issues, changing decision-makers, and the special challenges faced in the health care services environment.

According to AFSM “The pressure of medical cost containment is not likely to subside in the near future. Cost pressures will continue to influence the direction of health care and health care services around the world.” Experts say business downsizing is not over, it is just changing directions. Buyers of medical equipment services are beginning to look for “one-stop” solutions. Vendors capable of providing complete solutions will be positioned to profit from this trend.

The opening keynote speaker was Jeffrey Fisher, M.D., vice president and medical director of MPE Communications. Dr. Fisher, who has addressed the World Health Organization in Geneva, Switzerland, who spoke on “The Technological Future of Health Care.” The keynote was followed by a presentation by Steve Downton of Coopers & Lybrand on recent services benchmark findings unique to the medical services sector.

Over a three-day period, the conference featured expert presentations on trends in biomedical engineering, new strategic directions, safety issues, multivendor services marketing, and the parallels in the IT and medical sectors. Gailord Gordon, CCE presented on how the shift in the economic organization underlying the health care delivery system has accelerated the emergence of a major new market for medical equipment services. Program Chairman Walt Gasparovic, president of The Gasparovic Group, moderated a panel discussion of health care services users.

AFSM International provided this forum “for discussion and understanding of this critical issue in

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response to needs identified in the medical services community, which is a significant segment of the association’s membership”.

ABET SEEKS EVALUATORS FOR ACCREDITATION PROGRAMS

Gerald R. Goodman, CCE
Member, Technology Accreditation Commission of ABET, IEEE Representative
The IEEE Educational Activities Board coordinates the IEEE involvement in the accreditation of electrical engineering and electrical engineering technology programs at US Colleges. The programs in this grouping include biomedical engineering and biomedical engineering technology programs. The IEEE is one of over 20 professional engineering societies participating as members of the Accreditation Board for Engineering and Technology (ABET).

The IEEE strives to involve industry-based individuals in the accreditation process. To that end, the IEEE provides a one-day training course for qualified individuals selected as program evaluators. Evaluators usually participate on one evaluation team each year, in the Fall. Evaluation visits last from 2-3 days, with two day typical. Clinical engineers are well positioned to participate in this activity due to their educational and work experience in electrical, electronic, computer, and/or biomedical engineering and engineering technology. This is an opportunity to lend your expertise and provide a service to your profession. You can obtain more information from me at 713/483-7842, E-Mail GGOODMAN@JAI.JSC.NASA.GOV or you can obtain an application package directly from the IEEE through Angela Wyckoff, 908-562-5484, E-Mail A.WYCKOFF@IEEE.ORG.

FINDING INFORMATION
By now everyone knows that the ACCE has contracted with ECRI to serve as their Secretariat. Official correspondence to the ACCE should be addressed to: ACCE, 5200 Butler Ave., Plymouth Meeting, PA, 19462-1298. Our phone number is 610-825-6067.

The IFMBE is pleased to announce that they have arranged a server on the World Wide Web. You can find their home page in Brussels (University of Brussels, Medical Faculty) at: http://vub.vub.ac.be/~ifmbf.html When you log on you will find all sorts of information on the various segments of the Federation. This server is updated regularly with information about upcoming world events.

AAMI has also improved their communications capability with the introduction of a FAX on demand service. You can now call AAMI 24 hours a day to request information at 800-351-AAMI (2264). By following a few simple on-line instructions you can get ICC Examination Dates (DOC #275), a CCE Application Form (DOC #295), Certification Renewal Information (DOC #305), a Registration Form for the 31st Annual Meeting (DOC #260), and other important information.

BOOK ANNOUNCEMENT
MEDICAL INSTRUMENTATION FOR NURSES AND ALLIED HEALTH-CARE PROFESSIONALS
Richard Aston, Ph.D., PE East Tennessee State University
Katherine Kay Brown, M.S.N., RN, C.C.R.N., Allegheny General Hospital
This book, first published in May 1994, is intended to increase the health-care provider’s understanding of medical instrumentation. Many new and complicated instruments have been introduced into the health-care field in recent years. This trend has resulted in a need to understand equipment safety and develop safe operating procedures. This book will help the health-care professional with preventative maintenance and troubleshooting, as well as repair of equipment implanted in, or attached to the patient. It will also help in understanding the medical complications that can

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evolve from equipment use in order to be able to respond immediately to patient symptoms. By presenting the basic background necessary to understand the issues surrounding hospital-based equipment, Medical Instrumentation for Nurses and Allied Health-Care Professionals will provide the user with the background for understanding the equipment manuals supplied by the manufacturers for their specific models. This book answers the specific questions health-care providers have about therapeutic equipment including internal and external pacemakers and defibrillators, IV pumps, catheters, ventilators, and surgical devices. The special needs of the health-care provider are served by extensive discussions of the medical indications involved in the use of the equipment.

The 352 page book is available from Jones and Bartlett Publishers, One Exeter Plaza, Boston, MA 02116 or by calling 800-832-0034. ISBN 086720-688-8. The cost of the book is $34.95.

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**CALL FOR PAPERS**

General and student papers are being solicited on new developments in theory, concepts, applications and techniques in all facets of Biomedical Engineering for the 15th Southern Biomedical Engineering Conference. This conference will be held from March 29-31, 1996 in Dayton Ohio. Although considered to be a regional conference, abstracts are being accepted from all parts of the world. If interested please contact: Prakhulla K. Bajpai, Professor of Physiology at the University of Dayton at 513-229-2135 or by E-Mail PBAJPAI@DELTA.CS.WRIGHT.EDU

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**Fifth Annual AIMBE Meeting: The Impact of Bioengineering and Medical Technology on the Quality of Life, March 10 - 12, 1996, Washington, DC,**

Call Dov Jaron, Conference Chair at 215-895-2215 or email: dov.jaron@coe.drexel.edu


Contact: Prakhulla K. Bajpai, 513-229-2135 or by E-Mail PBAJPAI@DELTA.CS.WRIGHT.EDU

AAMI 31st Annual Meeting, June 1-4, 1996, Marriott Hotel, Philadelphia, PA, Call 703-276-0793

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**Late Breaking News!!!**

On January 10, 1996, the ACCE Board of Directors approved a marketing agreement with Morse Medical. With this agreement, Morse Medical will market and distribute ACCE products.

Current ACCE products include the ACCE membership directory, Clinical Engineering plaque, Code of Ethics plaque, ACCE membership lapel pin, and the Guidelines for Medical Equipment Donation.

For further information, contact Wayne Morse at (206) 236-0628.
ACCE ADVOCACY AWARD NOMINATION

I ___________________________ , a member of ACCE in good standing nominate:

(type or print your name)

__________________________________________ , a clinical engineer □ yes □ no (if yes must be an ACCE member)
Street/Box: ___________________________________ Phone: __________ FAX __________
City ___________________________ State ______ Zip _________ Country ________________
(type or print all information)

__________________________________________ , a clinical engineer □ yes □ no (if yes must be an ACCE member)
Street/Box: ___________________________________ Phone: __________ FAX __________
City ___________________________ State ______ Zip _________ Country ________________
(type or print all information)

__________________________________________ , a clinical engineer □ yes □ no (if yes must be an ACCE member)
Street/Box: ___________________________________ Phone: __________ FAX __________
City ___________________________ State ______ Zip _________ Country ________________
(type or print all information)

for the (check only one - use separate form for different award nomination)
□ ACCE Professional Development Award
□ ACCE Professional Achievement Award

based on the □ publication □ presentation (check one) __________________________
(type or print the title(s))

______________________________

which was published in or presented at __________________________
(type or print publication or location)

______________________________

on (give dates of publication or presentation and attach one copy of the article or presentation transcript) __________________________
(type or print date(s))

Mail to:
George I. Johnston
5462 S.W. Dover Lane
Portland, OR 97225

FAX to:
George I. Johnston @ (503) 245-5603

REMEMBER: Closing date for nominations is March 1, 1996!