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 they are serious in their dedication to the development of standards.

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-
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 anesthesiology workstation with support from the Anesthesiology Patient Safety Foundation (APSF). Our first prototype workstation had a rule-based intelligent alarm system. 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. We were forced to write rules with widely varying thresholds and multiple combinations of monitored variables.

We began to write rules with widely varying thresholds and multiple combinations of monitored variables.

When we reached a conclusion, we were forced to write rules with widely varying thresholds and multiple combinations of monitored variables.

The prototype neural network based alarm system identified critical breathing events with 95% accuracy and reduced the time to diagnose and repeat breathing system faults by 43 seconds. Working under contract with Ohmeda, we plan to integrate intelligent neural network based breathing circuit alarms in the Ohmeda Monitor System.

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.

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References

1. Loeb RG et al., Anesthesiology 1989;70:999.

INTERFACE is the official newsletter of the Society for Technology in Anesthesiology. 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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The newsletter is also available on the STA website.

Perspectives on Technology

TOPIC: Standards

We encountered a difficult problem as we expanded the rule-based intelligent alarm system to handle a wide range of patient conditions...

...the development of the best standards is impossible without participation of clinicians...

The Industrial Perspective

Gregory Wolczko
Manager, Medical and Industrial Standards
Ohmeda
Madison, WI

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. Regrettably, 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 use. The "silent partner" helping to protect patients, manufacturers, and clinicians consists of the many available equipment/device standards.

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 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 manufacturers 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 these 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 efforts, ventilators, anesthesia machines, and respiratory gas humidifiers are critical to the development of equipment meeting the standards of American National Standards Institute (ANSI) Committee 7-79 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, ventilation, anesthesia machines, and respiratory gas humidifiers are not included in the list of medical devices most frequently reported to the FDA in recent years as malfunctioning by the U.S. General Accounting Office. Medical devices are not included in the list of medical devices most frequently reported to the FDA in recent years as malfunctioning by the U.S. General Accounting Office. Medical devices are not included in the list of medical devices most frequently reported to the FDA in recent years as malfunctioning by the U.S. General Accounting Office.

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

The Medical Industrial Bus (MIB) is a set of international standards that define a family of standards to provide comprehensive communication and information exchange in hospitals and healthcare settings. MIB standards are designed to address clinical problems and improve the effectiveness of services by establishing a set of requirements for the separation of communication, connection, and control into layers: physical, data, transport, session, presentation, and application. The 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: P1073.1 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 BCCs 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 human resources within 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 in six or eight 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 P1073.1 provides are not needed for some devices and a complete overhaul of communications, its completion has been deferred pending approval of the P1073.1 and P1073.2.

Implementation

Conceptually, the MIB can be thought of as an information pipeline that connects a medical device and a computer. Several logical units have been defined to support the communication process. See Figure. Individual device manufacturer requirements but with the network via their device communication controller (DCC). Multiple DCCs are connected to a bedside connection controller (BCC) in a star topology. In this bedside sub-network, BCCs provide power, timing, and data transmission 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 or more devices which 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 reports them to the host computer. Individual medical devices will have integrated DCCs which is may be connected and disconnected from the BCC as the patients needs change. The MIB subdivides communication functions into logically separate modules.

Pre-existing International Standards Organization (ISO) data communication and networking standards have been as 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 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.

REFERENCES

1. American Society of Anesthesiologists: Standards for basic intraoperative monitoring of adult patients. ASA - and research departments of universities, had contributed professionals and dedicated physicians.


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 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 medical device regulatory standard. Efforts to develop a regulatory standard for apex monitors were initiated several years ago and have nearly doubled the FDA's medical device program staff. The two voluntary standards organizations are presently developing standards specifying alarm signals for anesthesiology 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) 140 1938.

...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.

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 Medical Device Warning Signals. 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.

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 standards for medical device alarms. 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 regarding 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. The ASTM F-29 Committee on Medical Devices F-29 Subcommittee on the Technical Advisory Group for ISO Committee 121. It was also agreed that two members 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 elements of the Patterson sounds in the standard initially in the international draft, while allowing for greater flexibility in the acoustic 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 Varenne, 1200 Geneva, Switzerland. Copies of both DIS 9703 and the ASTM F-29 report committee can be obtained from ASTMM 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 readings are suggested:


EEG and Evoked Potentials: Intracranial and ICU Monitoring

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

Contact: Mrs. Carolyn Schoenau
Dept. of Anesthesiology
University of Florida College of Medicine
PO Box 13417
Gainesville, Florida 32604
Phone: (904) 392-4859
FAX: (904) 392-7026

UPTCIMING EVENTS

ASA Annual Meeting
Contact: American Society of Anesthesiologists
125 Boone Highway
Park Ridge, Il 60068
(600) 652-8666

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 Kasuza
STA Interface
P.O. Box 382
Hastings, Michigan 49058
(800) 875-2325
(616) 945-5110

STA to Host Events at ASA

STA sponsored activities at the annual meetings 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 the 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 26 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 Medical Center, and Education: What Will We Teach? (A. Knott, 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 Kasuza at the STA office. The cost of the dinner is $35. Tickets for the breakfast panel can be obtained from the ASA.
Organizations Involved with Anesthesia Standards

- Association for the Advancement of Medical Instrumentation (AAMI)
  1330 Washington Blvd
  Suite 400
  Arlington, VA 22201-4598
  (703) 525-4890 x250

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

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

- Compressed Gas Association (CGA)
  1215 Jefferson Davis Highway
  Suite 501
  Arlington, VA 22202
  (703) 979-6900

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

- Institute of Electrical and Electronics Engineers (IEEE)
  Engineering in Medicine and Biology Society
  PO Box 247
  Dubuque, NC 27715
  (919) 493-3225
  E-mail: IEEEBM@MAVS.BITNET

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

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

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

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

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.

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

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

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

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

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

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

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 AAMI Human Engineering Committee has developed the official AAMI practice statement 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 chairs; 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 1986. The guidelines are currently being revised and are to be published 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 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 Obeliska. Although there are many members on the committee, those in regular attendance at recent meetings include Carl Pantolak (SpaceLabs), Dennis Seng (NLR Regulatory Commission), Peter Cardenstein (from the FDA Center for Devices and Radiological Health), Jerry Chalkin (an industrial consultant), Matt Weinger (an anesthesiologist at UCSLD), 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 auxiliary presentation of information. This new section will draw heavily from ongoing work on standards for alarms.

The first complete version of the proposed revision will be discussed at the upcoming 1991 AAMI meeting in San Francisco. After committee approval the revised document will be released for response. The draft will then 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-friendy 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, 703 525-4600, ext. 205.

—Frank E. Block, Jr.
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, predominantly in the United States, have subscribed to ECRI’s evaluations and test criteria go beyond minimal performance and allow us to identify optimal designs. This is an important step 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.

ECRI and Standards

Standards committees are often composed of manufacturers and users (physicians, nurses, technologists, and clinical engineers) who may approach the standards writing process with conflicting agendas. The user wants the standard to improve the design while some manufacturers want minimum 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 step 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.

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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 medical companies or own stock in these companies. Twenty years ago, ECRI, a nonprofit organization, took the stand that the safety and performance of our equipment. It is the goal of these efforts to minimize the use of 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 121 has the same scope of activity as ASTM but 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 by the U.S. by HMAA, AAMI, and ANZI. 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 Economic European 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 conflicting standards in these countries. Two European standards writing organizations, with scopes similar to the ISO and IEC, Comité Europeen De Normalisation Electrotechnique (CENELEC) respectively, were charged with fulfilling this need. International Standards were to be adopted whenever possible, but new standards were developed if ISO and IEC standards were not. The United States cannot participate directly in the inner workings of CEN and CENELEC has been, and continues to be, in competition with each other. As a result, the U.S. is the only country in which American interests, both industrial and medical, can be protected. Luckily, the cooperation of CEN, CENELEC, and the corresponding U.S. organizations is excellent in the field of anesthesiology, with the exception of transesophageal echocardiography.

As new technology is developed and becomes accepted into anesthesia practice, the need to develop standards will continue. We 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 encouraged if we are to espouse the peace of mind generated by implicit trust in the safety and performance of our equipment.

Parallel activities in standardization are taking place internally, with active participation by U.S. manufacturers and users. It is the goal of these efforts to minimize the use of 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 121 has the same scope of activity as ASTM but 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 by the U.S. by HMAA, AAMI, and ANZI. 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 Economic European 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 conflicting standards in these countries. Two European standards writing organizations, with scopes similar to the ISO and IEC, Comité Europeen De Normalisation Electrotechnique (CENELEC) respectively, were charged with fulfilling this need. International Standards were to be adopted whenever possible, but new standards were developed if ISO and IEC standards were not. The United States cannot participate directly in the inner workings of CEN and CENELEC has been, and continues to be, in competition with each other. As a result, the U.S. is the only country in which American interests, both industrial and medical, can be protected. Luckily, the cooperation of CEN, CENELEC, and the corresponding U.S. organizations is excellent in the field of anesthesiology, with the exception of transesophageal echocardiography.

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