

ACCE News

Volume 2, Number 3 March – April, 1992

A Message from the President

A major accomplishment from ACCE, since the last edition of ACCE News, was the preparation of a response to the FDA regarding its proposed regulations implementing the Safe Medical Device Act of 1990. The text of that response is included in this edition of ACCE News.

Two aspects of the ACCE response are unique. First, among the many responses that the FDA has received, only ours represents the position of practicing clinical engineers. Our perspective is vital as professionals who respond to medical device failures on a daily basis.

Another unique aspect of our response, at least in comparison with the several other responses I have read, is that we have balanced our questions and criticisms with constructive recommendations and offers of assistance. ACCE has now demonstrated its ability to quickly offer practical, professional expertise in response to critical issues in the healthcare delivery system. Many thanks to Tom Bauld and the SMDA Task Force for their work.

Some other initiatives that are underway:

- ACCE is co-sponsoring (with Texas Children's hospital) a symposium entitled, "First Experience with the Safe Medical Devices Act." The symposium will be conducted by a variety of professionals from hospitals, manufacturers, and the FDA. Its purpose is not only to present information but to promote communication among the participants. This co-sponsorship opportunity was presented by Yadin David, Past-President of ACCE.
- At the request of the ICC Clinical Engineering Board Of Examiners, ACCE is conducting a feasibility study regarding a continuing education requirement for CCE recertification. ACCE Members will soon be receiving a questionnaire to provide direction to this effort. Tom Judd, the ACCE representative to ICC, is leading this effort.
- The ACCE Board of Directors has established a task force for purposes of financial planning and investigation of secretarial services. I will be heading the task force and I welcome comments and volunteers.

I am proud of the accomplishments of our fledgling organization. Thanks to all members for your participation and support.

Matt Baretich

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Inside ACCE News

What's Happening	2
Board of Director's Meeting Report	2
Nominations for Board of Directors	2
Annual Membership Meeting	2
Notes from Around the World	3
ACCE's Reply to the FDA on SMDA	3
Detailed Comments and	
Recommendations to the FDA	4

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ACCE News

What's Happening

The previous issue of ACCE News brought to light that publishing a newsletter with all volunteers is not something that makes for solid deadlines. With the best efforts of all involved we were late in getting some very important news to our members. What we have done is to back up our closing dates and will try to get the newsletters out on a timely basis. Please accept our apologies.

An update on the advanced clinical engineering workshop will be presented at the AAMI conference in June. Work on the next one is already underway with a May/June 1993 time frame in Boston a strong possibility. Many of those who taught in the program and want to ship items to the students should investigate the "M" bag system from the post office. You can send about 30 pounds of books and printed material to most parts of the World for about \$15.00. The only restriction is that the bag cannot contain any non-printed material.

One of our editorial staff, Grant LaFleur, recently returned from a teaching trip to Nicaragua and El Salvador. When you see him ask about the ride in the back of a pickup.

At a recent clinical engineering roundtable, the discussion on simulators for teaching brought out the fact that we need simulators that can generate random conditions, teaching specialists to respond to the unexpected. If you have any suggestions, please pass them on to the newsletter.

If your hospital has a large number of NJH or D of D research contracts you should meet with your internal audit department to make sure the equipment database program you are using meets the current OMB A133 requirements. Many programs do not. If you do not have a corrective plan in place when the Federal Government comes in to audit the research activities it could cost the hospital some research funding. Several hospitals lost multi-million dollar grant renewals because the equipment tracking system did not meet the OMB requirements.

Board of Directors' Meeting Report

The ACCE Board met on November 2, 1991, at the Hilton Disneyworld in Orlando Florida, some of the topics covered were:

- Design of membership certificates and a corporate seal.
- Empowerment of the nominating committee for the upcoming elections.
- Dues renewal letters are being sent out.
- The work on the bulletin board is progressing.
- A new column, to be written by Gerald Goodman, will be appearing from time to time in the newsletter on emerging professional issues.

- The ACCE is working with the ICC on continuing education requirements.
- The Planning Committee reported that there are four specific areas; 1) peer affiliation, 2) continuing education and training, 3) liaison with other groups and 4) accreditation.

In other actions, the Board received a report by Ake Oberg of ICFMBE who reported that at their April meeting they will review the progress of ACCE and will be investigating starting a similar organization in Europe.

The Board, on advice from the Membership Committee, voted to confirm membership to Marvin Shepard, David McCanna, Thomas Romeyn, Ebin Kermit, Alan Levenson, Alfred Jakniunas, joining them is student member Eric Backensto.

Nominations for the Board of Directors

By the end of May, elections will be held for five positions on the ACCE Board of Directors:

Vice-President (President Elect) – The Vice-President will serve a one-year term then move to President for a one-year term.

Secretary – The Secretary serves a one-year term and can be re-elected once to that position. Wayne Morse has served two terms as Secretary and cannot be re-elected to the position.

Treasurer – The Treasurer serves a one-year term and can be re-elected once to that position. Larry Fennigkoh has served two terms as Treasurer and cannot be re-elected to the position.

2 Members-At-Large – Each Member-At-Large serves a two-year term and can be re-elected once to that position. Tom Bauld and Ira Tackel have served one term as Members-At-Large and can be re-elected to these positions.

Positions which are not up for election are the following:

- Matt Baretich will move from President to Past President.
- Joe Dryo will move from Vice-President (President Elect) to President.
- Gerald Goodman and Phil Katz will serve the second year of their two year terms as Member-At-Large.

This year's Nominating Committee consists of Matt Baretich (Phone: 303-270-8351), Yadin David (Phone: 713-770-1800), and Joe Dryo (Phone: 516-144-1420). Please call any member of the Nominating Committee by April 24, 1992, to nominate candidates for the open positions. A mail ballot will be distributed in May.

Annual Membership Meeting

The ACCE Annual membership Meeting will be held on June 2, 1992, in conjunction with the AAMI Annual meeting in Anaheim, California. AAMI has generously allowed ACCE to use one of its meeting rooms in the Anaheim Marriott Hotel. Our Meeting will be held from 7:30 P.M. to 9 P.M. in the Grand Ballroom.

A report in the Clinical Engineering update of the IFMBE Newsletter recounted problems with medical devices when mobile phones were used. The Newsletter is not aware of any similar problems here in the United States.

Look for changes in the IEC 601 Standards on lasers and shortwave therapy devices. If you are purchasing lasers or therapy systems made outside the United States you should review the new standards to assure that the devices will meet our standards.

The Institute of Engineers in Australia is planning to establish a College of Biomedical Engineering.

Also from Australia is an inquiry about setting up an engineer swap where clinical engineers would swap positions for a period of time, up to one year. If anyone is interested in participating, please contact the newsletter.

ACCE's Reply to the FDA on SMDA

The following is a letter written to the FDA, dated February 20, 1992 from ACCE President Matthew Baretich, P.E., Ph.D. commenting on the Safe Medical Devices Act of 1990. Following the letter are detailed comments and recommendations

The American College of Clinical Engineering is a professional organization of clinical (and biomedical) engineers working in the healthcare delivery system. Our constitution states that we seek to "promote the safe and effective application of science and technology to patient care." Therefore, we welcome this opportunity to work with the Food and Drug Administration to insure cost effective implementation of the Act.

In this document, we focus on the requirement that "device user facilities" 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 to a patient."

The text cited above calls upon healthcare institutions to make judgments about the causal relationships between medical device faults and adverse patient incidents. ACCE believes that this judgment requires thorough knowledge of (a) the design and function of medical devices, (b) the potential failure modes of medical devices, and (c) the physiological effects of these failures. Among healthcare professionals, clinical engineers are unique in having this combination of knowledge. Indeed, hospitals with fully qualified clinical engineers on staff depend heavily on them for investigation of device related incidents. Therefore, ACCE believes that the participation of clinical engineers is vital to the gathering of high quality information with respect to this Act.

As detailed below, ACCE is concerned that:

- The costs of reporting, storing records, and follow-up discussions with FDA and manufacturers will be excessive;
- The regulations extend beyond the language and intent of the legislation;
- The reporting form is too complex and calls for conclusions that many institutions will be unable to provide;
- The definitions of several key terms lack clarity;
- The risk of liability to institutions and their staff will increase, especially with respect to reporting of "user error";
- The quality of the information submitted will be inconsistent;
- The codes associated with the form are overly detailed and difficult to use;
- The location and identification of disposable devices will be difficult or impossible in many cases; and
- The constructive relationships between users and manufacturers are likely to deteriorate.

We present our concerns and recommendations in the following pages as constructive criticism from an organization which shares the Food and Drug Administration's objectives regarding the safety and effectiveness of medical technology. To achieve our common objectives, the American College of Clinical Engineering offers its practical expertise in hospital based technology management. We are prepared to help design and test a program that will allow healthcare delivery institutions to economically produce high quality data for use by FDA in meeting the objectives of the Safe Medical Devices Act of 1990.

Detailed Comments and Recommendations

Our understanding of the purpose of medical device problem reporting activity is taken from the language in the Act and its associated regulations:

- Congress intended "FDA ... to protect the public from potentially hazardous devices, as well as from devices with confirmed hazards."
- The Act addresses the perception that relatively few significant device problems were received by FDA through the existing manufacturers' medical device reporting (MDR) process.
- FDA wishes to "protect the public health by helping to insure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use."

ACCE affirms its support of the purposes of the Safe Medical Device Act of 1990 and understands that there have been difficulties in acquiring valid information about the degree and extent of device malfunctions or misapplications of devices. However, it is our judgment that portions of the regulations developed by FDA to implement the legislation will not achieve the desired results. Our reasons and suggested recommendations are as follow.

1. Cost of reporting: The extent of work required by users in reporting as proposed is prohibitive and expensive, particularly with respect to the following activities:

- a. Data collection and investigation of many more incidents. Additional screening and analysis for FDA submissions and additional internal processes to track submissions, FDA and manufacturer follow-up inquiries, revisions, and six month reports.

Recommendation: Limit reportable events to those significant ones by a clearer definition of devices, events, and injuries.

- b. Typing and photocopying of reporting forms.

Recommendations: Develop electronic means to report device problems; distribute computer-readable versions of the final form in standard word processing formats or in ASCII format.

- c. Creation of additional files for all non-reported as well as reported events

Recommendation: Delete the requirement to maintain files of non-reported incidents.

2. Extension beyond SMDA intent: In many aspects of the proposed regulations (inclusion of the employees as well as patients, requesting access to patient medical records, developing a file system for all events investigated but not reported, and requiring exceptional details on the form, etc.) FDA has exceeded the intent of the Act.

Recommendation: Revise and simplify the process and conform more closely to the Act.

3. Complex Form: The extremely detailed data elements involving device failure analysis, conclusions about user error, and the likely impact of device failure are too complex and go beyond what is needed to identify devices with problems.

Recommendation: We propose a two level form with minimal pertinent information provided by the small general facility and a more detailed form for those institutions that have access to either in-house or consulting clinical or biomedical engineers.

4. Definitions: There is little practical guidance given as to how to distinguish reportable events from non-reportable events. The definitions provided are vague and open to a variety of interpretations. There will be no consistency throughout the healthcare industry as to what events are reportable.

Recommendation: Clarify the language for "device", "serious illness", and "serious injury". Provide representative examples of the types of events that are serious illnesses or injuries.

5. Increased risk of liability: We are concerned that personnel in device user facilities will experience increased liability exposure. We also believe that even the perception of increased liability exposure will interfere with existing quality improvement efforts that have proven themselves to be highly effective.

- a. Reporting instances of user error is believed to be an unacceptable risk to many institutions. It will increase the institution's exposure to lawsuits because of greater availability of information to plaintiff's attorneys. There will be access to information in reports to manufacturers via the Freedom of Information Act once a manufacturer reports to FDA.

Primary recommendation: Provide total confidentiality and protection of the reporting entity and all its personnel from any legal proceedings involving any device for which a valid, truthful, report has been submitted. Include coverage for all preliminary reports and follow-up documents or conversations.

Alternative recommendation: As an alternative, provide anonymous reporting of user error through a third party.

- b. In many cases, determining with certainty that user error was the cause is not possible because of an intermittent problem in a device, a set of conditions of use that cannot be recreated, the influence of disposable components that cannot be retrieved, or the interaction of the signals from the patient with the device that are not able to be duplicated.

Recommendation: Since the proposed regulations request conclusions that may not be supportable, we suggest that reporting be required only in instances where it is evident that poor labeling or device design directly caused the user error.

- c. When user error has occurred, it is the type of event that is used in internal quality assurance processes to improve staff training and performance. Typically, reports of adverse events are made on an "incident form" that is a confidential document, protected from disclosure because of its use in improving the quality and safety of the patient care environment. We are concerned that users will not report incidents involving user error within their facilities for fear of liability.

Recommendation: To encourage reporting of user errors, provide total confidentiality and protection of the reporting entity and all its personnel from any legal proceedings involving any device for which a valid, truthful, report has been submitted. Include coverage for all preliminary reports and follow-up documents or conversations. Confidentiality and protection from use in legal proceedings should only be assured if the institution has used the incident in its internal quality improvement process.

- d. Failure to follow manufacturer's recommendations for service intervals or procedures, despite professional engineering judgment to the contrary, may be used as a point of contention should litigation develop. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has recognized that specific situations may appropriately lead to modification of manufacturer's recommendations.

Recommendation: Delete the request for such information from the report form.

6. Quality of information: There is no assurance of the quality of the information provided for a reportable event. Such assurance could be established if qualified individuals were responsible for completion of the forms. In many hospitals, there will be clinical or biomedical engineers who can make assessments of device failures because they understand the device operations, and can determine failures and their relationship to the device's interface with the patient. However, in many more hospitals, there will be a lack of a qualified expert in medical devices.

Recommendation: We propose a two level form with minimal pertinent information provided by the small general facility and a more detailed form for those institutions that have access to either in-house or consulting clinical or biomedical engineers.

7. Reporting codes: The codes associated with the form are overly detailed and difficult to use.
 - a. They are scattered throughout the "Interim Guidance" document; some are in the main text and others appear in long lists at the end.
 - b. They are duplicative to some degree.
 - c. There is a lack of patient injury codes.
 - d. Although manufacturers may need such information as they investigate the specifics of device failures, user facilities do not need to investigate in great depth in order to identify a problem for FDA to respond to and to carry out the intent of the legislation.

Recommendation: Since many ACCE members have designed and implemented computerized management systems to track device services, investigations, and failures, we recommend the development of a joint task force of FDA and ACCE representatives and others to revise the form and the codes.

8. Disposable devices: Disposable devices contribute greatly to the operating expense of medical equipment and are often involved in an incident. There are large numbers of items in use and in the delivery stream, and there is extreme difficulty in acquiring the packaging materials identifying lot numbers once a device is placed in use.

Recommendation: Develop ways to uniquely identify defective disposables by inspection of the device itself.

9. Relationships between users and manufacturers: Because of inherent self-interest, institutions and manufacturers will be even more inclined than now to blame each other for specific incidents. Each party will attempt to minimize their liability exposure instead of working cooperatively to understand a problem and see that it is resolved.

Recommendation: Eliminate the data fields on the reporting form which call for conclusions or judgments; require submission of only facts.

Alternative Approaches for Medical Device Problem Reporting

There are several alternative approaches to the process of medical device problem reporting that ACCE proposes for consideration:

1. Use a statistical sample of institutions rather than universal reporting.

Comment: This would permit a lower cost process to be tested for validity and effectiveness of uncovering prior problems and it would reduce over-reporting of the same problem.

2. Pilot test whatever program is developed to determine its effectiveness and to evaluate problems and improvements to the process before widespread implementation.

Comment: This would reduce costs and promote greater confidence in the final program.

3. Require each healthcare organization to prepare and submit a plan for FDA or third party (e.g., JCAHO) approval that addresses an integrated "Total Quality Management" approach to managing device incidents. Provide some guidance as to time frames when actions need to be taken and a broad outline of what the policy should include. Assess fines if the documents are not received by a certain date.

Comment: This forces each institution to devote the effort to develop a coordinated plan with a degree of consistency across the nation.

4. Provide the resources to develop a training program for FDA staff in medical device incident reporting and investigation.

Comment: This would provide a consistent training program for all FDA staff persons charged with incident investigations and enforcement practices.

5. Provide funding for ACCE or another entity to develop a plan to evaluate the cost-effectiveness of the FDA's medical device problem reporting system.

Comment: This would set up a non-biased review of FDA implementation of the ACT.

6. FDA could consider using an external agent or professional organization to collect and summarize information from users.

Comment: Based on the expected quantity of information to be submitted and the lack of an electronic means for submission, coupled with the shortage of FDA personnel, computer software, and other resources, it may be most effective to introduce a qualified third-party to receive the initial reports and to forward "non-identified user" information to FDA.

Questions for FDA Response

There are several questions that ACCE believes FDA should address:

1. What feedback does FDA intend to offer to the users and manufacturers that will provide useful information and demonstrate the validity of this effort? How will that feedback be communicated?
2. How will FDA identify patterns of individually-minor but collectively significant dangers as determined from repetitive reports from many institutions?
3. How will FDA determine the quality of the reports it receives?
4. How will FDA involve the medical and other healthcare-related organizations to enhance and improve the process of medical device reporting?
5. How can FDA structure its relationship with the US medical device manufacturers in order to both improve the safety and effectiveness of devices as well as the competitive position of our manufacturers in the world market place? What negative consequences will these regulations have on our international trade balance?
6. How can we justify the increased cost of these regulations in an era of already high costs of healthcare? Where is the analysis that predicts a net reduction in the cost or improvement in the quality of care if reporting is accomplished? Can FDA provide a summary of the calculations used to determine the implementation and annual operating costs?
7. Does FDA intend to send field inspectors to healthcare institutions to investigate specific events involving medical device incidents or will FDA concern itself with documents reviews to identify real and immediate dangers to patients? What are the priorities and how will resources be distributed?