INTERFACE

SOCIETY FOR TECHNOLOGY IN ANESTHESIA

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Standards: Are You Confused?

Equipment standards are intended to eliminate confusion about how medical devices must be designed and should function. The topic of standards, however, is extremely confusing. The large number of organizations involved with standards activities pertaining to anesthesia makes it difficult to determine their identity, let alone an understanding of their activities. This issue of Interface provides an introduction to the most active standards activities. Commentary is also included regarding the impact of standards activities upon clinical practice.

There are several aspects of the standards process that deserve emphasis. First, the majority of standards that pertain to anesthesia, and medical equipment in general, are not mandatory standards. That is, there are few legal guidelines to enforce compliance with standards. Compliance with standards is on a voluntary basis which works well because of the quality of the organizations involved.

Organizations involved with standards generally fall into two categories, those that actually write standards and those that oversee and coordinate the standards writing process. For example, the American National Standards Institute (ANSI) is not involved with writing standards. The ANSI mission is to oversee and coordinate American standards activities as well as serve as a contact for international standards organizations. ANSI maintains an accreditation process for domestic organizations involved with writing standards. Organizations that receive ANSI accreditation have proven that

see "Standards & Confusion" on page 33

Standards Development for Anesthesia Equipment: OVERVIEW

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In no specialty practice of medicine is the relationship between a physician and his equipment closer than in Anesthesia. Successful navigation of an anesthetic experience always depends upon the skills and knowledge of the anesthetist, and the inherent safety and performance of his apparatus. Standards activities are the process by which the essential safety and performance of our equipment is defined for the benefit of practitioners, manufacturers, and most importantly, patients.

Standards are intended to insure essential safety and performance of anesthetic equipment. Most standards are developed by a voluntary consensus method following a defined set of due-process rules. An accredited standards writing organization initiates the development of standards which are then published and finally accepted and implemented by the manufacturers and users of the equipment. The end result is a Voluntary Standard, different from a Mandatory Standard, in that the authority is based on voluntary acceptance, rather than enforced by law. Despite the absence of legal coercion, compliance with well conceived voluntary standards is universal. In short, the method works!

Standards activities applicable to anesthesia began in 1956 when the American Society of Anesthesiologists agreed to sponsor the formation of Committee Z-79 of the American Standards Association (now American National Standards Institute or ANSI). Over the last 35 years, the amount of standards activities have grown, so that today a multitude of organizations develop and publish standards of interest to the anesthesia community nationally and internationally.

Nationally, ANSI Z-79 was dissolved in 1983 and its activities were transferred to the American Society for Testing and Materials (ASTM) Committee F-29 on Anesthesia and Respiratory Care, which has revised the old ANSI standards, and produced many of its own. In addition to ASTM, several national organizations are active in the development of voluntary consensus standards of interest to anesthesiologists: the Association for the Advancement of Medical Instrumentation (AAMI), the National Fire Protection Association (NFPA), the Compressed Gas Association (CGA), the Health Industry Manufacturers Association (HIMA), and ANSI. Prac-

see "Overview" page 34

INSIDE THIS ISSUE:

STANDARDS ACTIVITIES EXPLAINED!

Human Engineering
Alarm Sounds
The Medical Information Bus
The Role of the FDA
ECRI activities

- Neural Network Research
- Index to Volumes 1 and 2

Focus On Research

Neural Networks

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Artificial neural network research has become an important part of the activities of the Bioengineering Division, Department of Anesthesiology, University of Utah. In 1985, we began to design an anesthesia workstation with support from the Anesthesia Patient Safety Foundation (APSF). Our first prototype workstation had a rule-based intelligent alarm system.[1] We encountered a difficult problem as we began to expand the rule-based intelligent alarm system to handle a wide range of patient conditions, patient sizes and different modes of ventilation. Our "expert" needed to write rules with widely varying thresholds and multiple combinations of monitored variables.

Help came from Brigham Young University. After finishing a M.S. degree in our lab, Joseph Orr went to BYU where he took an engineering graduate course on neural networks. Being aware of the challenges facing our anesthesia workstation group and seeing the potential of neural networks, he returned with a new approach. Neural networks provided a mechanism, through backward error propagation, whereby "rules" could be generated automatically. Neural networks learn to recognize alarm events through training, by "seeing" examples. The capability of a neural network alarm system can expand as the number of incidents it is trained to recognize increases. As new sensors are added or as the operating range expands, additional training data is added to the original data. Training a neural network may require several hours to develop a new set of optimum rules (network weighing values) for its learning algorithm. Because training can be conducted by a technician rather than an expert, the new rules are not influenced by the bias of an individual expert.

Limitations

The neural network approach is limited by the completeness of the training set. It cannot be expected to identify faults which are not included in the training. A second disadvantage is that a network cannot explain why a conclusion was reached while an expert system has a definite set of rules that can justify a conclusion.

Our prototype neural network based alarm system identified critical breathing circuit events with 95% accuracy and reduced the time to diagnose and repair breathing system faults by 43 seconds.[2,3] Working under contract with Ohmeda, we plan to integrate intelligent neural network based breathing circuit alarms in the Ohmeda Modulus CD Anesthesia System.

References:

1. Loeb RG et. al., Anesthesiology 1989;70:999.
2. Orr JA et. al., Anesthesiology (Suppl) 1990;73:A445.
3. Orr JA et. al., Anesthesiology (Suppl) 1990;73:A447. ◆

■ *"We encountered a difficult problem as we began to expand the rule-based intelligent alarm system to handle a wide range of patient conditions..."*

INTERFACE is the official newsletter of the Society for Technology in Anesthesia. The newsletter is published quarterly and mailed directly to the membership of the society. Copies are also distributed to companion societies in Europe and Japan. The editor invites suggestions, contributions and commentary about published items. Please send all correspondence to:

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Perspectives on Technology

TOPIC: Standards

■ *"...the development of the best standards is impossible without participation of clinicians..."*

The Industrial Perspective

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Manufacturers of medical equipment are constantly being challenged by the fast pace of technological advancement. New technologies are effectively creating better and safer methods for diagnosing and treating patients. Regretfully, this fast pace of technological advancement has the potential for misunderstanding, misuse, misapplication, and/or accidents. Fortunately, both clinicians and manufacturers have a "silent partner" in their cooperative efforts of trying to reduce the risk of bringing new devices safely into clinical practice. The "silent partner" helping to protect patients, manufacturers, and clinicians consists of the many available equipment/device standards.

Standards are Important to Industry

Equipment/device standards are extremely valuable to manufacturers. Using well written standards, manufacturers can determine and demonstrate positively the "Minimum Performance and Safety Requirements" for a specific device, while at the same time providing sufficient leeway for continually advancing technologies.

Standards with their minimum requirements, also serve to protect the physicians, since these standards provide harmonized requirements for the devices regardless of who manufactures them. Responsible manufacturers of medical equipment participate actively in the development of these equipment/device standards in order to utilize the available technology as well as further the goal of increasing the safety and performance of the wide variety of products. These manufacturers understand that continuous participation in producing standards increases the acceptance of their products.

Almost all medical equipment manufacturers have encountered those users who will not purchase equipment which does not meet at least the specified standards requirements. In fact, it is now becoming increasingly frequent that medical products before being used in certain cities or foreign countries, or sold to some state or federal government agencies, must demonstrate compliance to the specified standards by an approved testing organization.

Manufacturers who are serious about their participation in the development of standards are consistently supporting the various standards organizations through various forms of funding and membership dues, as well as allocating their experts and time. These

see next page

■ *"Should a patient injury be related to the use of that equipment [not meeting standards], the potential for defense in a malpractice action is undercut."*

The Clinical Perspective

Debra R. Milamed, M.S., Associate in Anesthesia
John Hedley-Whyte, M.D.
David S. Sheridan, Professor of Anaesthesia and Respiratory Theory,
Harvard University, Boston, MA

Clinicians use medical technology on a daily basis with little or no knowledge of the many standards activities governing medical equipment. These standards activities are quite diverse and the details are, in general, of little concern to the clinician. Nonetheless, standards do guide the design of this equipment and therefore will influence patient care. Furthermore, standards can have important medicolegal implications.

The Impact of Equipment and Practice Standards on Clinicians

A sensible clinician will not use equipment that fails to meet standards requirements without compelling reasons that are well documented. Should a patient injury be related to the use of that equipment, the potential for defense in a malpractice action is undercut. The standards written by the American Society for Testing and Materials (ASTM) Committee F-29 on Anesthetic and Respiratory Equipment and the International Standards Organization (ISO) Technical Committee 121 on Anesthetic and Respiratory Equipment are prospective, that is, the standards apply to equipment manufactured after the standards are accepted. Nonetheless, plaintiffs' attorneys can, and do, persuade juries that equipment should be retrofitted to comply with current standards. Practice and monitoring standards advocated by the American Society of Anesthesiologists (1,2) are based on the use of equipment meeting the standards of American National Standards Institute (ANSI) Committee Z-79 and its successor ASTM Committee F-29.

Performance versus Design Standards

ASTM Committee F-29 attempts to write performance rather than design standards. Performance standards should better specify how the device will function in the clinical environment. Despite these efforts, ventilators, anesthesia machines, and respiratory gas humidifiers are among the ten devices most frequently reported to the FDA in recent years as malfunctioning by the U.S. General Accounting Office.(3)

Design standards are appropriate for equipment interfaces where the needs for interchangeability of parts and prevention of hazardous misconnections must be addressed. The lesson of the 1988 airplane

see next page

The Industrial Perspective

continued from page 27

manufacturers justify this work on standards based upon the conviction that compliance to standards enhances the safety, performance, and quality of their products.

Clinician Involvement a Concern

Regretfully, the funding of the participating physicians is an ongoing issue of great concern. Many of these highly motivated and dedicated clinicians are being forced to support their standards activities from their own personal incomes.

In the past, organizations - such as the ASA - and research departments of universities, had contributed professionals and funds to cover the expenses incurred by physicians involved in the development of standards. However, it now seems that this is a very rare situation. Understandably, participation by some of the best minds in the various clinical fields has been declining. This decline has become a serious concern to standards writing organizations, manufacturers, and clinicians as the development of the best standards is impossible without participation of clinicians who are the highly specialized individuals understanding the applications and use of the technologies.

Since the ability of manufacturers and the standards writing organizations to subsidize clinicians might be construed as a conflict of interest, the responsibility of supporting clinicians must be assumed by the hospitals and universities that employ these dedicated physicians.

Our position is that universities and hospitals have an obligation to share the self-imposed responsibilities of equipment manufacturers with regards to standards development, and assume a fair share of the costs associated with the development of standards.

The work in writing standards shall be considered not a burden, but rather, a duty to our communities and our nation for the betterment of humanity. ◆

Standards: The Clinical Perspective

continued from page 27

disaster at Ramstein, Germany, when emergency medical crews discovered that German hypodermic syringes were incompatible with American Luer-connectors, emphasizes this point.(4)

Harmonization of Alarms

Standards are designed to address clinical problems, which is why clinicians are an integral part of standards activities. This has been most apparent in the efforts of the ISO's Technical Committee 121 on Anesthetic and Respiratory Equipment, Subcommittee 3, to produce an international standard for alarm systems in the operating room and intensive care units. Here the success of any system of visual or auditory alarm signals for patient monitoring devices depends on being maximally informative and minimally disturbing to operating room personnel.(5) ISO has just published a Draft International Standard for Visual Alarm Signals(6) and Subcommittee 3 of TC 121 has recently approved a First Working Draft of a standard for auditory alarm signals.(7) These standards may improve the effectiveness of alarms and also reduce training costs.(8)

Role of the FDA

The FDA publishes its medical device problem reports and related literature on magnetic tape and in print, and lists recent publications in its monthly Medical Devices Bulletin. This information is available to manufactures as well as clinicians. The Safe Medical Devices Act of 1990 (SMDA) requires that facilities report instances where medical devices have caused or contributed to patient injury or death to the manufacturer, if known, or to the Secretary of Health and Human Services. As of November 28, 1991 such reporting will be mandatory, and the FDA will be authorized to impose civil penalties for noncompliance. Forthcoming regulations will detail the reporting responsibilities of physicians and other medical personnel.(9)

The SMDA saddles health care facilities with still more reporting requirements but carries the potential for enhanced user input to manufacturers of medical devices. It may also give plaintiffs' attorneys increased opportunities to prove malpractice when unwary clinicians utilize equipment that fails to meet standards requirements.

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1. American Society of Anesthesiologists: Standards for basic intraoperative monitoring effective January 1, 1991. Directory of Members 56:670, 1991.
2. American Society of Anesthesiologists: Standards for postanesthesia care to become effective no later than January 1, 1992. Directory of Members 56:672, 1991.
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6. International Organization for Standardization: ISO/DIS 9703, Part I, Anaesthesia and Respiratory Care Equipment — Visual Alarm Signals. ISO, Geneva, 1991.
7. International Organization for Standardization. ISO/CD9703, Alarms for Anaesthesia and Respiratory Care Equipment, Part II, Auditory Alarm Signals, First Working Draft, ISO Technical Committee 121 on Anaesthetic and Respiratory Equipment, Subcommittee 3, 1991.
8. Hedley-Whyte, J.: Anesthesia vapor monitoring: questions to be answered. In Continuous Anesthesia Gas Monitoring, ASTM STP 1090, J. Hedley-Whyte and P.W. Thompson, eds., pp. 3-6. Philadelphia: ASTM, 1990.
9. FDA holds meeting on user reporting requirements of Safe Medical Devices Act. Medical Devices Bulletin (Center for Devices and Radiological Health, Rockville, MD) 9(5):1-2, 1991. ◆

The Medical Information Bus

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The Medical Information Bus (MIB) is a proposed international standard for bi-directional connection and communication between medical devices and computing resources within a medical institution. The MIB is not an electronic data "bus" in the traditional sense, but rather a specialized local area network that has been optimized for use in the medical setting. In essence, the MIB provides a logical association between a patient and those medical devices connected to, monitoring, or otherwise generating data related to that patient. The MIB committee consists of representatives from medical device manufacturers, clinical computer systems vendors, biomedical engineers and clinicians. Their work is sponsored by the IEEE Engineering in Medicine and Biology Society and officially referred to as proposed standard P1073.

Objectives

The initial objectives of the MIB committee have evolved into a set of requirements for the MIB. These requirements are: 1) to enable all medical devices to interface with host computers in a standard fashion independent of the vendor, 2) to be appropriate for the acute patient care setting, 3) to be highly reliable, both in terms of transmission accuracy and data delivery, as well as network availability and survivability, 4) to accommodate frequent changes in type and location of equipment, 5) to provide a simple, non-technical user interface and 6) to be cost effective.

Implementation

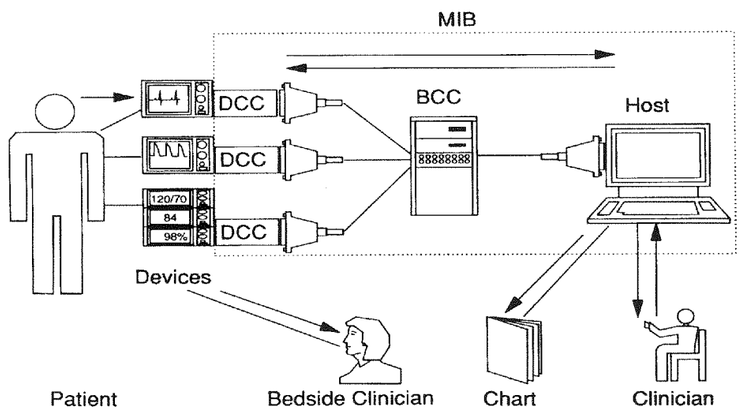
Conceptually, the MIB can be thought of as an information pipeline that connects a medical device and a host computer. Several logical units have been defined to support the communication process. (See Figure) Individual devices communicate with the network via their device communication controller (DCC). Multiple DCCs are connected to a bedside communication controller (BCC) in a star topology. In this bedside sub-network, BCCs provide power, timing and data communication signals to each DCC using a unique MIB-defined connector and cable. One or more BCCs attach to the host system as a multi-drop network. Each BCC is associated with one and only one patient although a patient may have more than one BCC. All communication between devices and hosts uses a standard language called the Medical Device Data Language (MDDL). In a typical arrangement, a bedside BCC manages communication from individual DCCs and movement of data to and from a host computer. Individual medical devices will have integrated DCCs and may be connected and disconnected from the BCC as the patient's needs change.

The MIB subdivides communication functions into logically separate modules. Pre-existing International Standards Organization (ISO) data communication and networking standards have been utilized as much as possible. New standards have been proposed only as dictated by the needs of new concepts. ISO 7498 (OSI Reference Model) calls for the separation of connection, communication and dialog control into layers: physical, data link, network, transport, session, presentation, and application. This approach ensures that changes can be made in the future to a given layer, eg. Physical, without invalidating the rest of the standard.

A Family of Standards

The MIB proposed standard actually encompasses a family of standards: 1073.1 which specifies the overall MIB architecture and the communication language MDDL, 1073.2 which specifies the bedside communications sub-network and 1073.3 which defines how multiple hosts can manage information about a given patient. To guarantee vendor independence, the MIB specifies all aspects of device intercommunication - from the physical connectors and voltage levels to the application language (MDDL). The combination of the necessity for high reliability, flexible topologies, ability for dynamic reconfiguration of components of the network and a unique application interface eliminated the possibility of using existing data networks.

The draft of the proposed P1073.2 standard has been written and approved by the MIB committee. The standard was submitted to the IEEE Standards Board and was approved on the first ballot. Several editorial changes need to be made to P1073.2 although release is expected soon. P1073.1 is being rewritten to reflect a major upgrade of the MDDL and will likely be completed six to nine months after P1073.2. Devices equipped with DCC's, or DCC's for retrofitting existing devices, should begin to appear in about eighteen months. The final document that the committee will complete is P1073.3. Since the multi-host capabilities P1073.3 provides are not needed to establish basic device and host communications, its completion has been deferred pending the approval of P1073.1 and P1073.2. ◆



Block Diagram of MIB Implementation

FDA and Medical Device Standards

Fifteen years ago the 94th U.S. Congress amended the 1938 Food, Drug and Cosmetic Act giving the Food and Drug Administration (FDA) additional authority to regulate medical equipment. A key provision of these "Medical Device Amendments of 1976" called for the FDA to develop and issue regulatory performance and safety standards for certain categories of medical devices. In the course of determining which medical devices would be included, it became apparent that the FDA was faced with an enormous task. More than 1000 medical devices were identified as requiring a regulatory performance and safety standard.

Resources Needed to Implement Standards

The FDA estimated that it would take a staff of 500 professionals more than a decade to develop all of the regulatory standards needed to fully implement the new law. In addition, a permanent staff of 200 professionals would be needed just to carry out the ongoing maintenance task of reviewing and revising these regulatory standards every 5 years. The hiring of an additional 500 professionals just for the regulatory standards program would have nearly doubled the FDA's medical device program staff. The funds for such an increase in staffing were never made available.

101st Congress to the Rescue

In the course of crafting "The Safe Medical Devices Act of 1990" the 101st U.S. Congress provided the FDA with the relief it requested. This latest amendment to the 1938 Food, Drug and Cosmetic Act, enacted this past November, removed the requirement that FDA issue regulatory standards for every device formerly classified into the standards category. Regulatory standards are now only one of several options which the FDA may employ to regulate medical devices in this category.

Current Regulatory Standards Activities

The FDA has yet to issue its first regulatory medical device standard. Efforts to develop a regulatory standard for apnea monitors were initiated several years ago and are nearing completion. At this time more than 10 man-years of professional staff time have been invested in this single standards writing project. It is expected that an additional 2 man-years of staff time will be expended before this standard is finally issued.

Voluntary Consensus Standards

The FDA has been active in national and international voluntary consensus standards development efforts starting even before passage of the 1976 medical device amendments. After 1976 the level of FDA participation increased substantially and has increased further in recent years. More than 140 FDA professionals are currently participating in 29 different standards writing organizations involved in developing or revising some 300 individual medical device standards.

Participation in the development of voluntary consensus standards is a cost effective alternative to regulatory standards. FDA believes that most U.S. voluntary consensus standards for medical devices do adequately address the more important performance and safety issues and U.S. manufacturers do, for the most part, comply with these standards. In such cases it is FDA policy to defer development of a corresponding regulatory standard.

The information for this article was provided by Peter Carstencen, US Food and Drug Administration. For more information on FDA's medical device standards program he can be contacted at U.S. Food and Drug Administration, Center for Devices and Radiological Health, Mail Stop HFZ-220, 5600 Fishers Lane, Rockville, MD 20857 (301-443-6597). ◆

ALARM SIGNALS FOR ANESTHESIA AND RESPIRATORY CARE EQUIPMENT: National and International Standards Efforts

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Two voluntary standards organizations are presently developing standards specifying alarm signals for anesthesia and respiratory care equipment. Nationally, the American Society for Testing and Materials (ASTM) Committee F-29 has developed a draft specification for both audible and visual alarm signals which is currently in balloting. In the international standards arena, the International Standards Organization (ISO) Technical Committee 121 is proceeding with the final stage of balloting and comment on Draft International Standard (DIS) 9703 which addresses requirements for three levels of visual signals only. Once approved, this will be published as the first part of a two-part International Standard on this topic. At a recent meeting of the ISO Committee in Ottawa, Canada, it was agreed to begin work immediately on the second part of the standard which will address the issue of audible alarms.

"... opposition centered around the inclusion of such specific requirements in the standards without clinical trials to demonstrate their effectiveness or their general acceptance by clinicians."

The Patterson Sounds

Work on this topic began several years ago in the international setting with the development of a draft standard that addressed both visual and audible alarm signals. The audible signals specified by the draft were developed by Dr. Roy Patterson of the Medical Research Council Applied Psychology Unit in Cambridge, U.K. The requirements for the "Patterson" sounds are quite specific to the extent that they have received patent protection in the U.K.

Although Dr. Patterson and the Medical Research Council agreed to freely license the use of these sounds to manufacturers, there was opposition to their inclusion in the international and national drafts for alarm standards. Much of this opposition centered around the inclusion of such specific requirements in the standards without clinical trials to demonstrate their effectiveness or their general acceptance by clinicians. No consensus could be reached on inclusion of the specific "Patterson" sounds in the international draft, and the document went forward in the ballot process with requirements specified only for visual alarm signals.

ASTM Committee F-29 functions as the U.S. Technical Advisory Group for ISO Committee 121. In this role, it votes on behalf of the United States in matters related to ISO/TC 121. At the recent Ottawa meeting, the U.S. delegation proposed a compromise position to the inclusion of the very specific sounds developed by Dr. Patterson, and it was agreed to use this position as the basis for creation of the "Part Two" of the International Standard. This compromise preserves the essential human factors aspects of the sounds proposed initially in the international draft, while allowing greater flexibility in the acoustical construction of the sound for each alarm category.

A copy of DIS 9703 can be obtained by writing to the International Standards Organization, 1 rue de Varembe, 1200 Geneva, Switzerland. Copies of both DIS 9703 and the ASTM F-29 committee report can be obtained from ASTM but one must become a member first at a cost of $50.00. The address is: ASTM, 1916 Race Street, Philadelphia, PA 19103.

For a more detailed understanding of the technical aspects of this topic, the following reading is suggested.

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UPCOMING EVENTS

ASA Annual Meeting

American Society of Anesthesiologists Meeting. October 26 through 30, 1991. San Francisco, California. Contact:

American Society of Anesthesiologists
515 Busse Highway
Park Ridge, Ill 60068
(800) 562-8666

STA '92

Second annual meeting of the Society for Technology in Anesthesia, January 29 through February 1, 1992. US Grant Hotel, San Diego, CA.
Contact:

Gerri Kuzawa
STA Interface
P.O. Box 382
Hastings, Michigan 49058
(800) 875-2525
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EEG and Evoked Potentials: Intraoperative and ICU Monitoring

January 3-5, 1992 at Lake Buena Vista Palace Hotel, Walt Disney World Village, Orlando, Florida.
Contact:

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STA to Host Events at ASA

STA sponsored activities at the annual meeting of the American Society of Anesthesiologists have been well received in the past and this year should be no exception. The STA dinner will be held Sunday evening, October 27 at Le Meridien hotel. Festivities will begin at 6:00 PM with a cocktail reception. Dinner will follow the reception at 7:15 PM and include a lecture by James L. Adams, Professor of Mechanical and Industrial Engineering at Stanford University. Dr. Adams is well known for his book entitled "Conceptual Blockbusting" which explores the process of creative thinking. He has strong interests in factors affecting creativity, innovation and general problem solving.

Most clinicians practice with little concern about the implications of electrical power failure. After all, every hospital has backup generators to provide electricity in the event of a utility failure. Backup generators can and do fail however, leading to prolonged loss of electrical power in the operating room. The STA breakfast panel, "When the Lights Go Out" will discuss the problem of power failure in the operating room. The panel will be held Wednesday, October 30 at 7:30 am in the San Francisco Hilton Grand Ballroom Salon A. Topics to be discussed include: Prevention: Power Distribution and Backup (S. Eames, Datascope Corp.), Causes: Anatomy of Some Failures (D. Paulus, MD, Univ. of Fla.), Experience: Working in the Dark (J. Feldman, MD, Yale Univ. and D. Cullen, MD, Harvard Univ.), Engineering: Your Machine Really Will Work (R. Saunders, MD, Cedars-Sinai Med. Ctr.), and Education: What Will I Teach? (A. Keats, MD, Texas Heart Inst.). Members of the audience will be encouraged to share their experiences and help shed some light on this rare but challenging problem.

STA requests pre-registration for the Sunday dinner through Gerri Kuzawa at the STA office. The cost of the dinner is $45. Tickets for the breakfast panel can be obtained from the ASA. ◆

Organizations Involved with Anesthesia Standards

Association for the Advancement of Medical Instrumentation (AAMI)
3330 Washington Blvd
Suite 400
Arlington, VA 22201-4598
(703) 525-4890 x250

Particular expertise in standards pertaining to ECG monitoring. Currently developing human factors standards for medical equipment.

American National Standards Institute (ANSI)
11 W. 42nd St.
NY, NY 10036
(212) 642-4969

ANSI does not write standards, their mission is to coordinate and accredit American standards activities and serve as a contact for international standards organizations. The term "American National Standard" indicates ANSI accreditation.

American Society for Testing and Materials (ASTM)
1916 Race Street
Philadelphia, PA 19103
(215) 299-5400

Many anesthesia equipment standards including gas machines and ventilators. Currently balloting a standard specifying requirements for visual alarms.

Compressed Gas Association (CGA)
1235 Jefferson Davis Highway
Suite 501
Arlington, VA 22202
(703) 979-0900

Develops standards related to the processing and delivery of medical gases.

Health Industry Manufacturers Association (HIMA)
1030 15th St. NW Suite 1000
Washington, DC 20005
(202) 452-8240

An association of manufacturers that encourages and facilitates participation by industry in the standards process. Not a standards writing organization.

Institute of Electrical and Electronics Engineers (IEEE)
Engineering in Medicine and Biology Society
PO Box 2477
Durham, NC 27715
(919) 493-3225
E-mail: EMBS@DUKEMVS.BITNET

Major activities include writing the Medical Information Bus (MIB) and MEDIX Standards. MIB is a device intercommunication standard. MEDIX will apply to information exchange between hospital information systems.

International Standards Organization (ISO)
1 rue de Varembe
1200 Geneva, Switzerland

International organization developing standards for anesthesia equipment. Also involved with the ASTM alarms standards. Maintains liaisons with major US standards writing organizations.

International Electrotechnical Commission (IEC)
3 rue de Varembe
1200 Geneva, Switzerland

International counterpart to ISO for the development of standards pertaining to electrical equipment.

National Fire Protection Association (NFPA)
1 Batterymarch Park
Quincy, MA 02269
(617) 770-3000

Private association dedicated to reducing risk of fire injury. Two major activities focus on writing fire safety standards before and after a building is constructed.

The Association for the Advancement of Medical Instrumentation (AAMI) Human Engineering Committee

The AAMI Human Engineering Committee has developed the official AAMI practice recommendation entitled "Human Engineering Guidelines and Preferred Practices for the Design of Medical Devices." It should be noted that this document is a set of guidelines and not a standard. Like all AAMI committees this committee has two chairpeople. The "User Co-Chairman" is a clinician or other end-user and the "Industry Co-Chairman" represents a manufacturing company. For many years the User Co-Chairman was Dr. Leslie Rendell-Baker of Loma Linda Medical Center. It was under his guidance that the first version of the recommended practice was published in 1988. The guidelines are currently being revised with a second edition planned for publication in early 1993.

The guidelines deal with those human factors which make a device "user-friendly" and apply to the entire spectrum of medical devices including those designed for home use. For example, various types of controls and displays, requirements for operation in sitting and standing positions, and alarms are all discussed. Specific recommendations have been derived from human factors research including government, military, and aviation research activities.

Regular Meetings

The committee usually meets twice a year for two all-day meetings. These meetings are held at the AAMI annual meeting and at the annual meeting of the American Society of Anesthesiologists. Anesthesiologists have historically been well represented on the committee although members from other disciplines are welcome. The present User Co-Chairman is Frank E. Block Jr., MD from Ohio State University and the Industry Co-Chairman is Christopher Goodrich from Ohmeda. Although there are many members on the committee, those in regular attendance at recent meetings include Carl Pantiskas (SpaceLabs), Dennis Serig (Nuclear Regulatory Commission), Peter Carstensen (from the FDA Center for Devices and Radiological Health), Jerry Chaikin (an industrial consultant), Matt Weinger (an anesthesiologist at UCSD), Larry Dallen (an anesthesiologist from Canada), and Dr. Paula Sind (a human factors expert from the Florida Institute of Technology, with a special interest in medical devices for the disabled).

Revision in Progress

The need to revise the guidelines was recognized even as the first version was being published. The revision process is focused on two areas of recent development in medical devices. The first is the increasingly computer-like nature of medical devices. Specialized input and output devices such as touch screens, mice, trackballs, and joy-sticks will be addressed. Guidelines for menu structures, data formats, and general program operation will also be included. The second area of revision will be alarms and auditory presentation of information. This new section will draw heavily from ongoing work on standards for alarms.

> *"The guidelines deal with those human factors which make a device "user-friendly" and apply to the entire spectrum of medical devices ..."*

The first complete version of the proposed revision will be discussed at the upcoming 1991 ASA meeting in San Francisco. After committee approval the revised document will be released for response. The draft will first be sent to the AAMI membership for comments. The comments are then reviewed, changes made as necessary and ultimately the AAMI membership must approve the document by ballot before it becomes official. A final version of the revised document is planned for 1993.

The guidelines are not intended to guarantee a successful design of a device. A device needs to undergo substantial user testing in order to establish its usability. Rather, the guidelines should provide a reasonable method for developing a user-friendly device. The ultimate goal, of course, is to promote better and safer medical devices in the future.

The committee welcomes new members who wish to become involved. Interested parties who do not have the time available to join the committee as members can be placed upon the mailing list and will receive meeting announcements and notices of the committee's progress. If you have further questions about the committee, or if you would like to attend the upcoming meeting in October, please contact Dawn Helsing at AAMI, 703 525-4890, ext. 205. ◆

— Frank E. Block, Jr.

STANDARDS & CONFUSION

continued from first page

their standards writing activities follow certain due process rules including adequate disclosure of the proposed standard before acceptance. Any standard that is advertised as an "American National Standard" has been written by an ANSI accredited organization.

Interestingly, some of the most active ongoing standards activities, such as the AAMI Human Engineering Committee, emphasize how equipment will integrate, both electronically and with the user, rather than specifying the design of a particular device. This is not surprising, given the trends towards increasing integration of equipment and data communication between devices.

The table on page 32 provides a listing of the major organizations involved with anesthesia standards. Information about existing standards and/or becoming involved with new standards activities can be obtained by contacting the organization's office. Commentary about the impact of standards is also invited and will be published in the newsletter.

- J. Feldman, MD

ECRI, Standards & Improving Medical Devices

Michael Argentieri
Director of Research
ECRI
Plymouth Meeting, PA

Twenty years ago, ECRI, a nonprofit organization, took the stand that the safety and efficacy of medical devices should not be determined by hindsight. Since that time, ECRI has become one of the world's leading organizations committed to the improvement of healthcare technology. ECRI publishes comparative evaluations, safety alerts, risk management, and guidance articles on medical devices. Approximately 3,000 hospitals worldwide rely on ECRI for information on the safety, selection, management, and application of medical technology. In addition to publishing information about medical devices, ECRI provides consulting and accident investigation services.

Throughout its history, ECRI has supported and participated on the committees for many voluntary standards, such as those produced by the International Standards Organization (ISO) and the American Society for Testing and Materials (ASTM). In our experience, the greatest value of this work has been in establishing standard test methods and in defining minimal performance standards.

ECRI and Standards

Standards committees are often composed of manufacturers and users (physicians, nurses, technicians, and clinical engineers) who may approach the standards writing process with conflicting agendas. The user wants the best or optimal design while some manufacturers want minimal performance specifications. As a result, the standard becomes a compromise defining minimal performance. The finalization of a document describing a standard can take a long time, as long as 5 or 10 years in some cases. As a result, standards may become available at the end of a product's life cycle. Out-of-date standards inhibit the use of new technologies and innovative designs and unnecessarily increase costs when out-of-date requirements must still be met to remain compliant with a standard.

Consumer product testing organizations, such as ECRI, work on behalf of the user and patient. Our evaluations and test criteria go beyond minimal performance and allow us to identify optimal designs. This is an important issue, since hospitals can no longer afford to purchase minimally performing technology. The lack of conflicting agendas also allows ECRI to complete even the most complicated evaluations in less than one year. For example, ECRI's evaluation of laser-resistant tracheal tubes was published within one year (Health Devices 1990 Apr; 19[4]) of our learning that some tubes did not adequately resist laser energy. Shortly after this evaluation was published, an ASTM committee was formed to study laser-resistant tracheal tubes. Two members of ECRI's engineering staff serve on this committee and are helping to develop guidelines and test methods.

These comments are not intended to cast doubt on the merit or usefulness of standards. ECRI would not invest time and money participating on standards committees if this were true. Instead, the intent is to point out that standards do have some limitations and are not the ultimate solution for improving medical devices.

Whereas most users have little idea about the content of standards, ECRI educates users as to which device is best to buy. This educational approach encourages manufacturers to produce an optimal product in a timely manner since the user won't purchase a suboptimal product. In the end, this directly benefits both the patient and those manufacturers willing to change their devices for the better.

It is also important to realize that ECRI's evaluations do not occur in a vacuum. Many of the world's most respected clinical, industrial, and academic experts review our work and provide guidance. Equipment evaluations are commonly reviewed by 20 to 30 people, including clinical specialists and those individuals in industry who have a vested interest in scrutinizing our approach.

Objective Approach to Evaluation

To insure that evaluations done by ECRI are completely objective, ECRI does not accept funds from manufacturers nor is work undertaken on their behalf. Gifts or grants from medical firms are not accepted. Staff members are not permitted to consult for medical companies or own stock in them. Individual federal tax returns, from the custodian to the president, are audited to insure conformance to our rules.

ECRI's process is also unique in that it does not accept letters to the editor in our primary journal, Health Devices. Our objective is to settle differences of views and controversies before we publish. Health Devices is intended to provide unequivocal guidance, not to undermine decisiveness among those individuals in our member hospitals who must come to grips with making practical decisions.

ECRI believes in the process of developing standards. We participate in this process to apply knowledge about the performance of products in the definition of standards. Our other activities augment the standards process by helping users distinguish between products that satisfy minimal performance criteria and those that offer optimal design features. ◆

OVERVIEW

continued from page 1

ticing anesthesiologists are active participants in the various committees of these organizations, indeed, many are chaired by anesthesiologists. There is surprising little overlap in effort among these varied groups, probably due to the participation of the same physicians and manufacturers over the years. It goes without saying that the commitment, both in time and money, made by these individuals and companies is very substantial.

Parallel activities in standardization are taking place internationally, with active participation by U.S. manufacturers and users. It is the goal of these efforts to minimize incompatible standards among countries, thus enhancing free trade while protecting consumers from inferior designs. The International Standards Organization (ISO) and the International Electrotechnical Commission (IEC) develop and publish international standards which have a worldwide impact. ISO Technical Committee (TC) 121 has the same scope of activity as ASTM F-29, with very active participation by the United States. IEC TC-62 is charged with writing standards on the Safety of Medical Electrical Equipment, and participation in its subcommittees is coordinated in the U.S. by HIMA, AAMI, and ANSI. Liaison between ISO TC-121 and IEC TC-62 is excellent. The U.S. is also represented at the Joint Technical Advisory Group on Medical Equipment, an overseeing combined group of the ISO and IEC.

With the maturation of the European Economic Community and the implementation of a true Common Market in Europe, the need arose for the publication of European standards that would be adopted by all the countries of the EEC, thus preventing trade barriers based on differing standards within countries. Two European standards writing organizations with scopes similar to the ISO and IEC, Comitè Europèen De Normalisation (CEN) and Comitè Europèen De Normalisation Electrotechnical (CENELEC) respectively, were charged with fulfilling this need. International Standards were to be adopted whenever possible, but new standards were to be developed if ISO or IEC standards were not. The United States cannot participate directly in the inner workings of CEN and CENELEC, but has been, and continues to be, promoting the completion of international standards suitable for the European needs. This is the only way in which American interests, both industrial and medical, can be protected. Luckily, the cooperation between ISO/IEC, CEN/CENELEC, and the corresponding U.S. organizations is excellent in the field of anesthesia equipment technology.

As new technology is developed and becomes accepted into anesthesia practice, the need to develop standards will continue. I would like to encourage more anesthesiologists to become involved in these endeavors. It is a satisfying experience, albeit time consuming and expensive, and must be accomplished if we are to continue to enjoy the peace of mind generated by implicit trust in the safety and performance of our equipment. ◆

Index to Interface, Vol. 1, No. 1

Agent Specific Analysis 2

APSF, Anesthesia Patient Safety Foundation Meeting 6

Devil's Advocate
Agent ID: Another advertising gimmick 2

EEG 4

ESCTAIC, European Society for Computers in Technology, Anaesthesia and Intensive Care 6

ISCAIC, International Society for Computers in Anesthesia and Intensive Care 6

Perspectives on Technology,
New Technology 3

STA
ASA Events 5
board of directors 2
newsletter 1
president's message 1

STA '91 6

Index to Interface - Vol. 2, Nos. 1-4

AAMI, Association for the Advancement of Medical Instrumentation 25, 29, 32

ASTM, American Society for Testing and Materials 25, 32

Alarms,
Improving 2
Sounds 30

ASA, American Society of Anesthesiologists
QA Panel 4
Dinner: Alarms 6

ASATT, American Society of Anesthesia Technicians and Technologists 13

Devil's Advocate,
How To Solve the Alarms Problem: Think Japanese! 2

Drug administration,
closed-loop delivery 11
PCA 11
pharmacokinetic (PK) infusion 19
CCIP (Comp.-controlled infusion pump) 19

Echocardiography,
transesophageal (TEE) 3

ECRI 34

Electronic mail (E-mail) 10

ESCTAIC (European Society for Computing and Technology in Anaesthesia and Intensive Care) 5

FDA, Food & Drug Administration 30

Health care costs 17

Human Engineering 33

Human Factors Society (HFS) 21

IEEE, Institute of Electrical and Electronics Engineers 29, 32

ISCAIC (International Symposium on Computing in Anesthesia and Intensive Care), ... 22

Kitz, R.J. M.D. 9

Malpractice Insurance,
Technology and 18

Measurements,
hemoglobin desaturation 23
oxygen saturation 23

Medical Information Bus (MIB) 29, 32

Outcome Studies 18

Patient monitors,
capnography 23
pulse oximetry 18,23

Patterson Sounds 30

Perspectives on Technology,
Echocardiography 3
Closed-loop Drug Delivery 11
Pharmacokinetic Drug Administration . 19
Standards 27

Pulse oximetry 23
Prospective evaluation of 18

Quality assurance,
system database 7
data capture 7

SIGMSFI (Special Interest Group on Medical Systems and the Functionally Impaired) 21

SIGnatures 22

STA
ASA Dinner 5, 6, 31
Alarms 6
ASA Panel 4, 31
Quality Assurance 4
When the Lights Go Out 31
history of 1
Compuserve Special Interest Group (SIG) 12,22

STA '91
meeting report 15
membership meeting 9
distinguished lecture 9

STA '92
announcement 21

Standards
overview 25
FDA 30
clinical perspective 27
industrial perspective 27
alarm sounds 30

Technology
assessment 23

TEE (Transesophageal Echocardiography) 3