First ACCE Symposium

The Future of Clinical Engineering

May 30, 1998 -- Philadelphia, PA

ACCE Mission

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

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Program

Welcome

Frank R. Painter, CCE
President, American College of Clinical Engineering

The American College of Clinical Engineering is pleased to present the First ACCE Symposium, **The Future of Clinical Engineering**. The College has matured to the point of having its own program, unique in its focus on clinical engineering professional matters. We regard the Symposium as one of the important parts of ACCE educational offerings along with Advanced Clinical Engineering Workshops, Audio-Teleconference Series, web page, special publications and the newsletter. We thank Ira Tackel and Thomas Jefferson University for hosting the Symposium. We appreciate the efforts of our panelists Malcolm Ridgway, Larry Hertzler, Tom Bauld, and Greg Davis in preparing speeches which will form the basis of much of the discussion we will hear today. Jennifer Ott, ACCE Secretary, excelled as Symposium Committee Chairman, joined in her efforts by her hard-working Committee members. I look forward to informative talks, lively discussion and useful interchange of information and ideas. An afternoon recapitulation, poster session and tours of the Biomedical Instumentation Department of Thomas Jefferson University Hospital will round out the program. I thank all of you, members and non-members alike, for making the effort to attend this seminal event in the life of ACCE. I thank all of our corporate sponsors whose generous support ensured the Symposium's financial success.

Introduction

Ira S. Tackel
Director, Biomedical Instrumentation, Thomas Jefferson University Hospital

I would ask all of the panelist and the Symposium participants to consider several philosophies as appropriate for the discussion we will have today. First, *business people who don't question the assumptions made going into a problem, often end up solving the wrong problem.* Secondly, *The risk of inaction is greater than the risk of proceeding.* Next, The *status quo* can be too comfortable. And finally, *A competitive world has two possibilities for you: You can lose or, if you want to win, you can change.*

In moderating the Symposium today I bear in mind several thoughts which consider approaches to the future. In the words of Helen Keller, "*Avoiding danger is no safer in the long run than outright exposure. Life is either a danger adventure or nothing,.*" From a business perspective it has been well said that, *To become great as a company, you must view tomorrow as more important than today.* I caution you; *If we hide behind the past we will never get to the future.*

I am honored to be in the company of our four panelists, extraordinarily, knowledgeable individuals cumulatively representing 100 years of experience in clinical engineering. Remember, as we look to the future, if you don't care where you are going, any road will get you there. Today, we expect to learn where we are going and develop strategies for getting there.

Invited Speakers

Thomas J. Bauld, III, Ph.D.
Director of Clinical Engineering, University of Michigan Health System
Founder and Past-President ACCE

Forecasts are difficult risky at this time of rapid change. Keep well read to catch trends and position yourself for what is coming, The FDA web site identified the technologies of the next decade: computer related technologies, molecular medicine, home and self care, minimally invasive procedures, combination of device-drug hybrid products, organ replacement and assist devices. rends, remember the pendulum, major direction may be temporary variation. many institutions gone back and forth in-source and out-source. For small institutions, independent service organizations (ISOs) may be preferred. ISOs, however, cannot offer the same services as an in-house program in large institutions. As mentioned at HealthTech '98 which I attended recently, the medical services industry is a $40 Billion/year. One computer company only did a billion dollars in business last year. ISO leaders in computer hardware support. A trend I have observed is that instrumentation is constantly improving becoming increasing more reliable, suffering far fewer hardware failures, and incorporating self-diagnostics. Such self-diagnostics has been a major boon to the imaging industry. One must strongly question the need for periodic inspection and maintenance of medical devices. Our studies at the University of Michigan Hospitals have shown but a few failures are detected and few corrections are made during regularly scheduled inspections. Although experience has permitted us to virtually eliminate electrical safety inspections, I still see institutions that place inappropriate emphasis on electrical safety inspections. People who see their major role in life as electrical safety inspectors are not doing any favors to a patient's safety and his pocketbook. A health care systems change, more training is needed in computers and computer networks. The consolidation of health care systems, aggressive ISOs, government antitrust suits, such as those involving such companies as General Electric and Microsoft, could impact the service business. The low-hanging fruit of contracts ripe for consolidation or elimination has been snatched and squeezed dry. It doesn't exist anymore in most places.

Regulatory compliance issues are of immediate concern for clinical engineers. The U.S. Food and Drug Administration recently promulgated Advanced Notice of Proposed Rulemaking contains wording that threatens to drive up the cost of service without achieving any recognizable benefit. New rules relating to the Good Manufacturing Practices current affecting manufacturers, if enacted and applied to remarketers, refurbishers and servicers would be a major set-back in health care cost-control efforts. I advise you all to spread word, read the ANPR, respond in writing to the FDA and urge colleagues to do likewise. An ACCE position paper on this matter will be released shortly. Acquisition and planning strategies must look at overall return on investment. Although a formal rigorous methodology is employed by some institutions, most never evaluate through a post-implementation study programs that claimed to have financial or clinical benefit. Educating ourselves and our staff is critical. We must acquire new skills while maintaining flexibility and adaptability. An in-house department must be in position to never say no. Don't miss any opportunity to be of value to your institution, to grow and to be a success, whether that opportunity lies in information technology, TV systems, communication systems, central sterile supply, or materials management.

Gregory J. Davis, MBA, CCE
Director of Engineering Services, National MD

As society has changed health care over the last 15 to 20 years so has clinical engineering also changed. The days of a clinical engineer, three technicians and routine electrical safety inspections in a 250-bed suburban hospital are numbered. Four issues leap to mind as I look at the health care environment: 1. **Value in cost control**, 2. **Synergy of consolidation**, 3. **Regulatory burden increase**, and 4. **Putting engineering back into clinical engineering.**

(1) Cost containment decisions will no longer be made on cost alone but rather on cost and value. Clinical engineers need to follow the health care consumer and provider and be part of that equation. Looking at the variables in value, one finds that the numerator is cost and the denominator is what is delivered and how the need of the customer is meet or exceeded. The denominator needs close monitoring. Determining the cost of technology used to be simple. Now, with changes in clinical environment, cost of ownership and service become more complicated requiring the consideration of such issues as cost leases, pay by the drink, and cost of reportable.

(2) Synergy will dominate consolidations of the future. In **consolidation of services**; two sides; out-source (GE), hospital side, networks, for profitable, trend in regional networks forming. mergers and acquisition effect clinical engineers, changes not by our decision. challenges-- look at information structure, look at information systems. goes well above and beyond merging two data bases. One needs to look at overall culture philosophy on how information is gathered and used. Clinical engineers need to show interest and creativity in helping to participate in that change. As entities become more consolidated there is more chance to participate in training. Maximize the efficiency and effectiveness of your technical resources. The bottom line reason for hospital and company mergers is **synergy**. It makes no sense to merge with each business entity going independently their separate ways. Due attention must be paid to possible counter productive cultural clashes when mergers occur.

(3) The **regulatory** environment has changed from merely dealing with the Joint Commission on Accreditation of Healthcare Organizations and from needing to know simply what the letters NFPA stood for to ominously impending FDA regulations heading in the direction of an **ISO 9002**. Clinical engineers instead of counting the number of PMs performed must ask why they are being done at all.

(4) Finally, let us put engineering back into clinical engineering. In a recent discussion with Dr. Jim Phillips, anesthesiologist at Brigham and Women's Hospital in Boston, I agreed with his opinion that **clinical engineers need to engineer the clinical environment.** Changes in the clinical arena open opportunities such as engineering safety in the OR, designing ICU equipment layout, refining endoscope imaging and storage systems. The clinical engineer should and can go beyond equipment selection, repair and maintenance to equipment application, physician and nurse training, and assistance in device utilization.

Monitor these four areas and act accordingly, your future depends on it.

Larry Hertzler, MBA, PE, CCE
Vice-President and Chief Financial Officer, Medical Technology Management, Inc.

Before looking into the future, lessons can be learned from the past. We were content to know that Biomed Bubba could fix 'lectrical stuff. We saw plant maintenance people, carpenters, plumbers, pressed into service to do leakage tests; We felt safe that the terror of micro-shock which had been lurking everywhere was held at bay by semi-annual inspections; Jobs were plentiful as complicated technology demanded university-trained clinical engineers with degrees. Diagnosis Related Groups (DRGs) turned up the pressure to limit my service costs. But costs continued to climb.

Today, under great pressure to reduce costs, we still don't know where the fluff is and don't have the information to make the right decisions, but we arbitrarily reduce budgets by 10%. We have all heard the claim by those desiring to take over your operations, *"I can reduce your budget by 10%."* New term crept into the vernacular such as *re-engineering and right-sizing;* but these were merely euphemisms for layoffs. These are the times of mergers and acquisitions. There is strength in numbers, e.g., joint purchasing groups and physician groups. A great deal of sales and marketing effort is being expended on asset management. Asset management, now there is a good catch phrase, some good buzz words. Says the administrator, *"I'll buy it; I don't know what it is; but it sounds good."* The outsourcing tactic used in health care and clinical engineering, *"I can get people off the payroll"* is giving way as the pendulum swings back. In-sourcing is the comeback kid.

My crystal ball reveals much. The in-sourcing pendulum will continue to swinging back as contracts expire and people realize that work can be done on the inside for greater value. But lest we place all our chips on in-sourcing, stagnant in-house programs will prompt managers to consider out-sourcing. There is not a consistent trend one way or another; opportunities exist for either in-sourcing or out-sourcing.

Partnerships and strange partnerships buzz word, hiding behind not making a decision; More mergers and acquisitions are definitely in the future. Systems will get bigger; all the pieces of healthcare will agglomerate; even without knowing it hospitals are learning home health care.

Asset management will flourish even in the face of ambiguity over its meaning. *"Does this not create confusion?"* you say. Yes; and confusion will reign but that will be good for business. If you can confuse people they will buy it. Consider the following definition of asset management: *"A nebulous high cost product that elicits Pavlov's response in healthcare administrators, yet can not fully be measured by any means or agreed upon by any two individuals, and therefore cannot be delivered other than in marketing literature, sales pitches, presentations at national meetings, and panel discussions."* Everyone appears to have his own definition of asset management. I am convinced it is still a good thing whatever it is.

The real future is synergy-ships: more than what benefits both partners, more than joining two parties. In the future even as we have seen in the past, in many business ventures the stronger took over the weaker. This strategy will continue but for a time businesses will actually get together and help each other out. I don't know what asset management, true asset management, means. Clinical engineers will use real and believable data and will develop ways to use the data to benefit health care. The smart administrator will emerge, administrators smarter because they stay around for more than just two years and utilize real performance measures, cost, customer satisfaction, code compliance, and clinical outcomes. The clinical engineer must get tied into clinical outcomes. Those that can will be the winners. Step up to the plate and get a hit.

Malcolm Ridgway, Ph.D.
Vice-President Technology Management Master Plan, COHR, Inc.

The question I most dread is, *"What do you do?"* Sitting on the plane to Philadelphia, my wife turned to me and said *" Could you explain to this lady what it is you do again?"* What do we do? Our job can be out-sourced to the out-sourcing business, known in the trade as Service Outsourcing Business (S.O.B.s). I'd like to say. I'm an accountant. That would end the conversation. I challenge you to write one sentence on the back of a business card stating what you do. Mine is 7 words.

There is more to asset management than maintenance and maintenance management. Asset management is a *Comprehensive Medical Equipment Management Program* with three parts. The first two are traditional: (1) maintenance management services and (2) regulatory compliance services. The third part is clinical technology optimization (CTO) services. CTO consists of managing the equipment budgeting process and analyzing, re-engineering and optimizing technology intensive clinical services (TICS).

Technology Intensive Clinical Services (TICS)

Diagnostic Imaging
MRI Scanning
CT Scanning
Mammography
Cystoscopy
General radiography
Teleradiology
PET Scanning
SPECT scanning
General nuclear medicine
Radiological ultrasound
Image management systems

Cardiovascular Services
Angiography
Cardiac catheterization
Pacemaker implantation
Cardiac ultrasound
Interpretive ECG

Surgical Services
Electrosurgery
Endoscopy
Stone management/
Cryosurgery
"Gamma knife"
Anesthesia delivery
Anesthesia information management

Women's Services
Obstetrical ultrasound
Electronic fetal monitoring
BMD radiography
Steriotactic breast biopsy
Endometrial ablation
Cancer Services
External beam radiotherapy
Brachytherapy
Treatment simulation

Patient Monitoring
Physiological monitoring
Telemetry monitoring

Respiratory
Ventilators

Lasers
Surgical lasers
Ophthalmological lasers
Dermatological lasers
Otolaryngological lasers

Clinical Laboratory
Chemistry analyzers
Hematology analyzers
Microbiology
Immunology
POC analyzers
Automated cell imaging analyzers

Maintenance management is keeping the facility's medical equipment operational and performing properly and safely for the least cost. This doesn't mean you do it yourself necessarily but rather making sure that the job is done right. Regulatory Compliance means complying with the regulatory requirements relating to the facility's medical equipment for the least cost. This is not a given. People spend lots of time on this. There is a trick to doing this for the least possible dollar.

The **New Frontier** for clinical engineering is comprised of professional, knowledge-based services. Clinical Technology Optimization (CTO) Services are new "knowledge-based" services. CTO strives to have the right medical equipment available, a service comprised of three parts:

1. Determining when equipment should be replaced. Our firm calls this preliminary equipment replacement planning (PERP).
2. Planning new technology-intensive clinical services (TICS), helping administrative people to know what new businesses they should be in as far as services involving lots of technology,

working with technology assessment, evaluating the proposal from the clinician submitted to hospital administrator. With a PET scanning proposal, for example, look at the proposal as a business and ask if this is a business the hospital should be in and how should it be run and whether it is profitable or has the appropriate financial performance.

3. Selecting and acquiring new equipment making this process an informed decision

CTO analyzes and optimizes the return on investment, e.g., the financial performance of the facility's TICS. This re-engineering territory that clinical engineers should claim.

Whether or not the above service should reside in house or contracted out should be decided by the in-house purchaser.

Anticipated Evolution of Demand

	Today	3 yrs	5 yrs
Maintenance Management Service	50	45	40
Regulatory Compliance Services	45	30	10
CTO 1 Equipment Budgeting	5	15	15
CTO 2 Re-engineering/optimizing TIC	....	10	35
	100	100	100

Managed time and materials is the way of the future. While the low-hanging fruit has been squeezed dry, there is still money to be squeezed out of maintenance. Some money remains in regulatory compliance, but the main areas are CTO 1 and 2. For every dollar saved in the traditional areas, there are two dollars to be saved in CTO. It is more difficult to prove that money can be saved, however, because there is not a line item budget identifying the money currently being spent on technology selection. Believe me when I say that there are white elephants out there that are huge and fat; it is low hanging meat, if you will, no longer fruit. It is more difficult to prove to a contractor that savings are there. The above Anticipated Evolution of Demand shows regulatory compliance going down. JCAHO is backing off. Passing JCAHO is no longer a matter of preparing paper work. much more fundamental than that.

My idea of how things are going to change is shown below:

On-Site versus On-Call Support
(In-House versus contract)

	Today	3 yrs	5 yrs
On-site support - management and analysis:	5	10	20
On-site support - first call and specialty:	65	70	70
On-call specialty support - via T&M:	10	10	10
On-call specialty support - via FSA:	20	10	....
	100	100	100

Certain things should be done on site. More services will be provided on site whether the support is on the payroll of the hospital or on the payroll of the contractor is immaterial. A clinical engineer gets a better deal working for a contractor than a hospital. I am not a great lover of hospitals. They have treated the clinical engineer shabbily. When push came to shove clinical engineers were shoved out of the balloon.

Future belongs to you people, the way to make it what you want it to be is to invent it. Its up to you to decide what clinical engineering is going to be in the future and help make it happen.

Open Forum

Ira Tackel -- Joel Barker, illustrating paradigm shift, relates the following. In 1969 the Swiss had 95 % of the watch business. Swiss watch industry exhibited an LED watch at the 1969 World Watch Congress. It was designed in Switzerland, the chips were by Texas Instruments. The Swiss said it would never fly. Today the Swiss have 10% of the watch market.
If you don't embrace a paradigm shift (its a true change in character of healthcare)

A couple years ago, Thomas Jefferson University Hospital was in downsizing from a 700-bed to a 450-bed center city tertiary care medical center. The market was driving us down. Jefferson was considering purchasing a competitor, Pennsylvania Hospital, as was the University of Pennsylvania. The University of Pennsylvania was considering purchasing the Rothman Institute also. The Rothman Institute generates 45% of the income of Pennsylvania Hospital. Rothman said if you align with U of P we are leaving. U of P acquired Penn Hospital and Rothman walked. Rothman Institute is now at Jefferson. Jefferson is at 600-beds with its operating room at capacity. All this happened over the last month. We must be prepared to jump on opportunities of cost containment.

Dave Bell - We have some out-sourcing. There are a few medium-sized , fairly large institutions in the Philadelphia area that have decided to out-source. What is the decision making process? Is the size of a clinical engineering department a factor? What about smaller one- or two-man departments?

Malcolm Ridgway-- The reason people consider to out-source is that they believe the salesman. He presents something different in the package. Although it hasn't been addressed as an issue, people are seeing something they think they want.

Ira -- If you look at the sales literature of companies such as CIC , Fisher Biomedical, *et cetera*, you will see in big bold letters, **Guaranteed 25% Savings**. It's the potential savings against what? Service contracts and some nebulous pot? If you can't measure it how can you decide what you are purchasing?

Bob Berkovits - Clinical engineers should be systems engineers and generalists also. On the chart Malcolm Ridgway noted many areas of medical technology and equipment. We must consider rehabilitation and assistive device technologies. Look at broader areas we can come up with new important ideas.

Tom Bauld - In response to Dave Bell's question, it is easier for some administrators to wash their hands of the management process in their institutions, especially when they look to consolidations where the world is more complicated. As management positions are cut, the manager's ability to manage is compromised. It is easier to cut management responsibilities.

Malcolm -- Job 1 is not fixing equipment; it is maintaining control. Contractors are providing management overview for the hospital. How often have we heard, "*I'm so busy I've got a shop full of equipment.*" ? If that's your attitude you'll go the way of the Dodo bird. Above all,

hospitals are looking for management. which has to be honest and delivered in terminology that the hospital understands.

Elliott Sloane -- I offer a paradigm shift not generally publicized. Vencor, Inc. runs 40 or more hospitals. Highly few patients on ventilator care, wound care, orthopedic surgery recovery. Standardization rules. In all facilities nationwide one finds one head wall system, one single model of ventilator, one three-channel patient monitor, one electric bed, one pulse oximeter, one computer system with interface to the infusion pump and monitor. There is common software allowing respiratory therapy to dial in patient identification to get patient data. Not a single clinical engineer exists in their hierarchy. X-ray systems connect by way of teleradiology to Louisville headquarters to be read immediately by radiologists. Portable X-rays are in each facility. Emergency rooms are empty except for basic equipment. Their hospitals are licensed as acute care hospitals. A sign is displayed telling the patient that if care is needed beyond that which the hospital has ability to provide that care will be arranged for you.

Engineers have been slaughtered in the marketplace for decades if not centuries. We get myopic we focus in and fall in love with technology we deal with. There are different paradigms. We must look at them and re-engineer ourselves.

Malcolm Ridgway -- Other hospitals follow the Burger King philosophy of *we'll do it your way*. Even in hospitals that serve a range of patients, one will find a well-designed environment and product flow.

Alan Lipschultz -- I disagree with Tom Bauld on the reason out-sourcing occurs. My feeling is that it is the lack of trust. Administrators are not taking the easy way out, they are not comfortable with the data they are getting. .

Ira Tackel -- Why are they not comfortable?

Alan Lipschultz --. I think salesmanship and PR is a big part of it.

Ira Tackel -- If your administrator is not comfortable with the data he is getting ...

Alan Lipschultz -- That's a problem.

Ira Tackel -- Who is at the root of that problem?

Alan Lipschultz -- I am.

Ira Tackel -- Many of our colleagues aren't doing their job up to the expectation of the administration

Malcolm Ridgway -- Lest we get into too much self flagellation, clinical engineers are at a disadvantage in the hospital where politics is important. It is hard to shift from the way we did things ten years ago. The contractor presents a new picture. It is hard for clinical engineers to retread. How do you put a new face on? How do you reinvent yourself?

Larry Hertzler -- The credibility issue is one of the biggest. The consulting theory applies, the farther away you come from, the more you know and the more you charge. Some people figure you have the experts in your own back yard but don't believe what they are saying so you hire someone from outside. Suddenly it is Gospel. But that is part of the sales strategy. At BJC Health Systems, we bid against outside contractors that have credibility. They compete every day at he level of the decision makers, people who don't bat an eye when they sign a $15M clinical engineering department over. Most departments don't deal with the president, or CFO of the system or hospital; but that is where the outside contractors come in and that's where they make the excellent sales presentations. Some of the pitches are actually true. It depends on how good you are at marketing at the same level.

Greg Davis -- I don't believe it is necessarily salesmanship or good data nor how good or bad a job you are doing. It is the market place itself that causes hospitals to focus on where they are spending their resources. In general that is why outsourcing has grown. It's not just clinical engineering, plant engineering, linen, or food service upon which hospitals are focusing. I remember a few years ago that hospitals were trying to be all things to all people. I worked for a hospital involved in real estate and other borderline areas. Hospitals that focus on patient care have a lot less resources to deal with. Worrying about primary care providers is why hospitals instead of competing locally are networking locally. Creating the marketplace that allows for good salesmanship allows for stumbling blocks of bad data.

Ira Tackel -- The catch-all phrase hospitals are getting back to is their *core competencies*. I submit that what we do, technology management in a very broad sense, in fact, can be one of those core competencies if it becomes not a problem for administration. If you are transparent, if what you do is not a problematic for administration and it becomes routine, that is a win-win situation. Why would administration want to out-source and perhaps spend more? Ideally when Fisher Biomedical, Service Master or GE come through the door, you want the hospital CEO to tell them that they should talk to the director of clinical engineering because he or she is going to be able to assess the value of what is being sold. The CEO should say, "*I don't want to talk to you.*"

Tom Bauld -- Anything can be out-sourced. When at HealthTech '98 I heard talk of out-sourcing radiology. While I'm not directly involved in this area, I have a colleague who is, the manager of the radiology department. The talk and the session was not about out-sourcing radiology service, it was the whole 9 yards, reading interpretation, technologists, any combination of services you want. Out-sourcing companies can handle anything and everything, from a piece to the whole operation. They will do work flow analysis, they will buy equipment. Payment can be made on each exam or a fixed annual contract. The ER and Information Technology departments are targets for out-sourcing. Nothing is sacred. I used to think they were picking on us. They are looking at everything. It is much more global, more pervasive than I had thought. 25 years from now there could be 10 companies out there that do everything for any healthcare organization. Our institution has looked at a couple of mergers and acquisitions. We collaborate with Michigan Health in the Ann Arbor area for a couple years to achieve a larger, stronger, more effective organization. A consulting firm analyzed the prospects. After a twelve-month period it was

concluded that less than 15% of the operation could be saved by consolidating. There was no good opportunity to save money, so they dropped the whole thing. Now, a possible alliance with Henry Ford Hospital and their cancer center with the University of Michigan Hospitals has been announced.

Malcolm Ridgway -- I don't think you should get fixated on low bid. There is more to contracting than the lowest price. Hospitals now are into value and they are looking for what they get for the dollar. It is easy to be cynical and say its just the low bidder. It is not the low bidder. Hospitals are more sophisticated than that now. One of the challenges we've got is to show what value we bring. Larry was not the low bidder but he got the contract because he was able to show that what he had was the best value. It's not just the low bid mentality. It's not that simple. We have to quantify what it is we bring to the table as well as what it costs.

Al de Richemond -- Perhaps it is obvious, but one of the underlying things for any engineering discipline is safety, making and maintaining the safety of technology. One of the main responsibilities of clinical engineers in the hospital is maintaining the safety of technology for the users and the patient. That has not been addressed here. It is tied up with the cost issues and everyday issues of clinical engineering. What do you have to say about this?

Tom Bauld -- A lot of the issues of safety have been focused in the wrong direction for a number of years. Safety is more a factor of utilization of equipment and application of technology than it is in the design and manufacture of equipment. Standards developed have done an excellent job in ensuring that most equipment is relatively safe and trouble free. Problems still lie in the application of the training and the human factors side of things. This is where clinical engineers can have a significant impact and where we have a lot cut out for us to do.

Larry Hertzler -- I concur that safety issues are in the training and operator education area and unfortunately that is an area where clinical engineering programs are failing overall. They are giving cursory inservices. For the most part it is the clinical side that is providing the core education and safety training on how to utilize devices along with the manufacturer. This is clearly an area were some clinical engineers departments can excel.

Greg Davis -- I would include this in my Engineering the Clinical Environment category. We need to focus, as we did in the past, on how the equipment is being used and making sure the equipment is safe.

Malcolm Ridgway -- Absolutely safety is one of the primary considerations. But the problem is that in the past it has been used as a red herring. Safety has been overplayed. We are all familiar with the electrical safety issue. We have failed in that we have grasped at straws by alluding to the fact that the sky would fall if we did not do our PMs and electrical safety checks. I think we have lost credibility in that area. However, I think the real issues of safety, the equipment user problems, are extremely important. It is very important that you do a good job of showing that you are on top of the safety issues. and anyone who can't do that will be vulnerable to being vetoed no matter what the cost. It is a matter of doing that engineering and real systems analysis to address the real safety issues and forget the red herring.

Bob Morris -- I would emphasize the value side comments that all the panelist have made. Hospitals, even in fierce competition, will joined together to do things of mutual value that do not give one partner a competitive advantage over the other. For example, in Portland, Oregon the three major health care conglomerates joined together and out-sourced all hemodialysis to a private third, outside company. Dialysis is important because it serves as a feeder to kidney transplantation, a fairly profitable segment of the hospital business. In another area, non-emergency laboratory services, competitors will join and build a high-tech laboratory that will get more value through sharing resources. Hospitals can be extremely competitive at one level, but at another level they can join together when it is in their mutual interest.

Malcolm Ridgway -- That is one of major shifts that has occurred in the past when hospitals were intentionally competitive with their neighbors but are now collaborating. This relates to the TICS analysis. Now the question is, *"How should we address cardiovascular services for example?"* We in the past would advise on the technological aspects of a service. The marketing part of that, helping hospitals to chose what business to go into, will really work out, things like reimbursement issues, sharing options. COHR is looking for people to help us do that which we have never done in the past. This has nothing to do with equipment. It is market analysis. Redeployment of equipment. This is a big part of some of the new challenges that should fit into the portfolio of the clinical engineering department in the future. How can the business serve the community and work for the institution.

Larry Hertzler -- When systems come together in a hospital sometimes it works better if it's partnering with an enemy because there is more of a common goal.. When systems come together, when hospitals join, things stagnate especially when they have duplicate services. Will it be a club or a new system, Are they going to get some of the synergy that comes from standardization issues in all walks of life. or are they going to argue about doing it my way or remaining the same? A good opportunity if you are in the middle of the issues is to make things happen. Don't sit back and wait.

Paul Sherman -- In a large organization, mostly in-house, one argument to make for keeping in-house rather than out-source is to make a profit and keep it in house. I've seen in my area clinical engineers moving out of administration and going into clinical services. This is one way of keeping clinical engineers active in the hospital.

John Hughes -- I have a new position with a new company neither of which is defined yet. What we are faced with in the clinical engineering profession is no different than that which is faced by every other profession in health care, whether it is nursing, laboratory, medical records, systems, anesthesiology. The others have the same fears, the same challenges, the same threats, but more importantly the same opportunity to demonstrate their value to the organization. As a profession we become so introspective that we fail to identify and learn what other professions have done when faced with the very same situation. How many people commonly read other publications outside of their field such as *Modern Health Care*, *Hospitals and Health Network*, or *Laboratory systems*? One of the major trends right now is that the Clinical Services Technology manager jobs are going to lab and radiology directors. Clinical engineers becoming more of a clinical

patient services-based function in the hospital is becoming more important. Encourage everybody to look at what is going on in the health care business rather than keeping ourselves isolated in our own individual silo. Learn from some of our highly-educated, learned, highly-qualified colleagues we work with every single day. .

Larry Hertzler -- It is true that the clinical engineering budget is from .5 to .7% of the total hospital budget, a minuscule amount. If the administrator is looking for low-hanging fruit, it will probably not be clinical engineering. But beware of the PITA (pain in the ass) factor. If you are a pain in the ass to the administrator and you represent only .5% of the budget you are a great candidate for out-sourcing. The administrator reasons, *"If I can get rid of that pain in the ass, even if doing that turns out to be a big mistake, I can deal with that minuscule amount of the budget."* Refocus on the issue of a million dollars even though it is only .5% of the hospital budget.

John Hughes -- Larry, you mentioned earlier, the emergence of the smart administrators in the future. While some might think that's an oxymoron, it gets back to the marketing salesmanship issue. It is our job to educate our administrator, colleagues, and decision makers about the value we bring. We need to educate ourselves but also the administrator, colleagues, and decision makers.

Larry Hertzler -- John chaired a session a while ago entitled, *If your boss doesn't understand its your own damn fault.*

Ira Tackel -- Are you a solution to the problem or a part of the problem? If you are not a solution, you are ripe for out-sourcing and rightfully so.

Bryanne Patail -- I detect some negativism toward out-sourcing. If we look at other professions such as lawyers and doctors some are self-employed. I think clinical engineering is maturing to where some of us are working as self-employed professionals. What's wrong with that? I think outsourcing is not bad. It is an opportunity to provide your services to more than one hospital. I am both. I am doing that. Beaumont Services Corp., a for-profit partnership, will sell services to affiliates or anyone else. On the Beaumont side I am the in-house guy. I can fine tune my services, my metrics, my methodology and then I can go out an sell to whomever wants to buy them. Outsourcing is good. Let's prepare ourselves for new technologies, such as, robots in medicine, minimally invasive procedures, telemedicine.

Malcolm Ridgway -- I second that. It is not an issue of in vs. out. If you work in a hospital you must ask what you do rather than who pays your paycheck. You are absolutely right on. We have been fixated in the past. If you can't get past that you will not survive into the future. It is that simple. You've got to look at what you do, how its done, and efficiencies and values and all that. Like contracted clinical services, *e.g.* contracted emergency services, when you go in you can't tell if it's out-sourced or not. A contracted ER could present a better environment for the emergency room physicians than being on the staff of the hospital.

Larry Hertzler -- It comes down to whatever is the best value. I agree with you Bryanne. There is no way that there is one answer for everyone. Combinations, not either or. Not a black and white situation by any means.

Tom Bauld -- Hospitals often take the position that there is only one way. A sound management process would dictate that all options be considered and analyzed.

Ira Tackel --In situations like that either politics is at work or someone is not doing their job. If administration is making that claim then someone is not educating them properly to the dynamics of the situation.

Bob Morris -- Clinical Engineers should be making that judgment within their area.

Tom Bauld -- Right.

Ira Tackel -- So either the politics allows that and they have established themselves as a the creditable entity within the institution or it is time to look for another position.

Ira Soller -- I want to stress the importance of continuing to educate the institution on what you are doing. I know that in my twenty years at SUNY Brooklyn, every time I walk by a president of the university (and there have been two or three in that time) he recognizes there is BME and he moves on. We must be doing something right. Around you administrators are changing at all levels. I stress the importance of going to clinical department meetings not only repairing equipment. We are taking on new technologies. We are the ones worrying about high definition TV about the Year 2000. When administration realizes that these issues are being addressed it becomes more confident in you. Writing technical articles and representing your hospital at meetings helps to establish you and your department as one of the leaders in the field. You know what you are talking about and are moving the hospital in the right direction. But, this is an ongoing process. To think that you did this 5 to 10 years ago and you had a reputation. You will find that many of your colleagues who have come to you for assistance have left. New people are there that do not understand the purchasing process and why clinical engineering reviews purchase requisitions. You have to retrain them, bring value to the table. I've reviewed this requisition for your department and have gotten a lower price and a longer warrantee period. Doing little things like that on a continuous basis are critical.

Malcolm Ridgway -- What do you think it would take to change your image from being the clinical engineer to being the chief technology officer?

Ira Soller -- By doing these kinds of things, Malcolm, without being given the title you are showing that you are the one who is worried about these issues, purchase requisition review, sole source committee and other technology issues that effect the whole hospital.

Malcolm Ridgway -- I think you should go home and imagine that they have screwed a new plaque on your door that says Chief Technology Officer and ask yourself what do I do differently with that new plaque on the door than I did yesterday or last week?

Martina O'Brien -- University Medical Center in Tucson -- Larry spoke of best value. To be of best value to the institution, we must ask what the hospital and its many departments value, finance, administration, clinical departments, materials management. How do we contribute? On top of that, we need to be measuring those values. We need to be measuring financial performance, technical performance, equipment safety, risk management as it relates to the technology. As Malcolm said earlier, we need to bring closure and answer the questions. We often start measuring but have no follow-up to determine if we are better or worse than five years ago. If we don't like the quality of what we are doing, how are we going to change? Engage in a collaborative effort. Involve all players in the institution. All clinicians and administrators should know you, you should be involved in committees. To provide best value you need to know what is going on in the rest of the hospital.

Sam Miller -- I will put a different spin on this and elicit comments concerning administration. What is the role of clinical engineers in administration? We are all good managers and people managers. When I left the hospital system 5 years ago I was assistant administrator of all service departments. It was easy, but a lot of time was spent in technical equipment asset management. I see a future in administration. Us and them, good guys and bad guys, these barriers should be broken down.

Ira Tackel -- A point well taken. Many of our colleagues provide more of an administrative function than technical function.

Larry Hertzler -- some have no business being in administration.

Ira Tackel -- You said it pretty well. Administrative wannabes who don't have requisite skills are set up for failure. Knowing what you can do is as important as knowing what you can't do. Knowing to get the skill sets to get there

Sam Miller -- We have a few MBAs in this room. If you want to go that route, you have to pick up the credentials to go there. It doesn't take much. You have to take a few more courses to get your ticket as a hospital administrator.

Binseng Wang -- Concerning the Symposium Theme, *The future of clinical engineering*, if we know the future we don't have to discuss it. Disappointed to not have heard anything new today. I will painting a gloomy picture, if the hospital decides to out-source or to in-source, there is nothing a clinical engineer can do about it. The people we need to help are not in this room. They are not even ACCE members. Those are the poor souls who don't know what is going on and still doing electrical safety checks every 6 months. Lot of critical and more pressing issues are not being addressed. Year 2000 issues. BMETs recommending to test all equipment. May not be wise to do so. FDA regulation pending servicers and refurbishers. The Association for the Advancement of Medical Instrumentation (AAMI) plans to set standard to regulate servicers. No regulation is not an option according to FDA. Mike Miller rejected ACCE request to place ACCE advertisement of this Symposium in BIT.

Ira Tackel -- The purpose is level try at a very high to discuss and present options for the future. We could have structured this to be purely technical such as Y2K but the Symposium Committee took another tack, a broad discussion about the future of clinical engineering.

Joe Dyro -- I should like to draw attention to the Poster Session (see below). Five highly qualified clinical engineers attending this Symposium will address specific technical issues, issues that should be of interest to Binseng and others including year 2000 preparedness, safety guidelines on fire hazards in the OR , impending FDA regulations on servicers and refurbishers, opportunities in clinical engineering consulting, and revised CAP rules on equipment inspections.

Dave Bell - I will raise the issue of educating ourselves for the future. Educating administrators can be difficult. We may not be up on things. What about the adequacy of the organizations to which we belong? AAMI is beginning to address my needs less and less. ACCE has made a great step with this useful ACCE Symposium. Binseng and I are on the membership committee. According to by-laws one who does not have a BS but is a director of a 30-man department cannot be a member of ACCE.

Larry Hertzler -- It's been clear that the type of education you need depends on where you are in the organization. If you are the head of a three-man department reporting to facilities it is difficult to learn to make a presentation before the President of the hospital because by your own position you will not be able to do that. If you do you would be jumping over the boss's head who would not react kindly to that. It's difficult to operate in that kind of environment. There needs to be education at a variety of different levels. Where you are placed in the hierarchy affects your ability to get things done. It doesn't mean that reporting to facilities is bad but it depends on the organization on how things are from a political and credibility standpoint with the departments you have to be in. There is some education that can be done for those individuals currently establishing themselves as a separate clinical engineering function. That increases your stature and may be right for your organization or it may not depending upon the type of organization.

Malcolm Ridgway -- The worst mistake one can make in running a seminar is to try to address different people in the audience, for example, to mix nurses with engineers and *vice versa*. The same is true with a professional association. What we have to do is determine what differentiates this group from others and use that as the criteria for membership. Membership should not be based on arbitrary things like credentials. When you apply for membership here, apply a test that asks, do you fit with the rest of these people? Because if you don't you're not going to get a fare thee well for participating. What you need to do is determine what is it that defines the commonality in this group. I have always said that the trouble with clinical engineering is that it has a personality disorder. Clinical engineering is at least five different things in my research including someone who manages an in-house department and someone who does system engineering. In the other extreme there are at least five different roles. And I think you have to ask are those composite five roles what we call clinical engineering or asset management or whatever the term is? We should stop stumbling with these terms and try functionally to define what it is that you people do and use that as a filter to say people who are performing a

substantial part of this function should belong to this organization. If you don't, then perhaps we should tell you to join AFSMI or ASHE or some other group. If that sounds overwhelming to do something like that, then you have a basic problem.

Binseng Wang -- Would you put that on the back of a business card, please?

Larry Hertzler -- I'd like to agree with Malcolm but I don't at all. One of the things that makes clinical engineering a particularly great profession is that there is a mix. We should invite more people into this organization who are not clinical engineers but rather nurses, physicians, administrators, and radiologists. These are the people to whom we refer when we say, I wish they understood me. If we can bring them into our organization to participate in these types of exchanges it would benefit us and them. If you can't speak to your own administrators perhaps you can speak to someone else's administrator and try to understand how that works. I'd like to see more walks of life within health care and just within business in general because we are facing business issues to be speakers or members. I think we'd have better opportunities to create synergy for learning amongst ourselves.

Dave Francoeur -- I agree with Larry. I am participating in this Symposium although I am not a member of ACCE. I agree with Dr. Bauld's comments regarding the overemphasis on electrical safety and the negligible level of electrical hazards. I'd like to apply risk-based criteria to my preventive maintenance program. My staff and I meet to score the risk level presented by a particular medical device on an individual basis. My staff feels it would be wrong if inspection intervals were reduced. They equate number of inspections with quality of service. The technicians have two concerns: 1. if they don't have to do the inspections then they are out of a job and 2. they feel the customer needs this sense of security, albeit a false sense, that adds value. What I am looking for are the tools to enable me to explain to my staff that by reducing inspections you are freeing up more time to do things that will add more value. Where can I obtain or design such tool that can help me to convince my staff of the wisdom of adopting the risk-based criteria and the benefits of reducing unnecessary work permitting redirection of work to enhance quality and patient safety?

Tom Bauld -- The two reasons cited by your staff are held in common by many technicians who have worked for me. They feel they have always done it that way, they are comfortable doing it that way. They feel it is worth while doing. Many years ago when working at Sinai Hospital we recorded great volumes of data from inspections and preventive maintenance. We thought that the thousands of data points we collected would reveal significant trends which would allow us to improve the quality of our service and enhance patient safety. We couldn't even analyze these paper records. Now at the University of Michigan even with improved data management systems we employ a pass-fail criteria of safety testing. We did a study of a two-year period and found only eight instances of excessive electrical leakage. The problems occurred in commercial, non-patient-care devices, such as radios, televisions, and old devices that should have been retired 20 years prior. The data we have show that electrical safety testing is a non-productive piece of work. We have not demonstrated any significant failures. No significant risk to patients.

Ira Tackel -- The concern raised by Dave Francoeur can be the topic of a whole other symposium. I left the Hospital of the University of Pennsylvania in 1985 in part because of an adage there that can be expressed thistle, *Why spoil 200 years of tradition just for a little bit of progress?* And you can take that one step further into the modern day. The seven last words of a dying company are, *but we always did it that way*. Dave, I agree with Tom. What you must realize is that it is our job to be the visionary. It is our job to be on the cutting edge, to push the envelope, to be out on the limb a bit. Al Lapides of Replacement Parts Industries said it well, *If you are not making some mistakes, you are playing the game too conservatively*, I think that is true, you have to be on the edge just a bit or you don't make much progress.

Martina O'Brien -- I am also not a member of ACCE. Binseng made a comment early that we are preaching to the choir by have a symposium like this; however, I find it quite useful. I agree with the comments that were made about broadening the membership based upon functional responsibilities. If we are really going to have an impact on the practice of clinical engineering then to exclude people who are practicing clinical engineering is shooting ourselves in the foot and guaranteeing that we will always be preaching to the choir. So I would appeal to ACCE to consider revisions of the membership criteria. I would like to be part of this group.

Ira Tackel -- Your point is well taken and while it is on a subject which was not the crux of the discussion this morning there are a number of ACCE board members here today that may wish to comment of membership criteria.

William Hyman -- I would like to return to the risk-based criteria issue. We must consider from a risk management perspective the consequences of a patient electrocuted by one of those devices you determined did not need electrical safety testing. How would you explain your decision to have omitted these tests on such a device?

Ira Tackel -- I would submit to you that we here at Thomas Jefferson University Hospital have over 400,000 records on file that would suggest that there is virtually no risk of such an electrocution scenario. Now my colleagues from ECRI here today may disagree with that but I have data to support my position. Actually, Mark, I don't think you would disagree with me.

Mark Bruley -- I don't disagree with you.

Ira Tackel -- We have discussed this subject before.

Mark Bruley -- I disagree with Al (Al de Richemond) in regard to your comment, since I am sort of a maven of medical device accidents, ...

Ira Tackel -- Is that what you call yourself?

Al de Richemond -- That is not what he's called at the office.

Mark Bruley -- I can't think of a case where the failure to do electrical safety checks resulted in an accident in a way that would reflect poorly on a clinical engineering service or department.

Ira Tackel -- And you have a lot of data.

Mark Bruley -- Yes, I believe we do, spanning the last 25 years. If you are just talking about electrical safety as one example, to fault an institution for not having done and electrical safety inspection every six months or every twelve months and a capacitor goes bad resulting in a high level of leakage on a chassis for example and someone gets shocked, some other system had to have broken down as well such as using unprotected exteriorized pacing catheter leads. So it is applying the appropriate level of effort for the appropriate threat. This is what has to be reviewed and assessed.

Ira Tackel -- You simply have to consider the fact that we do not have unlimited resources in dollars. So one has to make choices and we are making those choices every day in the delivery of health care. We can't continue to provide services to everyone at every level. And we know that.

William Hyman -- I agree with you absolutely.

Ira Tackel-- Its a paradigm shift; you have to get there.

Elliott Sloane -- What is the panel's perspective on the value of associations and some of the conflict some of which hinges on the term, engineer. I would like to know the panel's perspective since you deal with international, national, regional and local organizations, of a certification that would be like a CPA; that would be something like a clinical technology management certification that the ACCE would administer. It would address risk, would address finance, would address selection, acquisition, and the broad scope of issues with which most of us deal. How would that be received? It is similar to how the medical profession has specialties and subspecialties that validate and authenticate ones credentials. It addresses some of Binseng's concerns and some of the current FDA issue as well. I would like to hear your thoughts about having a credentialling process that would address technology management, not engineering.

Malcolm Ridgway -- I would like to address that question in a historical context. I was a founding member of the board of examiners for the certification of clinical engineers. I left that board in protest in 1975 because I thought what they were trying to do was futile. I queried Mike Miller, President of AAMI, and Dr. Caceres, who invented the term clinical engineering, about the purpose of this new term. Dr. Caceres had a clear idea of what a clinical engineer was. It was nothing like what you think a clinical engineer is. However, I asked the basic question, what is the purpose of certifying clinical engineers? And there wasn't a purpose. I suggested one. At that time we were working for the hospital association and in-house departments were growing. I suggested that certification as a clinical engineer would serve the purpose of informing an administrator of a hospital that an individual had the experience and skills to run an in-house department. He might have been a salesman for Hewlett-Packard in a prior life but his colleagues would examine him to determine whether or not he had the basic set of skills to run a hospital department. If so he would be certified. This would become a recruiting aid for hospitals trying to start in-house departments. And that still is a problem. Who is the right person to do that? I would suggest that that is a legitimate basis for what you are suggesting, Elliott. I think if we

determine now what is a clinical engineer or an asset manager or an in-house manager, whatever we want to call him, let's identify that entity and let's say a group of his peers who would know one if they saw one said, yes this person has the background, the experience, and basic skills to be able to do the job. We will give him the Good Housekeeping Seal of Approval. There would then be a clear purpose and meaning in the certification program. I think it would have some value and it would be a service.

Elliott Sloane -- Could it be a respiratory therapist or a materials manager?

Malcolm Ridgway -- Correct. Most people are certified for different reason, but I think this would make sense in the context of the business that we are in. That's just my two cents worth.

Greg Davis -- It is not clear in my mind that the market place has established a need for certification. I do not see a lot of people coming to me and saying we need to have certified people performing these tasks. I am hoping that that will occur, I am a certified clinical engineer. I have gone through that. At the time I thought it brought value, but I think it brought more value to myself than to my employer. Let us identify the customer needs, such as management skills or equipment selection expertise, and then align and direct certification toward fulfilling that need.

Tom Bauld -- I don't know whether certification in the short term can add value to what we do or what we claim to do for hospitals. I agree with Martina O'Brien's point that functional performance is a major factor to be considered. Multiple credentials need to be examined. The hiring policy criteria of my University explicitly state what credentials one must have, for example, a bachelor's degree or equivalent. The University, however, is liberal in its interpretation of equivalencies. *Apropos* to this discussion, ten years ago in Michigan Bryanne Patail and I, among the founders of the Michigan Society of Clinical Engineers twelve years prior, opened the door of that Society. In those first twelve years, we observed that those whom we supervised, entry, middle-level, and advanced biomedical engineering technicians and supervisors, had no opportunity for participation in a regional professional organization. A dozen members of the Society, mostly departmental managers, had been able to meet regularly. However, a large gulf existed between us and the technician group. After arduous, lengthy, painful and intense debate we elected to open membership to anyone allied with us in the field. We did not have any credentials as a membership requirement at that point. Now, the Society has a mailing list of several hundred with an active group of 40 to 50. Membership is free. We went through a wrenching experience to discover that we were able to add value to our colleagues' professional lives by enabling them participation in a Society, a benefit that they did not have before.

Larry Hertzler -- I have served on the BMET Certification Board. I am a Registered Professional Engineer and a CCE. For any certification program to be meaningful, the certification process itself must be meaningful and held in high esteem. Of all the BMETs practicing in the United States, less than half are certified. Can one make the claim that those who are certified are better than those who aren't? I would say absolutely not. Looking at other walks of life, for example, it means something for a cardiologist to be Board Certified. Most of those cardiologist who can be Board Certified are. It is very meaningful. Until we get to the point

that the certification process we have has value and the people practicing want to achieve this goal, it will only be meaningful in a sales and marketing perspective. We can't even define asset management or what clinical engineers should do or what clinical engineering is. The last thing we need is another certification process that would put more letters after someone's name. It may or may not mean anything at all.

Binseng Wang -- From what I have heard from some of the speakers this morning there are some misunderstanding regarding ACCE membership criteria. Kelly Galanopoulos, Chair of the Membership Committee was not able to be here, but our President, Frank Painter, would like to clarify ACCE's policy.

Frank Painter -- I should like to read the ACCE membership criteria for an Individual and for an Associate member. An ACCE Membership Application Form and membership criteria are included in these Proceedings.

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

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

ACCE also has a non-voting, associate category, *an individual committed to the mission of the organization who has demonstrated a contribution to the advancement of the clinical engineering profession and meets other requirements established by the board.*

Both Dave and Martina have contributed substantially to the field.

Malcolm Ridgway -- Sounds like a good definition of a club.

Frank Painter -- I think that's wrong. I disagree. It is stated, *Recognition of exceptional contributions ... to the profession.*
As Malcolm queried, *do you fit with the group and will you get something out of the organization*? If the answer is yes then you should be a member.

Malcolm Ridgway -- It's an open environment, that is, if you get something out of it then you can join. A club would say, we will look at you and decide if you fit with us.

Frank Painter -- Larry vehemently disagreed with Malcolm then said the same thing that Malcolm said, that is, nurses, physicians and hospital administrators should be able to join. If they fit with the group and can get something out of it then that fits the definition.

Ira Soller -- While not wanting to interrupt this train of thought, I did have a question or rather a comment on electrical safety. At one time JCAHO required regular inspections then backed away from that to adopt the risk management approach. The very basis of risk management asserts that one is not required to do regular PMs on certain classes of equipment which may be electrically operated. That stand supports not doing electrical safety and taking it off the PM program after having considered all aspects of the device in question.

Lee Welter -- I like Elliott's concept but not for the reason on which much of the discussion has focused. The real value to a professional society such as the ACCE is to help to define the migration pathway, to determine the knowledge domains in which some degree of familiarity or mastery may be useful and valuable in advancing ourselves professionally. You talked about different topics and medical specialties. Many medical specialties arose not *de novo* but evolved gradually. Now the certification of physicians exists because people have acquired a certain body of skills and have determined the necessary qualifications for practicing that particular specialty and subspecialty of medicine. With regard to membership, it is not unusual for a professional society to have categories of membership such as a full voting membership for people who meet certain defined educational and experiential requirements, associate membership for people who do not meet that and perhaps do not wish to have the obligation and duties of full membership, and then a fellow status for people who have exceptional qualifications and/or achievements and contribution to the profession.

Tom Bauld -- ACCE has all those categories of membership.

Bob Morris -- There are two issues that relate to the electrical safety issue and other issues talked about. One which was in Ira's slide at the beginning is that you need to question assumptions. There are still people who are acting under assumptions not backed up by data or other reasons. The second thing on a different slide that Ira showed was the issue about thinking about the future. Are you spending any time thinking about the future? Most of us are involved so much in our day to day activities it takes a conscious effort to do that. I agree that it is absolutely essential to do. as it is to meet you obligations to your institution your administrator.

Malcolm Ridgway -- Now you are going to think about it and do something about it.

Bob Morris -- Absolutely!

Malcolm Ridgway -- Thinking about it one day a year on your birthday is not enough.

Bryanne Patail -- In developing ACCE's plans for Vision 2000, it was proposed to look at best practices in clinical engineering. For example, we would recognize those departments, independent service providers , or any entity that exemplifies best practices. With best practices defined in this way, buyers, purchasers and administrators would understand what clinical engineers should and can do. Defining the profession in this way would enhance credibility.

Ira Tackel -- How do you put teeth in it? You wouldn't go to a non-board certified cardiologist even though they exist. But, in fact, options exist today where you can do whatever you want

with regard to clinical engineering with no down side except maybe cost or something intangible. So how do you put the teeth in it?

Bryanne Patail - As an example we may wish to consider such organizations as the American Association of Blood Banks (AABB). The AABB has developed policies and procedures for handling blood and cross matches. By following these guidelines, that is, doing things in certain standardized ways, improved outcomes result, such as reduction in contamination and cross matching incompatibility.

Ira Tackel -- This is possible if we can link what we do through outcomes research.

Alan Lipschultz -- Returning to an earlier discussion concerning in-sourcing and out-sourcing, I belong to an in-house group that is not part of a shared service yet one of the things I have told my administrative people many times is that I out-source routinely. Every time I call in an outside vendor to service a particular instrument I am out-sourcing. I'm skimming the cream but I'm out-sourcing when necessary. I'm not trying to do it all in house. I believe firmly in out-sourcing when appropriate.

Ira Tackel -- When appropriate. You are taking the reigns to manage technology as you deem appropriate.

Alan Lipschultz -- The idea is to turn it around. People have heard that out-sourcing is good and are thus focused on out-sourcing. I want to turn it around and show them that I doing outsourcing. I believe in it.

Ira Tackel -- I will close by saying it has been a privilege to be in the company of these four knowledgeable and respected clinical engineers, movers and shakers of the industry. I value being in the company of them. I trust all of you feel as I do. I am not letting Malcolm off the hook. Please tell us how you define what you do in seven words.

Malcolm Ridgway -- I will tell you after you have read what other Symposium attendees have submitted.

Ira Tackel -- The following statements, broad, generic and to the point, were submitted:

1. Supervise, advise, and provide technology related services, Ira Soller
2. I manage the technology management process, Frank Painter
3. I motivate people and measure their performance, Dale Rose
4. Optimizing the utilization of clinical technology, Michael Schwartz
5. Manage and consult the optimal application of healthcare technology, Bob Morris
6. Help non-technical people how to understand medical equipment, Sam Miller
7. Technical expert in the medical environment, Paul Sherman

8. Translator, administrator - clinicians - technologist, Alan Lipschultz
9. I manage the effectiveness of the hospitals medical technologies, Martina O'Brien
10. What do you do? What are you?, Dr. Seuss
11. As an engineer, I help ensure the effectiveness of healthcare, Mark Bruley
12. Managing the appropriate application of medical technology, Lee Welter
13. I help hospitals solve their equipment problems, Malcolm Ridgway

Tom Bauld -- A word of advice I heard last night -- Don't expect the business to love you, you must love the business

Ira Tackel -- Words to live by.

Ira Tackel -- I thank the panelists. I thank the attendees. This is for you, the committee that structured this truly had the best interests of the attendees in mind.

Recapitulation

Ira Tackel -- Let us review of what took place today. Did what we provide fit the bill? Did today's symposium meet your expectations? If not, why not? How can we do better? In our never ending quest to fine tune the educational services ACCE provides its members and, in some cases, non-members, we try to meet the needs of our constituency, our peers, at least and so we are trying to get feedback whether there was value in the program. If so, how? If not, how can we improve with other topics or consider this topic further in the future?

Joe Dyro -- I have copies of the past several issues of *ACCE News*. These are available to those who don't regularly receive it. Remember, the newsletter is only as good as the contributions it receives from its members and, in some cases, non-members. For example, Martina O'Brien and Dave Francoeur, both of whom are here today and are not yet members, have submitted articles that have been published in the *News*, Martina on the Year 2000 and Dave on convincing the American College of Pathologists to relax its device inspection requirements.

Frank Painter -- Wayne Morse of Morse Medical has sent samples of ACCE products. These are on display at the table in the back of the room and are available for purchase.

Elliott Sloane -- *Can Wayne provide members with ACCE flak jackets?*

Tom Bauld -- Wayne can put the ACCE logo on anything you send to him.

Elliott Sloane -- It would be a good idea to have manufacturers and hospital administrators here to tell us what is on their minds and where they are heading. This valuable information is not available in any other setting. To know where we should go requires that we know where the rest of the market is going.

Martina O'Brien -- I concur. I brought up the same issue when I sat on the AAMI Board of Directors. I wanted to see health care administrators for improving the awareness of clinical engineering and allowing bi-directional communication to establish needs and expectations. Unfortunately this suggestion fell upon deaf ears. I am hoping that someone will pick up the ball so that this dialogue can be established.

Ira Tackel -- I have picked up that ball. On Monday at 2:30 PM I will be in the exhibit hall with Tom Lewis, my CEO from TJU.

Tom Bauld -- I should like to share with you my recent experience at HealthTech '98 in Nashville. This conference met the needs that Elliott described. A wide variety of health care professionals attended including CEOs, Chief Information Officers, and Vice Presidents from GE, Intel, IBM. This was a super meeting. I got a lot out of the meeting. Many ISOs, OEMs and clinical engineering in-house groups were in attendance representing the best balance I've ever seen to discuss issues dealing with management. The information exchange through dialogue was valuable at this well-run, professionally managed event. A CD-ROM of HealthTech '98 is available for purchase.

Ira Tackel -- One of the things I observed in this my first year attending HealthTech is that it is an interesting group, very diverse, but with a very small, less than 20%, representation by our peers, such as the clinical engineers present here. An unusual mix in a sense that saw at times vendors preaching to other vendors.

Frank Painter -- ACCE had general membership meeting there with 24 members in attendance. We discussed ACCE activities over the past 12 months and had open discussion. We plan to repeat that at the HealthTech meeting next year in Baltimore.

Paul Sherman -- Logistically I would be unable to attend both this Symposium and HealthTech.

Ira Tackel -- HealthTech is fairly new as HealthTech, two years I believe. HealthTech is trying to find its niche, its market. I am not suggesting what it should or shouldn't be. It will probably evolve in a couple years to become significant competition to AAMI with respect to its value from a clinical engineering perspective.

Malcolm Ridgway -- It is Jack Spear's intent to make HealthTech a meeting like that held each year in the fall by the Radiological Society of North America (RSNA). The problem is that it is in the wrong half of the year. It was co-sponsored by the American Society of Hospital Engineers (ASHE) and I think ASHE intended it to replace their mid-year meeting on clinical engineering; Independent Service Network International (ISNI) is trying to work out a deal with Jack that would make their mid-year meeting coincide with HealthTech. Next year's meeting in Baltimore in the Spring conflicts with ASHE, ISNI and AAMI. It would be excellent if it could be moved to the fall where it could be combined with an ACCE meeting. As Frank said, room, space and discount for ACCE members could possibly be arranged.

ISNI is a voluntary, not for profit association representing several hundred companies from the independent medical equipment service and computer service industries that are involved in the support of high - technology products in the domestic and international marketplaces. I am a member of the ISNI's Board of Directors and am coordinating a response from the ISNI to the FDA's ANPR.

Frank Painter -- HealthTech and Jack Spears have been very cooperative with ACCE helping us arrange our general meeting this year. We were close to holding an Advanced Clinical Engineering Workshop (ACEW) in Nashville. He asked if ACCE would co-sponsor an entire track throughout next year's meeting. ACCE will consider assembling a faculty to present such a track.

John Hughes -- I am Program Co-chairing of the AAMI meeting in 1999 in Boston. I will be calling on all of you and you will, hopefully, call upon me to contribute to that meeting. I've gone to HealthTech for its 5 years in existence. I started to go to HealthTech because they offered something that no other group did. RSNA is targeted at vendors selling equipment and the clinical people. Jack Spear's group has brought together the leading edge technologies in imaging, telecommunications and radiology. A totally different segment of the industry with information not available in any other place. I also heard from some of those in attendance that if

they had to attend one conference it would be HealthTech. I thought, for me personally, considering my objectives in attending that conference, and I don't mean to be disrespectful to conference organizers, the conference was diluted as it seemed to start taking the direction of being all things to all people which is one of AAMI's challenges. I certainly hope that Jack can manage that since he is a valuable contributor to the profession.

Ira Tackel -- It certainly is a challenge. I heard comments from a couple of vendors with which AAMI will have to contend. This is not a name-bashing meeting at all, however, some of the vendors on display at HealthTech made a strategic decision this year to display at HealthTech and not display at AAMI. This may be a wave of the future in terms of making choices. Again, it is a finite pot. We don't have unlimited resources and have to make strategic decisions. Now, back to whether we fit the bill.

Frank Painter -- I enjoyed the format of the Symposium where the audience provided most of the input and stimulation in determining the direction of the conversation, the questions, comments and dialogue. One does not usually have such a forum with its opportunity for in-depth discourse in the classical presentation format. With more of a free flow, sometimes getting of track, it for the most part provided an opportunity for a much more interesting discussion in that it allowed for conflicting points of view to be freely aired and a chance for resolution of some contentious issues. I hope we can find topics in the future that lend themselves to this format.

Martina O'Brien -- This is my first ACCE meeting. I liked the Symposium very much. I liked the format, I think having a panel with people who can respond to questions is very valuable. Another option is to have a controversial topic with audience participation which tends to take on a life of its own. Any thing that is more detailed could be deferred to an afternoon session. If we focusing entirely on technical presentations people don't interact as much. I really like this format.

Mark Bruley - Controversy and debate is needed and very critical but we need some time for the presentation of solutions to the problems that arise from the controversy and debate. While it would take more time it would broaden the Symposium.

Ira Tackel -- Concerning Symposium length, the Committee thought it best to start with the present format of a morning session with several activities in the afternoon such as summaries, tours and posters presentations.

Mark Bruley -- Telemedicine could fill an entire day.

Sam Miller -- I like the format of today especially since it was tied to AAMI meeting to help with the transportation costs and time efficiencies. With regard to problem solving, perhaps next year problems could be noted on the board, break out sessions held to develop solutions, and groups reassemble to report these solutions.

Frank Painter -- ACCE didn't hold this Symposium to make money. We intended it as an educational opportunity for our membership and other interested clinical engineers. Perhaps in '99 working with John Hughes we can do this next year in Boston at AAMI. That would be a nice compromise. It appeared that AAMI had some anxiety over our holding this Symposium when we did. We were of the belief that we scheduled this so as not to be in conflict with AAMI. Apparently AAMI changed their schedule resulting in some overlap of programs addressing clinical engineering issues.

John Hughes -- I should be pleased to work with the ACCE leadership in planning events for next year. This year's difficulties appear to have been the consequence of a breakdown in communications, parties not understanding each other's intent in time to change schedules.

Bryanne Patail -- I suggest that we have a morning session of current issues and an afternoon session of future issues. At this time I would like to recognize and thank the corporate sponsors of this first ACCE Symposium. Generous contributions to ensure the financial success of this meeting were made by Marquette Medical Systems, Siemens Medical Systems, Vitalcom and Zoll Medical Corporation.

Lee Welter-- Website communication of ideas, threads, discussion. Approach beyond printed paper of the newsletter. Take some of the threads to create a product for broader dissemination by e-mail. Brief e-mail catches the attention of administrators inexpensively.

Ira Tackel -- Would anyone wish to suggest topics for next year?

Paul Sherman -- I would be a good idea to bring in hospital administrators to the panel.

Martina O'Brien -- I would like to see more detail on the topics Malcolm discussed, clinical technology optimization and TICS. This is new ground for most of us. We could develop common strategies and consistent methods for how things are done. This would help everybody who is trying to do the same thing.

Tom Bauld -- I suggest topics in information technologies and imaging and that we invite some of our colleagues in these emerging professions to participate. This was suggested at a recent University Hospital Consortium meeting of clinical engineers. On another matter, I had a slide to show you illustrating a point in this area. However, after reviewing the content, I detected an element of profession bashing which I found disrespectful. Therefore I will not show this. I encourage us all to focus on building high level professional relationships and to discourage the critique of our colleagues in other professions even when it is done in jest.

Ira Tackel -- Should controversial topics be included I would suggest a subject near and dear to my heart, that is, medical equipment maintenance insurance or asset management. I propose a debate on the true cost bottom-line value of insurance or asset management programs, a debate pitting representatives of in-house or shared services programs against representatives of such organizations as CIC, Specialty Underwriters, and US Counseling that engage that provide this

service. Is this a scam? Let's debate it. Seeing the nodding of several heads, I sense there is some interest in such a debate.

Ted Cohen -- A debate would be worth while.

Bryanne Patail -- I want to hear about Year 2000.

Elliott Sloane -- There is enough brain power in here for people to take opposing points and argue them effectively. I think we can do and learn a lot more through this tactic.

Ira Tackel -- Maintenance insurance providers regularly try to sell Thomas Jefferson University Hospital on their programs.

Elliott Sloane -- Rather than having company representative debate, perhaps those that retain the services of these companies could debate.

John Hughes -- Would you invite your CEO to that debate, Ira?

Bryanne Patail -- We need more discussion on metrics, that is, the methodology of measuring metrics such as those Ted Cohen has been instrumental in developing.

Lee Welter -- Human factors and medical instrument design is of particular interest to me and may be to others involved in medical device design. Currently the AAMI Human Factors Standard is being revised by a reconstituted standards committee. The revisions will be used in part by the FDA as part of the Good Manufacturing Practices (GMP) to assist manufacturers to better design devices through human factors engineering. Some people on the committee could offer that expertise. I think clinical engineers involved in prepurchase evaluations would benefit from this

Tom Bauld -- I would like to see a group addressing the mobilization of the service force the folk that are doing field service from institutions. What technology tools such as telemetry are used to make the process effective.

Malcolm Ridgway -- Today we talked about some of the same issues which were discussed five to ten years ago. Is this simply the nature of this group? Some issues are as timely then as they are now. I thought some things that came up today such as electrical safety were dead and buried. Let's look at issues 5 years ago to see if they are still of interest. This would serve as a check and balance to make sure we are not recycling the same stuff.

Sam Miller -- What educational resources are available to help younger people in the profession to advance?

Ira Tackel -- Your comments will be given to the Symposium Committee to help it plan for the '99 Symposium. Again, I thank Larry Hertzler, Greg Davis, Malcolm Ridgway and Tom Bauld.

Poster Session

Surgical Fires Can Be Prevented

Mark Bruley

Q (Joe Dyro). Mark, would you describe what you a presenting?
A (Mark Bruley). Over the years, we have investigated many surgical fires. About 100 occur each year. Of those, 10 to 20 are serious. They are all pretty much preventable, not totally preventable; but great efforts can be made to keep most of them from happening by reducing oxygen concentrations during surgery. I am speaking of oxygen concentrations from open oxygen sources that are used during analgesia and local surgery as opposed to sources used during anesthesia.

Q. Don't the medical specialists who work with oxygen on a daily basis particularly in the operating room in providing therapy to patients know of the dangers associated with its use? Aren't they aware of the presence of combustible materials and sources of ignition when they are using oxygen?
A. No, in most cases they don't. It is mainly due to the lack of education within medical colleges of surgeons and anesthesiologists about the hazards related to oxygen enriched fire and flammability.

Q. Give me an example of how you would heighten an anesthesiologist's or a surgeon's sensitivity to this issue. What would you do to wake them up?
A. What is most important is that they have to realize that surgical fires are not usually predictable. Surgical fires occur with such rapid onset and incredibly fast flame spread.

Q. You show here what appears to be an operating room with surgical staff standing about a patient who is engulfed in flames. Is this an accident in progress or is it a staged demonstration?
A. This was staged in our operating room at ECRI. You can see my hand here holding a CO_2 fire extinguisher prepared to extinguish the conflagration. What we are showing is a generic surgical laser where a surgeon whose attention has been diverted has ignited the drapes covering the patient and hanging vertically from the operating table. Because the flame is on a vertical surface, the flame spread is much more rapid than if were just on a horizontal surface. We are illustrating a non-oxygen enriched fire which took only about eight seconds from time of ignition to what you see here, a two-foot high blazing inferno about the patients chest and head. If this had been an oxygen enriched fire the time for the fire to reach the intensity illustrated here would have been from 1/2 to 1 second.

We assisted ABC News in producing a recent 20/20 episode airing March 16, 1998 on surgical fires. We showed the hazards during surgery of oxygen-enriched flammability under surgical drapes as well as oxygen-enriched burning in endotracheal tubes as depicted in this picture. The fire shown here is burning on the inner surface of the tube. As you can see, the tube's cuff ,which provides a seal against the patients trachea, is still inflated. The fire is literally blow torching out. This flame will pulse out and back with each patient breath.

Q. I would imaging that such a flame would do some rather nasty things to the patient's lungs?

A. Yes, it usually destroys the trachea resulting in death.

Q. What reaction was there to the 20/20 episode?
A. I had feedback from the risk management department from a major hospital in Boston that several parents had come in and questioned the need for using open oxygen sources during to be performed on their children. Subsequent to the questions of the parents, the open oxygen sources were either minimized or not used. This is the lesson which we had hoped to impart.

Q. Al, do you become involved in the investigation of hospital fires?
A. Yes, I get involved in quite a few. But we see the same set of criteria. This never happened before. How could this happen?

Q. You are doing a valuable service by bringing this information to the public at-large and to the health care community. Thank you very much for this excellent poster presentation.
A. You are welcome. Al de Richemond and I thank you for inviting us. We are glad to be here.
include here two pages of ECRI recommendations

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Some Perspectives on Clinical Engineering Consulting

J. Sam Miller

Q (Joe Dyro). Would you care to say a few words about your poster presentation?
A (Sam Miller). This presentation illustrates the good points and the bad points of consulting. Many clinical engineers I have met are thinking about consulting. They think that there are big buck to be had in consulting. This presentation helps one understand what resources are needed to start the business and what returns might be expected.

Q. Have you brought hand-outs today for those who might be interested in getting started?
A. Yes, hand-outs are available here. Copies may be obtained also by contacting me directly after the Symposium. My coordinates are listed below.

Q. I understand that you also maintain a registry of clinical engineering and biomedical engineering consultants on the Web?
A. I am pleased to see that within our rather small community of engineers there are about 45 listed on the registry.

Q. Could you tell us about the activity on the web site?
A. We had over 6000 hits last year.

Q. How can someone follow-up with you to get more information on this presentation?
A. My coordinates are included here along with the abstract of my presentation.

Q. I thank you for this fine presentation and wish you the best of luck in your consulting activities.

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College of American Pathologists Device Inspection Rule Changes

David E. Francoeur

Q (Joe Dyro). Dave, one of the things that impressed me about your recent accomplishment is that you recognized a need and took action. You didn't just sit back and complain and do nothing.
A (Dave Francoeur). I was upset with the fact that we had to do electrical safety testing on laboratory equipment on an annual basis and thought it ate up a lot of our time and really did not add value. So I called the people at the College of American Pathologists (CAP) to ask if they felt that the current testing requirements were necessary. They responded by requesting that I send information to them explaining while such testing should not be required. I did that. CAP evaluated my response, we had several conversations on the matter, and I was given the option of submitting a proposal for the recommendations I felt to be more appropriate. I did that. CAP accepted my proposal with only minor changes.

Q. Did you do this by letter and telephone discussions?
A. Yes, let me work you through the steps I took. First I submitted a letter to my local CAP representative. She agreed with me and forwarded my letter to the President of the CAP. She indicated that both she and I were in agreement over the lack of need to do the inspections on an annual basis. I had several subsequent telephone conversations with the President who suggested I send him my proposed modifications to the existing testing protocols, CAP would study the proposal. I show here the initial requirement under which I show my proposed changes. The crux of the change is the following wording I suggested for criteria for inspection: *Upon initial use, after repair or modification, and when a problem is suspected.* I submitted frank painter and JCAHO statements supporting my position. This was agreed upon by CAP.

Q, Dave, you have performed a service beneficial not only to you and Bay State Medical Center but also to the health care community at-large. The kind of action you have taken is an example of action resulting in significant productivity improvement. What you have done will result in the elimination of useless work freeing up more time to do more important, more productive tasks. A bold stroke for cost effectiveness and productivity it is.
A. In our organization alone, we estimate 1/2 FTE in savings on an annual basis.

Q. What a significant savings. Multiply that by the number of facilities affected and the numbers become quite large.
A. A colleague responsible for Veterans Affairs Hospitals throughout the country said in a recent conversation that the impact of this rule change will be astronomically in reducing FTE requirements. Millions of dollars will be saved nationwide as a result of this work.

Q. Dave, I thank you for your participation in the ACCE Symposium and for your fine work which has resulted in significant improvements in technology management.
A. Thank you for the invitation to present in this poster session.

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FDA's Advanced Notice of Proposed Rulemaking

Thomas J. Bauld, III, Ph.D.

Q (Joe Dyro). Tom, would you run us through the main points of your presentation.
A (Tom Bauld). The FDA has published a document that is requesting information from the medical servicer community and the user community to find out whether there are issues of safety having to do with medical device servicers and medical device refurbishers. Is there data out there that would help them determine if a regulation is required? I have put together here a summary. The biggest issue is the concern over cost-effectiveness. As shown here, *The main issue is the cost effectiveness and lack of patient safety impact of proposed GMP regulations for medical device servicers and remarketers.*

Q. What is ACCE doing?
A. We are sending information to our members and to professional organizations. A formal response to the FDA is being prepared and will be published in *ACCE News*. We have been alerting our members through the News including a summary of the proposed FDA regulation of remarketers and servicers and recommendations for responding to the FDA's request for information.

Q. I see that Mark Bruley has a document that bears upon the subject of your poster presentation, Tom.
A. (Mark Bruley) Jim Keller and I have just complete this document, The ECRI Database Search Results (1977-1988(April)) related to the FDA's Advanced Notice of Proposed Rulemaking (ANPR) titled *"Medical devices refurbishers, rebuilders, reconditioners, servicers, and "as is" remarketers of medical devices reviews and revision of compliance policy guides and regulatory requirements request for comments and information."* This document is being forwarded to the FDA for their consideration. A review of the ECRI Heath Devices Alerts database over a span of 22 1/2 years revealed only 241 citations in which adverse incidents could be attributed to action taken by refurbishers, rebuilders, reconditioners, servicers, and remarketers.

Q. Tom, is ACCE on the same wavelength as ECRI regarding the ANPR issue?
A. Yes. We are both questioning the perceived problem and the response that would be appropriate.

Q. Looking into your crystal ball, realizing that ACCE, ECRI and a host of other organizations have responded to FDA questioning the need for regulation in this area, how do you think FDA will respond?
A. From my discussions with the FDA it appears that comments will be carefully considered. Furthermore it appears that the proposed regulations are not a *fait accompli*. By the close of the comment period, June 28, 1998, the FDA hopes to have comments from all those sectors directly affected by any proposed rule changes.
A. (Mark Bruley) On September 16 and 17 a two-day symposium sponsored by AAMI, ECRI, HIMA (Health Industry Manufacturers Association) and many others will address the ANPR. FDA expects that this forum will be an educational opportunity for them. A working group will

meet on the afternoon of the 18th. I have contacted ACCE regarding their involvement with this Symposium.

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Year 2000

Martina O'Brien

Q (Joe Dyro), What is the problem?
A (Martina O'Brien). The problem is that many computerized medical devices were never designed to handle dates with a four-digit year representation. So, for example, the year 1999 is represented in the code as year 99 and when we switch over to the year 2000 it is going to show a 00. Other systems whether it is an output device for a machine or another machine that that device is talking to is going to get the 00 and do any of a number of different things with it. It may print out a default year when the system was developed like 1985, it might print 1900, we've seen one device that will print out the year 19100. We've had devices that stay in 1999 but give us dates such as December 32, 33 and so forth. Also we see some devices where the date transition causes the machine to shut down all together due to some internal programming.

Q. Have devices been tested for what would happen that could adversely affect patient safety?
A. It is hard to test a machine to determine what happens at year 2000 without damaging the device irreversibly. I do know of a couple machines one will shut down and other will require reset to continue function by powering down and back up. One concern we have is that the machine may continue to function but may contaminate or corrupting trended patient data or calculations that they are required to do which could cause errors in dosages or with information used to base treatment. If and infusion devices begins to infuse at the wrong rate or stops completely this could be catastrophic for the patient. Some computers in nuclear medicine for dose calculation that are non-compliant that will not be functional. Some devices are parts of systems and will cause the entire system to fail.

Q. Now that you have sounded the alert and others have jumped on the bandwagon, what does a hospital do about the problem?
A. Hopefully, hospitals know about it and have formed groups within their institutions to develop effective strategies to deal with the issue. We have a high-level Chief Operating Officer who chairs the Y2K Committee. One reason for this high level representation is that significant expenditures are likely to be required for upgrading and replacing affected systems and someone who can authorize such expenditures needs to be involved. Authority to deal with the clinical staff to develop strategies if all affected devices cannot be replaced. What will we do if some types of equipment is non-functional or if there will be errors? What are the required communication and support logistics? The other dimension for administrators is communicating within their communities with the city government, with the utilities, with all of the other entities including the insurance payers and suppliers upon whom we rely to do business to make sure that they are dealing with the year 2000. It won't do us much good if we have arterial pressure monitors that work but cannot get the tubing and the transducers to allow us to measure. If we can't get surgical supplies or we can't run our sterilizers because we can't get water, gas or electricity. None of these things are assured. We do not know if the telephones in the area will be working. We will have to replace internal systems for all of that. So it does require someone at the executive level We are not going to necessarily be able to replace or fix everything that is not going to work right so priorities will have to be established and adhered to get through this the best we can.

Q. Is addressing and solving the problem being done by hospital's with their own resources? Do organizations exist that would be able to assist a hospital?
A. So far, unfortunately, it's been each entity for itself. The potential exists for cooperation on a community and statewide level. Government entities should be getting involved and coordinating activities. At present, because of a combination of reasons, both getting the information and having clean records of information and clear information Every hospital that is doing something about Y2K sending letters to every manufacturer with whom they do business. So we have the wheel being reinvented thousands of times, we have thousands of hospitals writing the same letters, requesting the same information of the same manufacturers.

Q. That would suggest the need for a national coordinating group. Does such an entity exist?
A. The UK, Canada and Australia is doing it. However, in the United States there is not an effective process in place as yet. FDA talked about having some information on the internet that they receive from manufacturers. There are some logistical problems with any massive data collection making sure of what is stated and what is not. But so far each hospital has to do most of the work itself. It would really help if at the government level they were at the very least coordinating the activities of government agencies and public utilities because that is a huge concern to us at the time of the year 2000 transition. We don't know if we will have telecommunications or any utilities.

Q. I hope that we don't review these proceedings in three years only to say, See, she told us so and we should have done something about it. But you certainly have sounded a clarion call to action. I thank you very much for your contributions in alerting the health care field to this serious problem. I would hope that you would be available to speak to those with questions of Y2K to give them the benefit of the work you have done to date.
A. Fortunately, information on Y2K is becoming more available as more people begin to work on the problem. A lot depends on what happens in the next few months. If this can be kicked up to the level of government mandating actions or coordinating activities among different entities it would save some of the leg work for some of the people at the bottom of the totem pole. That would make a lot of difference.

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Future Shock - Millennium Clock Kills Medical Devices

Martina O'Brien

Is anyone out there worried about and/or looking into the implications of Year 2000 on the operation of medical equipment? I did a small amount of checking around with various manufacturers. The result? - a wide spectrum of responses ranging from one manufacturer whose equipment is all Year 2000 compliant to others who plan to upgrade some but not all devices. Several responses fell somewhere in between. So my friends, non-upgraded medical devices such as ECG machines will simply die when the millennium arrives. This clinical engineer is concerned also about the impending demise of patient data management systems, syringe pumps, and laboratory analytic instrumentation, just to name a few examples.

Verbum sapiens et caveat valetudinarium!

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Biographies of Moderator and Panelists

Ira Tackel, Moderator

Ira is Director of the Department of Biomedical Instrumentation, Jefferson Biomedical Shared Services and the Department of Supply, Processing and Distribution at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania. He Directed the Department of Clinical Engineering at Hospital of the University of Pennsylvania, from 1977 to 1985.

He serves as Adjunct Faculty at Drexel University and Temple University in Philadelphia instructing students in clinical engineering, biomedical instrumentation and hospital administration. He participates in the Drexel Clinical Engineering Internship Program.

He holds a Master of Engineering with a Clinical Engineering Option and a BS in Biomedical Engineering from Rensselaer Polytechnic Institute.

In 1995, Ira received the Becton Dickinson Career Achievement Award from the Association for the Advancement of Medical Instrumentation. In 1993 he was selected by the Philadelphia Business Journal as one of Philadelphia's "40 under 40", a group of business and civic leaders all under the age of forty who have achieved measurable success in a variety of occupations.

Ira was a founding member of the American College of Clinical Engineering and served on the Board of Directors as Member-at-Large and then as Treasurer. He is on the Editorial Board of Health Devices. He is a member of the Philadelphia Area Medical Instrumentation Association (PAMIA), having served as President and Treasurer, and a member of the Institute of Electrical and Electronics Engineers Engineering In Medicine and Biology Society. He was Chairman of the University Hospital Consortium Clinical Engineering Council from 1994 to 1996.

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Tom is Director of Clinical Engineering at the University of Michigan Health System. His first professional position was at Sinai Hospital of Detroit over twenty years ago. There he created a clinical engineering department that grew to a staff of nine and served that 550-bed hospital.

Tom received a BS in Electrical Engineering and Ph.D. in Biomedical Electronics Engineering from the University of Pennsylvania in Philadelphia. At Penn, he excelled in both scholastics and athletics. He was 9 and 0 as pitcher of the champion BME softball team in the engineering graduate school softball league in the summer of 1970. One of his team mates was his best friend, Joe Dyro.

Tom was active in the inception of and a founding member of the American College of Clinical Engineering in 1990. He was on the Board for three years and then served two terms as the ACCE President. He is Chairman of the ACCE Ad Hoc Committee on FDA ANPR.

Tom was recently featured in **Profiles in Clinical Engineering** in the March 1998 issue of *ACCE News*.

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Greg is Director of Engineering Services for National M.D., a wholly owned subsidiary of GE Medical Systems. Prior to National M.D. he formed and directed a shared service biomedical organization and managed in-house clinical engineering groups.

For several years Greg served as Assistant Director of Clinical Engineering at University Hospital, State University of New York, Stony Brook. He then Directed the Clinical Engineering Department at Herman Hospital in Erie, PA.

Greg has served on the ACCE Board of Directors as Member-at-Large and has several committee responsibilities.

Mr. Davis has a BA from Illinois Wesleyan University, a M.S. from the University of Wisconsin - Madison, and an MBA from Gannon University, and is a Certified Clinical Engineer.

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Larry is currently the Vice President and COO of Medical Technology Management, Inc., a Clarkston, Michigan based consulting company specializing in the development and support of Clinical Engineering programs. Prior to joining MTM, Larry was with BJC Health System, most recently as the Director of Clinical Engineering.

Larry hold a bachelors degree in Electrical Engineering from Purdue University and an MBA from Washington University. He is a Certified Clinical Engineer and a Registered Professional Engineer.

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Malcolm Ridgway, Ph.D., CCE

Malcolm is Vice President for Technology Management with the MasterPlan Division of COHR Inc., where he is primarily responsible for the development of the company's asset management program and other value-added services.

He was Assistant Director of the University of Southern California's Biomedical Engineering Institute for two years before winning a grant from the W.K. Kellogg Foundation in 1974 to establish one of the nation's first biomedical engineering shared service programs under the aegis of the Hospital Council of Southern California.

Dr. Ridgway received his Ph.D. degree in Biomedical engineering from the University of Edinburgh in 1962 and remained at the Edinburgh Royal Infirmary as a biomedical engineer until 1966.

He was a founding member o the International Board of Examiners for Clinical Engineering Certification in 1975. He has received two special recognition awards from the American Society for Healthcare Engineering; in 1985 for outstanding contributions to the advancement of clinical engineering, and again in 1989 for outstanding contributions to healthcare engineering.

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ACCE Membership Categories

Individual

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

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

Fellow

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

Candidate

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

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

Associate

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

AMERICAN COLLEGE OF CLINICAL ENGINEERING

MEMBERSHIP APPLICATION FORM

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APPLICATION FEE: US $50 (fifty US dollars); Candidate Fee is $25.

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