A Message from the President

As I am sure everyone is acutely aware, the FDA has just issued regulations regarding Medical Device User Facility Reporting under the Safe Medical Devices Act of 1990. In short, hospitals are now required to report incidents "that reasonably suggest that there is a probability that a medical device has caused or contributed to the death of a patient, or serious injury or serious illness of a patient."

That mouthful of a phrase will be the subject of much discussion over the coming months. ACCE will be part of that broad discussion but, at this point, I want to focus on one particular aspect: What expertise is required to judge the probability that a medical device has been a causal factor in an adverse patient incident?

It is clear to me that a judgement of this type requires (a) a thorough understanding of device design, function and failure modes and (b) a thorough understanding of the physiological consequences of those failure modes. In other words, this judgement requires a clinical engineer. As I see it, this crucial aspect of the Safe Medical Devices Act is not within the professional purview of physicians, nurses, risk managers, or biomedical equipment technicians.

So, one of the messages that ACCE will be taking to the FDA is that clinical engineers are part of the team. We will also offer to help the FDA streamline its reporting program so that it gets high quality data with as little burden on hospitals as possible.

To that end, ACCE has established a task force under the direction of Thomas J. Bauld, Ph.D., Manager of Biomedical Engineering at the University of Michigan Hospital. A notice regarding the task force is included in this edition of ACCE NEWS. The notice asks for input from ACCE members and I urge you to provide it.

As someone who takes great pride in ACCE, I cannot resist pointing out that prior to the establishment of ACCE there was no organization to carry the opinion of clinical engineers to the FDA. Many organizations will have their say, but none speak unequivocally for us.

Matt Baretich
Mission Statement

In the last Newsletter the definition of a clinical engineer was published, along with the proposed Code Of Ethics and news of Board meetings. Unfortunately, the mission statement of the college was left out. The mission statement of the American College of Clinical Engineering is as follows:

1. To assist in the establishment of a standard of competence and to further the excellence of clinical engineering practices.

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.

As we continue with the development of our profession, the Mission Statement Of the College will be our guidance.

Advocacy Committee

Many of our members have asked what is the Advocacy Committee; and what does it do? To answer this question simply will not be possible without reviewing the statement of goals of the committee.

"The Advocacy Committee shall serve as a catalyst for action in support of the professional stature of the clinical engineer.

Through publicity, the committee shall promote clinical engineering in the media, academia, professional societies, and hospital administration.

With vigilance, the committee shall perform watchdog and oversight activities, especially in the media, journals, advertisements, meetings and professional societies.

In defense of exclusivity, the committee shall protect and preserve those elements of the profession that make clinical engineers unique and exclusive. It shall promote security of the niche of clinical engineering and encourage and promote recognition of the clinical engineering profession by law and regulation."

The chairman of the Advocacy committee is Joe Dyro, PhD, and in a recent interview reported on its activities in several areas. The monitoring of help wanted advertisements has shown that many employers have no idea what a clinical engineer is. Dyro gave two separate examples. 1) The advertisement read "Wanted, clinical engineer must have an Associate's Degree and 5 years experience in a hospital". 2) The advertisement read "Service Technician needed, BS required". In both cases the Advocacy Committee contacted the people who placed the advertisements with information on what a clinical engineer is, what our educational requirements are, and asked them to use the proper terms in the future. In another case, the Advocacy Committee worked with a hospital administrator who was in the process of hiring a clinical engineer and did not have a clue as to what the duties of a clinical engineer should be.

In other areas, the Advocacy Committee is opening a dialogue with JCAHO on concerns of clinical engineers with the survey process and trying to input ideas into the development of new standards.

If you discover items that should be brought to the Advocacy Committee's attention, please get them to Joe as rapidly as possible so responses can be made.

"Defending The Turf". This was the title of a Page one story in the October 18, 1991, Wall Street Journal. The article, written by Amal Kumar Naj, outlined the battles between several major suppliers of technology and third party service organizations. While much of the information was previously reported in "Second Source", especially the battle between GE and R-Squared over documentation and access to repair parts, much was new. What should be of major concern to all of us is the differences in prices between the manufacturer and other sources of parts. We, as clinical engineers, must be aware that part of our responsibilities are financial and if we do not check other sources of parts, we are not doing our jobs to the best of our ability. While Picker was portrayed as the villain in the article, most of us have had problems with other vendors. While clinical engineers employed by hospitals were not mentioned in the article there was an underlying word of warning to us in that if the third party service organizations are having problems; can we be far behind? If you run into problems, please let the Advocacy Committee and the Newsletter know. Collectively, the college may be able to assist you in getting the parts or documentation you need to properly perform your job. Remember that you have the final say on future purchases from that vendor, if they do not meet your needs do your best to be sure that they get no more of your business. Also, be sure to put on all purchase orders your need for access to documentation and parts and work with your Finance Department to hold up payment until your needs are met. By law, if the requirements for parts and documentation are on the purchase order when it is accepted by the vendor and they are not met you can hold up payment on that purchase order.
# ACCE Membership Roster

**American College of Clinical Engineering**

**All Members as of 10/1/91**

<table>
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<tr>
<th>No.</th>
<th>Name</th>
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<td>Altshuler Alex</td>
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<td>Bartich Dr. Matthew</td>
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Univ. of Colorado Health Sciences  
Medical College of Wisconsin  
Dybonics, Inc.  
Oakwood Hospital  
Quorum Health Resources, Inc.  
Graduate Health Sys., Philadelphia  
SunHealth, Inc.  
Zabolicki VA Medical Center  
Schumpert Medical Center  
Medical Center of Delaware  
Alaska Area Native Health Service  
SunHealth, Inc.  
Student Member  
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Erlanger Medical Center - Chattanooga  
VA Med Center  
Greater Southeast Comm. Hosp. - Wash., DC  
Sutter Health  
Johnson City Medical Center  
USAF Med. Logistics Office  
Waterbury Hospital  
Oregon University Hospitals  
SpaceLabs, Inc.  
USAF Med. Logistics Office  
USAF Med. Logistics Office  
HCA Wesley Medical Center  
Project HOPE  
University of Minnesota Hospital  
Student Member  
VA Medical Center - Allen Park  
Quest Publishing  
Bridgeport Hospital  
William Beaumont Hospital  
USAF Med. Logistics Office  
Amor. Children’s Hosp, Institute of Pediatrics  
Aspinwall VA Medical Center  
UMDNJ  
Auxilio Mutuo Hospital  
Children’s Hospital  
Karl Storz, Inc.-Lithotripspy Div. - Marietta  
Children’s Hospital Boston  
George Washington Univ. Hospital  
McGuire VA Medical Center  
Healthcare Engineering Consultants, Inc.  
MEDIQ  
Hospital for Sick Children - Toronto  
Independent Consultant  
Criticare Systems, Inc.  
George Washington Univ. Hospital  
Thomas Jefferson University Hospital  
CASMU  
Bronx VA Medical Center  
Fondo Nacional Hospitalario  
Yale University Medical School  
Mississippi Baptist Medical Center  
The Presbyterian Hospital  
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VA Medical Ctr./Engr. Training Ctr.  
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1991 - 1992

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FAX:  (313) 936-8987

Member At Large – Ira Tackel
Thomas Jefferson University Hospital
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FAX:  (215) 955-5867

All of the above members are up for reelection at the annual meeting in 1992. The following two Member At Large terms expire at the annual meeting in 1993.

Member At Large – Gerald Goodman
Texas Children's Hospital
PHONE:  (713) 770-1800
FAX:  (713) 770-1850

Member At Large – Philip Katz, Ph.D.
Graduate Health Systems
PHONE:  (215) 448-1505
FAX:  (215) 448-1580

FDA SMDA 1990
Notice – All Clinical Engineers

The new FDA Proposed Regulations were published in the Federal Register on November 26, 1991, just before the effective date of implementation required by the law. You are strongly encouraged to read the regulations and make your position known to the FDA in writing. There will be a 90 day period for receipt of public comments. Send comments to FDA Documents Management Branch, HFA305, Room 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

We, as professionals involved in equipment management, having the interests of the patient and the health care system in mind, must take responsibility to avoid a major increase in the bureaucracy involved with managing equipment related problems. We should look upon the comment opportunity as a way to indicate our support or concerns for the methods and extent of data reporting and propose reasonable alternatives. We need to avoid the pitfalls that accompanied the electrical safety hysteria. We all should be concerned with the implications of device problems, but not build a major new effort that is out of proportion to the risks.

continued on page 4
A Task Force consisting of Matt Baretich, David Harrington, Yadin David, Joe Dyro, Dave Dickey, Gaillord Gordon, Tom Bauld, and Dave Bell was created by the President to formulate an ACCE response. Your thoughts and comments are vital. Please send them to Tom Bauld, Chairman. His FAX Number is (313) 936-8897. Copy him with any response you or your institution sends to the FDA. We will maintain a file of all ACCE member comments.

The ACCE response will be based on developing a less demanding method than has been proposed in the FDA’s Interim Guidance Document, as well as an approach that will enable an effective data collection and feedback system that will benefit all major elements of the health care system.

We plan to offer our assistance at a meeting after comments are received but prior to the publication of the final regulations. Here, representatives from professional and trade organizations such as ACCE, AAMI, ACCN, AORN, ECRI, AHA, and HIMA would work with FDA staff to implement methods and reporting structures that follow from the legislation and the comments received.

**Comments on the AAMI/ECRI Meeting in Boston**

On November 28, 1991, the User Facility provisions of the Safe Medical Devices Act of 1990 took effect. The SMDA marks the first incursion of the FDA’s regulatory power into hospitals and other user facilities. To help prepare hospitals for these new regulations AAMI, ECRI, and the FDA have sponsored a series of day-long seminars. The first seminar was held in Boston on November 5, 1991. Chet Reynolds of the FDA reviewed the history of FDA involvement in medical devices, citing the 1976 Medical Device Amendment to the original Food, Drug and Cosmetic Act of 1934, the 1984 Medical Device Reporting Regulation, which required manufacturers to report device mishaps, and finally, the 1990 amendment which extended the requirements for reporting to the users of the devices.

Under this law, hospitals are required to report certain incidents that involve a “medical device” to the FDA and/or the manufacturer of the device within ten days of the hospital learning of a device related incident. There are civil and criminal penalties associated with the SMDA which will be activated in the future.

Generally speaking, incidents that must be reported under the new law are those: 1) Where facts reasonably suggest that there is a probability that a medical device caused or contributed to the death, serious illness, or serious injury of a patient; or 2) Where immediate medical or surgical intervention was necessary to preclude serious illness, injury or death to the patient. Reports concerning death are made to the FDA; those concerning injury or illness are made to the manufacturer, or to the FDA if the manufacturer is unknown.

The term “medical device” is broadly defined and may include almost any item used in a patient’s diagnosis, treatment or care other than a drug. Examples include catheters, beds, implants, ventilators, monitors, interconnecting components, and computer hardware and software.

The final regulations for the SMDA had not been completed by the FDA; an “Interim Guidance” document was distributed to the FDA at the Boston meeting. Two other excellent documents were also available at the seminar: “The Safe Medical Devices Act of 1990, Implications For Health Care Personnel” published by AAMI; and “Medical Device Reporting Under the Safe Medical Devices Act: A Guide for Health Care Facilities”, published by ECRI.

The Boston meeting was well attended by administrators, clinical engineers, risk managers, nurses, and physicians. Concern was expressed as to whether the FDA would be able to accomplish anything with the expected flood of data. The FDA is apparently also seeking reports of device failure due exclusively to user error or where the device itself did not fail but the patient was injured due to improper use of the device. There was also much concern over the disclosure of device incident information to the manufacturer, when a civil suit may put the hospital in an adversarial position with the manufacturer.

Regardless of how one feels about the ability of the FDA to manage the process or the details of the Act, the fact remains that the Act is now the law. Hospitals are well advised to develop or adjust their existing incident reporting system so as to provide timely reports, as required by the law. Clinical engineers and risk managers are expected to play central roles in preparation of the required reports; a task which can only be successful with involvement by nurses, physicians, and other hospital personnel.

Keep in mind that the purpose of the Act is to create a safer environment for patients and staff who are involved with the use of medical device. A goal which is consistent with the JCAHO’S theme of “Continuous Quality Improvement.”

Jeffrey Secunda
Children’s Hospital
Boston, MA