ACCE News

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American College of Clinical Engineering

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

Inside ACCE News

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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

In order to protect members' privacy when many of us used home addresses on our application, the membership roster only lists the member's name and their affiliation. The Membership Committee is preparing a new directory that will have the business addresses, phone and fax numbers.

American College of Clinical Engineering
All Members as of 10/1/91

No.	Name	Affiliation
1.	Altshuler Alex	Memorial Sloan Kettering Cancer Center
2.	Al-Fadel Hashem O.	Ring Faisal Specialist Hospital
3.	Alvarado Raul	Ministry of Health
4.	Argentieri Michael	ECRI
5.	Autio Dennis Duane	VA Minneapolis Medical Center
6.	Baretich Dr. Matthew	Univ. Colorado Health Sciences Ctr.
7.	Bauld Dr. Thomas	University of Michigan Hospitals
8.	Benson Daniel	Thomas Jefferson University Hospital
9.	Bell David	Thomas Jefferson University Hospital
10.	Ben-Zvi Dr. Seymour	SUNY - Health Ctr., Brooklyn
11.	Berger Jack	J.B. Thomas Hospital - Peabody
12.	Berkowitz David	ECRI
13.	Berumen Adriana Velazquez	
14.	Betts William	University Medical Center
15.	Blasingame Jon	Sutter Health Biomedical Engineering
16.	Brito Lucio Flavio	Hospital Do Sepaco
17.	Brody Mark	Baystate Medical Center
18.	Bronzino Dr. Joseph D.	Trinity College Biomed Instrumentation
19.	Canino Dr. Vincent	Milwaukee School of Engineering
20.	Carver Michael	USAF Med. Logistics Office
21.	Congdon Richard G.	Mass. Eye & Ear Infirmary
22.	Daken Richard	NYU Medical Center
23.	Dave Rupal	*Student Member*
24.	David Dr. Yadin	Texas Children's Hospital
25.	Davis Greg	Hamot Medical Center
26.	DeMelo Augusto Sergio	Bridgeport Hospital
27.	Dickey David M.	Washington Hospital Center
28.	du Toit Frieda	Grossmont Hospital
29.	du Toit Pieter	Hospital Engr. Consultants
30.	Dyro Dr. Joseph	SUNY at Stony Brook
31.	Eddy Roger	Texas Children's Hospital
32.	Edwards Les	N. Carolina Baptist Hospital-Winston Salem
33.	Eichel Thomas	Texas Children's Hospital
34.	English Mark C.	Hartford Hospital
35.	Fearron Brenton	Hospital for Special Surgery - New York
36.	Fennigkoh Larry	St. Luke's Hospital - Milwaukee
37.	Foster Barry	Mount Carmel Med. Ctr.
38.	Fox Forrest	The Methodist Hospital & Baylor Col. Med.
39.	Friedman Steven	Stanford University Hospital
40.	Furst Dr. Emanuel	University Medical Center
41.	Galanopoulos Kelly	Mt. Sinai Medical Center
42.	Goodman Gerald	Texas Children's Hospital
43.	Gordon Gailord	Kaiser Permanente
44.	Grimes Stephen	GENTECH - Saratoga Springs, NY
45.	Hall Jay	William Beaumont Hospital - Royal Oak
46.	Hammarman Henry	Abington Memorial Hospital - Abington
47.	Happ Joseph	Mount Carmel Health - Columbus
48.	Hare Danny	University Hospital
49.	Harrington David	New England Medical Center - Boston
50.	Haugen Gary	Riverside General Hospital
51.	Hensler Terrance	Medical College of Wisconsin
52.	Hernandez Diogenes	PAHO/WHO
53.	Hernandez Ernesto A.	Social Security Administration (ISSS)
54.	Hertz Ethan	Duke University Medical Center
55.	Hertzler Larry	Barnes Hospital - St. Louis

56.	Hines Edward	University Hospital, SUNY at Stony Brook
57.	Hughes John D.	Washington Hospital Center
58.	Ingebrightsen Jan P.	Univ. of Colorado Health Sciences
59.	Jablonski James	Medical College of Wisconsin
60.	Johnston George	Dybonics, Inc.
61.	Jones Charles S.	Oakwood Hospital
62.	Judd Thomas	Quorum Health Resources, Inc.
63.	Katz Dr. Philip	Graduate Health Sys., Philadelphia
64.	Kemmerer Charles	SunHealth, Inc.
65.	Kotter Gary	Zablocki VA Medical Center
66.	LaFleur Grant	Schumpert Medical Center
67.	Lara-Estrella Luis	
68.	Lipschultz Alan	Medical Center of Delaware
69.	Lodge Denver	Alaska Area Native Health Service
70.	Longo Dr. Salvador E.	Longo & Associates, Consult. Engr.
71.	Lynch Pat	SunHealth, Inc.
72.	Machado Gerson	*Student Member*
73.	Madani Mahmoud A.	King Faisal Specialist Hospital
74.	McAllester Spears	Erlanger Medical Center - Chattanooga
75.	McConnell James A.	VA Med Center
76.	McCullough Charles E.	Greater Southeast Comm. Hosp. -Wash., DC
77.	McCusker David	Sutter Health
78.	Moody Mark	Johnson City Medical Center
79.	Minsent Dennis	USAF Med. Logistics Office
80.	Mirsky Michael B.	St. Luke's Roosevelt Hosp. Ctr. -New York
81.	Montenegro Henry	Waterbury Hospital
82.	Morris Robert	Oregon University Hospitals
83.	Morse Wayne	SpaceLabs, Inc.
84.	Munger Joanne S.	USAF Med. Logistics Office
85.	Natale David	USAF Med. Logistics Office
86.	Neifert Roger	HCA Wesley Medical Center
87.	Nunziata Enrico	Project HOPE
88.	O'Dea Thomaa J.	University of Minnesota Hospital
89.	Ospina Sueacun Ana Maria	*Student Member*
90.	Ostrowgki Dr. Paul	VA Medical Center - Allen Park
91.	Pacela Dr. Allan F.	Quest Publishing
92.	Painter Frank	Bridgeport Hospital
93.	Patail Bryanne	William Beaumont Hospital
94.	Plourde Al	USAF Med. Logistics Office
95.	Ponikwo Witold	Amer. Children's Hosp, Institute of Pediatrics
96.	Prizio Joseph J.	Aspinwall VA Medical Center
97.	Reibman Francine	UMDNJ
98.	Rivera Hector E.	Auxilio Mutuo Hospital
99.	Roeble Thomas P.	Children's Hospital
100.	Rohaly Mike	Karl Storz, Inc.-Lithotripsy Div. - Marietta
101.	Secunda Jeffery	Children's Hospital Boston
102.	Shaffer Dr. Michael	George Washington Univ. Hospital
103.	Simmons Dr. Dave	McGuire VA Medical Center
104.	Slack Gary	Healthcare Engineering Consultants, Inc.
105.	Sloan Elliott	MEDIQ
106.	Smith Dr. John M.	Hospital for Sick Children - Toronto
107.	Stedman Julian	Independent Consultant
108.	Storch John	Criticare Systems, Inc.
109.	Swope Dr. John	George Washington Univ. Hospital
110.	Tackel Ira	Thomas Jefferson University Hospital
111.	Tevia Rick	
112.	Tonarelli Pedro	CASMU
113.	Varnum F. Scott	Bronx VA Medical Center
114.	Villamil Jorge E.	Fondo Nacional Hospitalario
115.	Virgulto James	Yale University Medical School
116.	Wainwright Fred	Mississippi Baptist Medical Center
117.	Wald Dr. Alvin	The Presbyterian Hospital
118.	Wang Dr. Binseng	NIH Clinical Engineering
119.	Wear Dr. Jamea	VA Medical Ctr./Engr. Training Ctr.
120.	Werner Anthony J.	SunHealth, Inc.-Medical Center, Beaver,PA
121.	Wixson Steve	Univ. of Alabama At Birmingham

A.C.C.E. BOARD OF DIRECTORS
1991 - 1992

President – Matthew Baretich, P.E., Ph.D.
Univ of Colorado Health Sciences Center
PHONE: (303) 270-8351
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Vice President – Joseph Dyro, Ph.D.
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Secretary – Wayne Morse
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Treasurer – Larry Fennigkoh, P.E.
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Member At Large – Thomas Bauld, Ph.D.
University of Michigan Hospital
PHONE: (313) 936-5056
FAX: (313) 936-8897

Member At Large – Ira Tackel
Thomas Jefferson University Hospital
PHONE: (215) 955-8655
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

National Engineers Week

All ACCE members are invited to celebrate the accomplishments and focus some special recognition or promotions during National Engineers Week, February 16 - 21, 1992. All members will receive an informational package from the National Engineers Week Committee. This package will contain ideas for interacting with local colleges and schools, as well as materials to use in radio and newspaper ads. Also, think about a reception at your hospital and involve all the engineers at the hospital.

STANDING COMMITTEE CHAIRMEN
1991 - 1992

Advocacy Committee – Joseph Dyro

ICC Representative – Thomas Judd, P.E.
Quorum Health Resources
PHONE: (404) 428-9948
FAX: (404) 428-9783

Membership Committee – Frank Painter
Bridgeport Hospital
PHONE: (203) 384-3037
FAX: (203) 384-3788

Planning Committee – Yadin David, P.E., Ph.D.
Texas Children's Hospital
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Public Affairs Committee – Ira Tackel

Ethics Task Force – David Harrington
New England Medical Center
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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.

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A Task Force consisting of Matt Baretich, David Harrington, Yadin David, Joe Dyro, Dave Dickey, Gailord 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, siting 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 manager 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
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