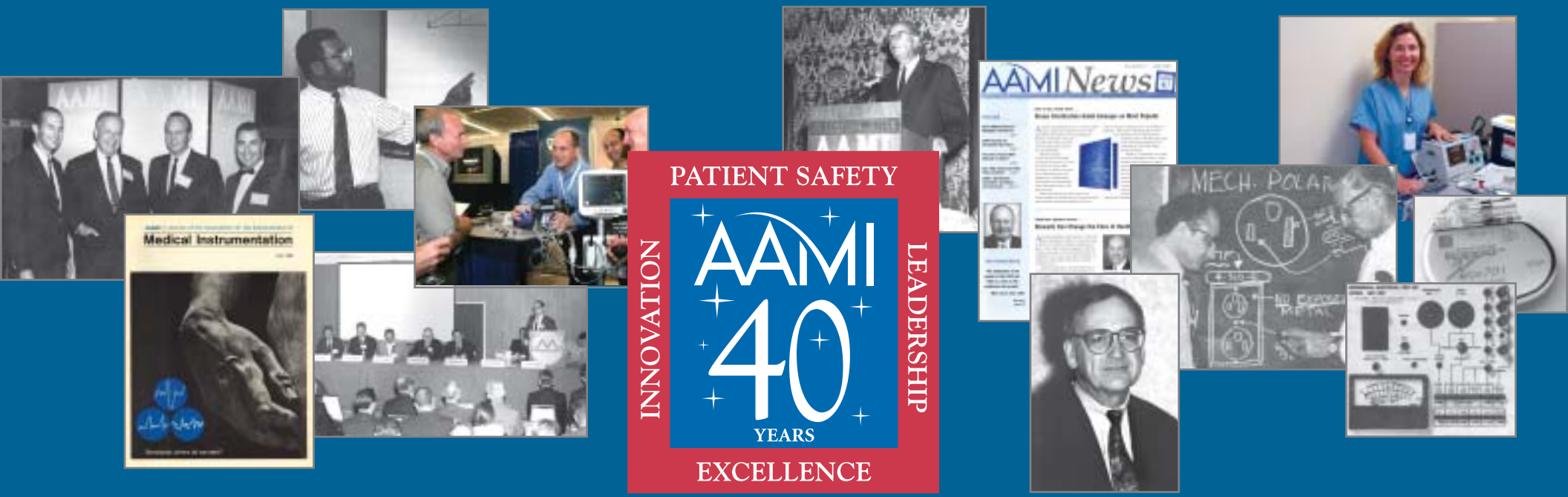
40 YEARS

OF PEOPLE, PROGRESS, AND PATIENT SAFETY



THE ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

About This Book

40 Years of People, Progress, and Patient Safety has been published in honor of the 40-year anniversary of the Association for the Advancement of Medical Instrumentation (AAMI), a unique alliance of the healthcare professions providing essential information on the development and use of medical instrumentation and technology.

ISBN 1–57020–285–0.

Researched and written by Jill Schlabig Williams and Kurt Larrick.
Cover design by Megan Maher. **Book layout** by Ruth Moyer.

40TH ANNIVERSARY COMMITTEE
Many thanks to the members of AAMI's 40th Anniversary Committee, whose guidance helped shape the contents of this book.

John Abele
William F. Betts, PE, CCE
Burt Dodson Jr., CCE
Robert C. Flink
Thomas S. Hargest, CCE
Adrian Kantrowitz, MD
Frances R. Koch, RN
Ray Laxton
David Link
Mike Miller
Marcy Petrini
John Post
W. Gerald Rainer
William A. Short, PE, CCE
Charles Sidebottom
Robert H. Stiefel, CCE
Laurence A. Tanner

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795
PHONE 703.525.4890
WEB www.aami.org

Table of Contents

Dedicated to the men and women who have served AAMI and the medical technology community with such distinction over the past four decades, and to those who continue carrying the torch to enhance patient safety through advancements in medical technology.

Introduction

When we embarked on this project to look back on AAMI's first 40 years in the medical technology field, we asked many people to share their thoughts and experiences. Memories came pouring in from all corners of the healthcare industry: the pioneering doctors and inventors who were so fundamental to AAMI's beginning; the skilled engineers and technicians who elevated their professions to become such important and respected members of the healthcare team; regulatory officials who have been committed to finding solutions instead of putting up barriers. Retired members, active members, students, and current and former staff chimed in.

From this broad cross section of responders, a unified view emerged: AAMI is a membership organization consisting of smart, dedicated, caring people guiding a remarkable progression of medical technology advancements that enhance patient safety. From these responses we have drawn the theme for this book: people, progress, and patient safety.

People. Professional organizations rely heavily on members volunteering their time and talents. AAMI has been blessed with a wealth of skilled and committed people whose leadership, hard work, and dedication have placed AAMI into the global healthcare landscape. This book mentions many, but by no means all, of the people who have contributed to AAMI's growth over the past four decades. Doing justice to all of the people who have played important roles in AAMI over the years would take a book 10 times this size.

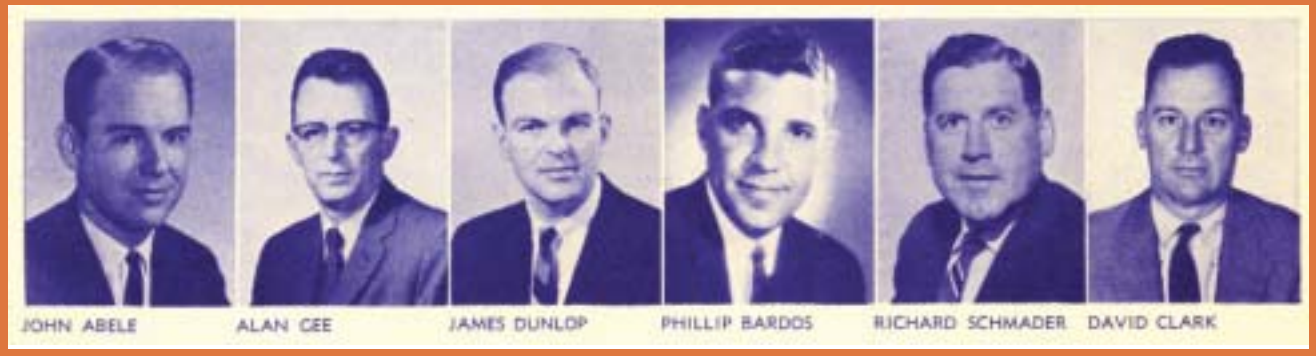
Progress. In AAMI's first 40 years, we have all had a front-row seat to an astounding era in which advances in science and technology have made the impossible possible. Medical devices have been invented and improved. New procedures and treatments have expanded boundaries of care. We've been first-hand witnesses to the birth and growth of medical device regulation and modern manufacturing processes. It has truly been a Golden Age.

Patient Safety. Quite simply, patient safety is why AAMI was founded. It's why AAMI worked so hard to establish a regulatory framework for medical devices and continues to this day to be an active participant in device regulation and government programs education. It's why AAMI launched its standards program and later expanded it to the international arena. It's why AAMI works tirelessly to provide professional and technical resources for biomedical equipment technicians, clinical engineers, and healthcare practitioners.

And it's why AAMI has, for 40 years, been able to bring together the best minds and unique talents of a diverse range of medical technology professionals to create a body of work which would otherwise have been impossible to accomplish. I hope you enjoy this book of memories as much as so many people from the AAMI family enjoyed being a part of them. Cheers to AAMI's first 40 years and your contributions to make it happen; and best wishes for the next 40.

Mike Miller, JD, AAMI President

P.S. I want to acknowledge the effort made by Steve Campbell, Jill Williams, and Kurt Larrick to make this book possible. They have committed themselves to making sure that the many people who have made AAMI what it is today are appropriately recognized and they have succeeded. This was no easy task.


JOHN ABELE
ALAN GEE
JAMES DUNLOP
PHILLIP BARDOS
RICHARD SCHMADER
DAVID CLARK


AAMI

CLOCKWISE, FROM TOP LEFT: The six members of AAMI's first Manufacturer's Advisory Board, formed in 1965. ***John Post, Warren (Zeph) Lane, Arthur C. Beall,*** *and* ***Bob Allen*** *at an early AAMI meeting.* ***John Abele*** *in a shot from a 1966 newsletter. AAMI's 1967 president and vice president,* ***Arthur C. Beall*** *[left] and* ***Harry Collumbine****. AAMI leaders pose for a picture during MEDAC '67.*

The Founding of AAMI

In the mid-1960s, a group of pioneering physicians, inventors, and manufacturers looked into the future and saw possibility. They realized that breakthroughs with transistors, plastics, synthetic materials, and modernized manufacturing processes had the potential to launch a Golden Age for medical devices, opening the door to treatments that only a few years earlier would not have been possible. They also knew that without vision and leadership, the doors to this promising future might never be fully opened. Without effective standards, appropriate regulation, education, and better support of a young, emerging industry—then a plethora of small companies—brilliant medical devices might never achieve their full potential to save lives.

These physicians and inventors knew that in order to bring new technologies and new treatments to patients, they would need to generate industry-wide cooperation and interdisciplinary communication among those who would be able to help usher in this Golden Age. They would need the help of the physicians who inspired, invented, and used medical devices; the manufacturing industry that would build safe devices and deliver them to the point of care; engineering personnel who would maintain the devices; and a government eager to bring medical devices under its regulatory watch.

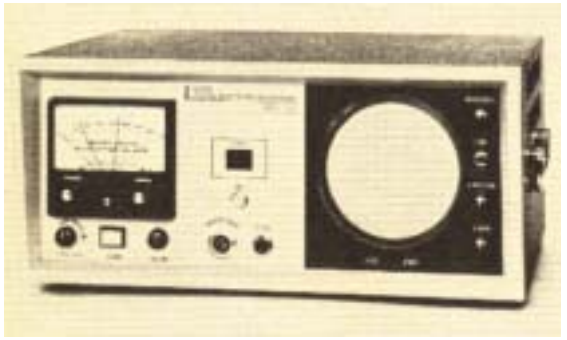
The story of AAMI's founding is the story of how a diverse group of experts who shared an interest in the advancement and safety of medical devices worked together to create a new organization, one that would ensure that the promise of emerging technologies would be realized.

The Mid-1960s: Explosive Growth in Medical Devices Creates Opportunities, Risks

By 1965, the use of medical devices in patient care was expanding rapidly. Medical devices were having a major impact on patient outcomes, and many physicians had a very personal relationship with devices. Physician-inventors like Arthur C. Beall, Jr., and Dwight Harken were struggling to find engineers to translate their ideas into lifesaving medical devices. At the same time, businessmen-engineers like Earl Bakken of Medtronic and John Abele, who later founded Boston Scientific, needed doctors to help their fledgling medical device companies refine and market their products.

Technicians in the armed services like Burt Dodson were running organized medical equipment programs, but the concept hadn't yet made its way into the private sector. Rumblings of problems with equipment safety in hospitals were laying the foundation for the full-blown electrical safety scare of the early 1970s. FDA was looking closely at medical devices, trying to determine how to regulate the technologies that were having such an impact on patient care.

And in Boston, MA, a handful of men looking to capitalize on the medical technology boom created a new organization they named the Association for the Advancement of Medical Instrumentation.



Early devices featured in AAMI's journal, Medical Instrumentation.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1965

First *AAMI News* bulletin published September 1.

1966

First AAMI annual meeting, called MEDAC '66, held in July in Boston, MA.

1966

John Post hired, first executive director of AAMI.

1965: AAMI Is Launched

Robert D. Hall, Robert J. Allen, and their colleagues were in the advertising business and worked for small high-tech companies in the Boston area. They had an idea to start an expo and a journal with advertising, hoping to attract manufacturers of medical devices. They approached John Abele, who was then working for a small medical device company, with their idea and recruited him to help them get the organization off the ground.

They realized that they needed to create a structure to attract physicians who could lend legitimacy to their efforts, so in 1965 they filed the articles of organization to create AAMI and began recruiting physicians to serve on its board of directors. The men created a green, pocket-sized pamphlet that described what AAMI was about, and succeeded in getting an article about the new organization in *The New York Times*.

Robert J. Allen and his colleagues in the marketing business came up with the idea of AAMI, generating revenue through an expo and journal.

THE NEW YORK TIMES, SUNDAY, JANUARY 2, 1966

FIELD OF MEDICINE TO GET VITAL AID

Physicians and Makers of Instrumentation Link Up

By JOHN H. FENTON

Special to The New York Times

BOSTON, Jan. 1—The final steps were completed here this week in setting up a communications system between the medical profession and manufacturers of medical instrumentation.

The setup has already been chartered as the Association for the Advancement of Medical Instrumentation, a nonprofit Massachusetts organization. The final acceptances of places on medical and manufacturers' advisory boards have been received.

Dr. John P. Merrill, director of the cardio-renal division of the Peter Bent Brigham Hospital, is chairman of the medical board. John Abele, vice president of Advanced Instruments, Inc., of Newton, Mass., is chairman of the manufacturers' board.

The association, called Amy by its founders, was the result of expressions by medical professionals, researchers, developers and manufacturers of medical instrumentation that there was a serious gap in communications between supplier and user.

The agency is to serve as an international forum for introducing and improving medical instrumentation through evaluation standards, symposiums and exhibitions and education, research and scholarships.

Problem of Transition

Operating on the premise that the proliferation of medical knowledge in the last five years has created a problem in the physician's transition "from the little black bag to the little black box," the new association has scheduled its first symposium in Boston, July 25-29.

Computers are examples of medical instrumentation used for administrative purposes, said Mr. Abele the other day. Those already were automating hospital procedures as well as being used for research analyses, he said.

"Integration of modern communication systems and automatic copying, photographing and printing equipment into hospitals and clinics are also classified as administrative medical instrumentation," Mr. Abele said.

But the transition to the black box, he went on, "has been considerably slowed by lack of meaningful interaction between the medical men and engineering groups."

With the increasing number of patients for each physician, Mr. Abele said, the development and practical use of medical instrumentation will permit the medical man to spend more time with individual patients.

Mr. Abele said that automatic monitoring instruments that recorded vital physical data on several patients at one time and reported those to a central nursing stations was an example of the use of instrumentation.

Need Becomes Critical

"As patients become numbers entered into a hospital computer, the need for radically improved communications between doctors and their engineer collaborators becomes critical," said Mr. Abele.

"Since nonstaff doctors will be entrusting their patients to the care of computerized systems and other automatic medical instrumentation, communicating the techniques, advantages and limitations to them is also important."

Among the companies that have accepted places on the manufacturers' advisory board, in addition to Advanced Instruments, Inc., are the American Optical Company, Arthur D. Little, Consolidated Electrodynamics Corporation, a subsidiary of Bell & Howell Company; International Equipment Corporation and the Smith Kline Instrument Company, a division of Smith Kline & French Laboratories.

Dr. Merrill's medical advisory committee includes Dr. Lewis W. Bluemle, director of the Clinical Research Center, University of Pennsylvania Hospital, Philadelphia; Dr. Millard N. Croll, director of the Nuclear Medicine Center, Hahnemann Medical College and Hospital, Philadelphia, and Dr. Matthey M. Patton, pathologist, Sacred Heart General Hospital, Eugene, Ore.

Where did AAMI's name come from?

Robert D. Hall, an advertising executive, came up with the name Association for the Advancement of Medical Instrumentation as a play on the name of the AAAS, American Association for the Advancement of Science.

1966

First issue of AAMI journal *Medical Instrumentation* published in July.

1967

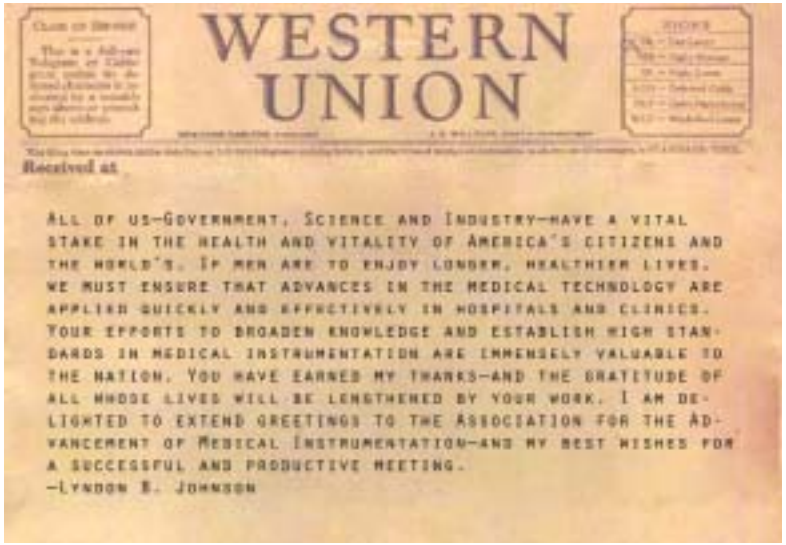
AAMI standards committee, chaired by Charles D. Ray, MD, announces in a March report AAMI's plans to enter the standards arena.

The AAMI Idea Catches On

AAMI's first newsletter appeared on September 1, 1965, and the journal premiered in July 1966. But the event that garnered AAMI the most attention was its first meeting, named MEDAC '66. It was attended by then FDA commissioner James L. Goddard, MD. Leading surgeons such as Beall and Harken, artificial heart pioneers Michael DeBakey and Adrian Kantrowitz, kidney transplant pioneer John Merrill, and cardiac surgeon and inventor Warren Zeph Lane took part in the meeting.

AAMI was an idea whose time had come. Businessmen (and they were all men then) saw an opportunity for visibility, an opportunity to influence the practice of medicine and see their technologies applied earlier. Physicians saw in AAMI an opportunity to develop education programs, standards, and communications that would perpetuate the flourishing development of exciting new technologies. Many were worried about how pending government regulation would affect innovation and development, and they saw the need for interaction between the stakeholders—doctors, industry, government, researchers, and engineers. AAMI was perceived as a vehicle through which diverse groups could achieve consensus on a number of issues that were defining the field.

Fortunately for AAMI, many leaders in the fields of medicine and business came on board to help the organization get started, taking positions as officers or directors. A manufacturer's advisory board and a medical advisory board were created, adding physicians to the leadership who would lend professional legitimacy to the organization. With so many well-known names in medicine on its side, it did not take long for the organization to get off the ground.



WESTERN UNION

Received at

ALL OF US—GOVERNMENT, SCIENCE AND INDUSTRY—HAVE A VITAL STAKE IN THE HEALTH AND VITALITY OF AMERICA'S CITIZENS AND THE WORLD'S. IF MEN ARE TO ENJOY LONGER, HEALTHIER LIVES, WE MUST ENSURE THAT ADVANCES IN THE MEDICAL TECHNOLOGY ARE APPLIED QUICKLY AND EFFECTIVELY IN HOSPITALS AND CLINICS. YOUR EFFORTS TO BROADEN KNOWLEDGE AND ESTABLISH HIGH STANDARDS IN MEDICAL INSTRUMENTATION ARE IMMENSELY VALUABLE TO THE NATION. YOU HAVE EARNED MY THANKS—AND THE GRATITUDE OF ALL WHOSE LIVES WILL BE LENGTHENED BY YOUR WORK. I AM DELIGHTED TO EXTEND GREETINGS TO THE ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION—AND MY BEST WISHES FOR A SUCCESSFUL AND PRODUCTIVE MEETING.

—LYNDON B. JOHNSON

President Lyndon B. Johnson sent a congratulatory telegram to AAMI extending best wishes for a successful meeting.

MEDAC '66 was a dynamite meeting. The giants in medicine attended. Those were the people who changed the world.

John Abele

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

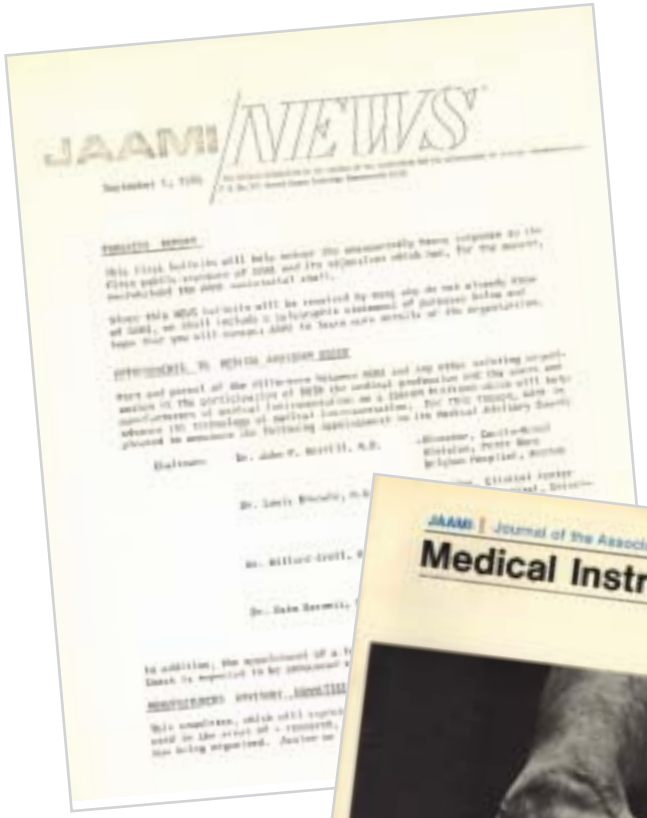
1967

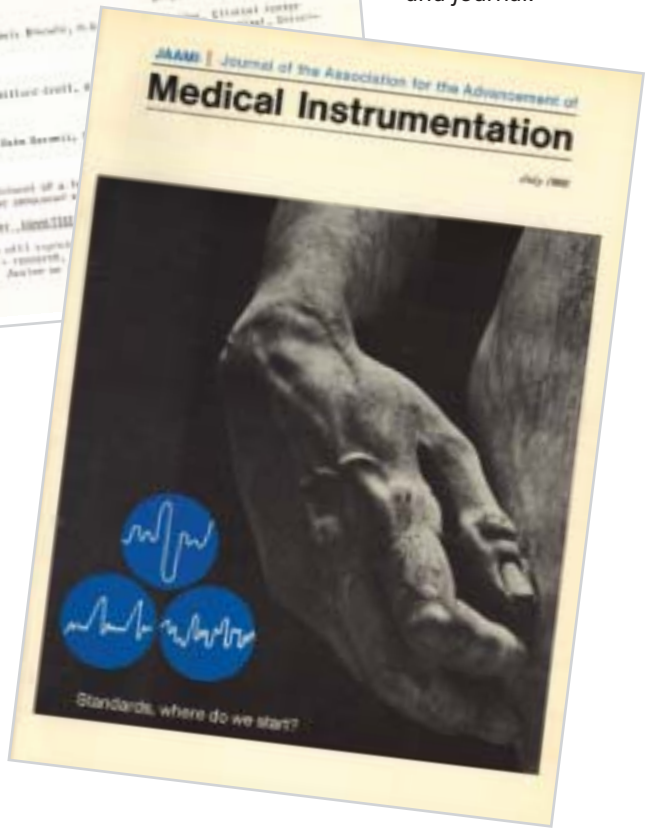
MEDAC '67 held in July in San Francisco, CA. Arthur C. Beall, Jr., MD, elected president.

1967

In a September 5 letter, AAMI president Arthur C. Beall announces reorganization of the association, the launch of a fundraising campaign to erase a $58,000 deficit, and the temporary halt of publication of *Medical Instrumentation* until a new publisher can be found.

Shots from MEDAC '66, AAMI's first meeting.





Cover shots of AAMI's first newsletter and journal.

1967

AAMI announces in November that it will help develop the first biomedical equipment technician (BMET) training programs and study the need for the profession in partnership with the Technical Education Research Center (TERC).

1968

New publishing contract for *Medical Instrumentation* announced with The Williams & Wilkins Company; journal resumes publication with January 1969 issue.

A Bumpy Transition to Physician Control

The transition from the initial organizers to physician control shook up the young organization. Publication of AAMI's journal, *Medical Instrumentation*, was halted while the board found a new publisher—Williams & Wilkins of Baltimore—and a new editor—Harry S. Lipscomb, MD, of the Baylor University College of Medicine. The revamped journal reappeared in January 1969. AAMI's third annual meeting—no longer called MEDAC—took place in Houston, TX, under Beall's leadership.

Significant financial problems also plagued the organization. A 1967 financial review showed that AAMI carried a $58,000 debt which the board rallied to eliminate. By the end of 1969, with the help of a hugely successful conference on medical device regulation, they had erased the debt and firmly established AAMI as a force in the medical device field.

Early Leaders Raised Funds to Keep AAMI Afloat

Arthur C. Beall, Jr., and John Kimbell (from Baxter Labs) became AAMI's chief fundraisers. "AAMI borrowed some money from individuals, and in many cases, those debts were forgiven," recalls John Abele. "Art Beall squeezed the arms of his corporate friends, and Medtronic and its founder, Earl Bakken, stepped in and saved AAMI many times."

Warren Zeph Lane [left] as AAMI's treasurer and John Kimbell [right] as one of AAMI's chief fundraisers worked in 1967 and 1968 to erase the $58,000 debt AAMI had inherited from its earliest leaders.

Harry S. Lipscomb, MD, took over as editor of Medical Instrumentation *with the July 1968 issue.*

AAMI Founding—1965 or 1967?

"The real AAMI was created in 1967, despite the founding of the shell that existed prior to that time," says Mike Miller, who came on board as AAMI's chief executive officer in 1969 and still holds that post today. "It's a real tribute to the strength and foresight of those early founders who cared enough and valued the idea of AAMI enough to wrest the organization away and raise the money to keep it going."

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1969

Association office relocated to Washington, DC, area from Boston, MA.

1969

Mike Miller hired as executive director.

1969

Successful fundraising campaigns led by Dwight Harken, Art Beall, and John Kimbell erase debt and give AAMI an operating surplus.

Physician Leaders Position AAMI for Future Success

From 1967 to 1969, AAMI's new physician leaders moved to position AAMI for future success. In light of the new legislative climate that was emerging as FDA regulation of medical devices became inevitable, they relocated the association's headquarters to the Washington, DC, area and began a search for a permanent executive director. They found Mike Miller, who had a law degree and an association management background with experience in lobbying and legislation. In hiring Miller, the board found an executive who would lead AAMI through the next four decades.

Since 1967, AAMI—with its volunteer leaders and growing staff—has had a profound impact on the medical device field. Building on the efforts of its early leaders, the organization has gone on to play key roles in regulation of medical devices, the emergence of the biomedical equipment technician and clinical engineering professions, and the creation of consensus standards and educational programs that have taken on global importance in ensuring the safety of medical devices.

When we interviewed Mike, we could see that he got it, that he was able to see the horizon. Mike understood how to deal with all the constituencies of AAMI and their unique concerns and emotional biases.

John Abele

Mike Miller Recalls the Early Days

"During my early years, volunteer leaders were always there to provide guidance to a very young and inexperienced CEO," says Mike Miller, who has helped to lead AAMI since 1969. He describes those early days as ones of great challenge. "When I arrived at AAMI, two organizational lawsuits were pending; we had no money; we had no staff. Officers had to sign personal notes to make sure payrolls were met. In a sense, AAMI existed in the offices of its leaders."

The most important issue facing the young organization was the emerging medical device legislation.

1969

AAMI holds "A National Conference on Medical Devices," supported through funding from the National Institutes of Health. This conference led to the release of the Cooper Report, which outlined a practical context and framework for legislation that was ultimately approved in the 1976 medical device law.

Founder Profiles

Dr. Beall knew how to work with industry better than anyone. He was devoted to AAMI's mission.

W. Gerald Rainer, MD

Dr. Beall was the epitome of a surgical statesman. He was a mentor to me and hundreds of surgeons he trained.

Kenneth L. Mattox, MD

The Beall Mitral Valve Prosthesis.

Arthur C. Beall, Jr., MD

Dr. Arthur C. Beall, Jr., was one of AAMI's leading founding physicians and served as AAMI's president in its formative years, from 1967 to 1969. He served on AAMI's Board of Directors for many years after and chaired most AAMI committees at one time or another. He helped create the concept of the Annual Conference, membership, standards program, journal, and a number of programs that exist today as he envisioned them. Working with other leaders in the field, Beall helped to develop the leadership and financial support necessary to move AAMI from a young and developing organization to what it is today.

Beall played a leading role in AAMI's efforts to ensure that medical device regulation reflected (and did not hinder) the unique contributions of medical device technology. Along with Dwight E. Harken, MD, Beall was one of the primary people who effectively conveyed the perspective of the patient, medical, industrial, and engineering community to the U.S. Congress. Beall was often referred to as the "Surgical Senator."

Beyond AAMI, Beall made a significant contribution to the healthcare field in general. He was a cardiac surgeon on the faculty of Baylor College of Medicine. In his research endeavors, Beall was well-known in the field of heart valve replacement, at one time developing a valve of his own design, which for several years was one of the most popular mitral valves.

No one contributed more to AAMI's inception, goals, and basic concept than Dr. Beall.

Mike Miller

Art Beall was a mover and a groover, the driving force in lobbying for reasonable legislation. He projected a good image for AAMI and was an excellent front man.

Larry Pilot

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1970

First Arthur C. Beall, Jr., MD Commemorative Lecture delivered by Dwight Harken, MD, during AAMI Annual Meeting. Harken was a last-minute stand-in for scheduled speaker Dr. Carl Walter, who came down with a sudden illness. Short on preparation time but true to form, Harken's presentation on periontogenic diseases was a highlight of the conference. In 1994, Beall would insist that the name of the lecture be changed in honor of his friend and colleague Harken. Beall secured a $35,000 endowment from Michael W. Dunaway, CEO of PSICOR, to sponsor the award, which to this day is known as the AAMI/PSICOR Dwight Harken, MD Memorial Lecture.

AAMI founders Art Beall [left] and Dwight Harken in 1984.

Dwight Harken knew everyone in the field, including at the National Institutes of Health. He provided strong leadership and used his tremendous connections to benefit AAMI.

John Post

Dwight Emary Harken, MD

Dwight Harken was one of the driving forces in AAMI's creation in the 1960s and a leader in the association for many years. He served as AAMI's president from 1969 to 1970. It was he who organized the 1969 National Conference on Medical Device Regulation held in Bethesda, MD. This conference led to the release of the Cooper Report which outlined a practical context and framework for legislation that was ultimately approved in the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Significantly for AAMI, this conference was also a financial success and gave the young organization a firm financial foundation for the first time. Harken served as editor of AAMI's journal, *Medical Instrumentation*, from 1974 to 1984.

Harken was truly a pioneer in cardiac surgery. In 1948, he became one of the first surgeons to perform mitral valve surgery on a beating heart. In 1960, he was the first to successfully insert a caged ball valve in the normal anatomic position. He was also first to carry out cardioversion with a Lown cardioverter, first to establish that direct current defibrillation caused less myocardial damage, and first to prove the safety of and to implant a demand pacemaker in a human recipient.

He was a giant in the field, a renaissance man. He often read books in the original Greek or Latin.

John Abele

Dr. Harken stands alone in providing time, energy, and resources to serve AAMI as a leader. He was very dedicated to the concept of AAMI and its success.

Mike Miller

1971

Lt. Col. Burt Dodson, USAF, appointed chairman of National Examining Board for BMETs with the goal of creating a certification exam.

1971

AAMI membership exceeds 2,000 individual members.

John Abele

John Abele was an AAMI leader from the very beginning, with his name appearing on the Articles of Organization filed in Massachusetts in June 1965. He served as chair of AAMI's Manufacturers Advisory Board and on AAMI's Board of Directors. He also volunteered one of his employees, John Post, to serve as AAMI's first executive director. In the mid-1960s, Abele was vice president and general manager of Advanced Instruments, Inc., a manufacturer of laboratory instruments and distributor of the first implantable pacemaker. In 1969 he joined with an inventor in a company called Medi-Tech, which developed catheter-based tools for cardiology. In 1979, he teamed up with Peter Nicholas to form Boston Scientific and today serves as its founder chairman. Boston Scientific is now an $8 billion worldwide company that focuses on minimally invasive products.

Phillip Bardos

Phillip Bardos was a founding member of AAMI's Manufacturer's Advisory Board and served as assistant chairman of the AAMI Standards Committee in the 1960s. He was then corporate director of development planning at Consolidated Electrodynamics Corp., a subsidiary of Bell & Howell Company. He held a master's degree in electronic engineering from Penn State.

John Post

John Post was AAMI's first executive director in 1966, after graduating from Harvard Business School. He participated in the first MEDAC meeting and managed the next two annual meetings in San Francisco and Houston. In 1968 he joined Hewlett Packard in its Medical Electronics Division but continued to assist AAMI in several roles, serving as AAMI's treasurer in the early 1970s and playing an active role in AAMI's early electrical safety work. His career at HP included product management, division marketing, manufacturing operations, field service, general management, and field sales.

Carl Berkley

Carl Berkley, an engineer, was an early AAMI board member. He was influential in early AAMI board meetings in establishing AAMI's new physician-based leadership in 1967. Berkley also served as chair of AAMI's Engineering Advisory Board, formed in 1967.

J. Scott Butterworth, MD

J. Scott Butterworth served as AAMI's first president, elected in 1966 at AAMI's first meeting, called MEDAC '66. He also served on the medical review board of AAMI's journal, *Medical Instrumentation*, starting with its second issue. A cardiac surgeon, Butterworth was a past president of the American Heart Association.

John J. Collins Jr., MD

John (Jack) Collins was a cardiac surgeon at Peter Bent Brigham Hospital and protégé of Dwight Harken. He joined AAMI's Board of Directors in 1969 and served as AAMI president from 1970 to 1971. He chaired AAMI's 5th Annual Meeting and played an active role in AAMI's efforts to influence the medical device legislation developed in the early 1970s.

John T. Kimbell

John T. Kimbell, vice president and later CEO of Baxter Laboratories, served on AAMI's Board of Directors for several years. A tireless fundraiser, he helped AAMI become financially stable in its early years. He also played an instrumental role in AAMI's efforts to influence medical device legislation in the early 1970s.

Warren Zeph Lane, MD

Warren Zeph Lane, MD, served as AAMI's treasurer in its formative years until his untimely death in May 1969. He played a key

role in helping AAMI stabilize its finances in those early days. A thoracic and cardiovascular surgeon, he practiced medicine in both New York and Connecticut. He was a member of AAMI's board of directors since its first election.

Harry S. Lipscomb, MD

Harry S. Lipscomb took over as the first editor of AAMI's journal, *Medical Instrumentation*, in 1968. He continued in that role until 1972, when Dwight Harken became editor. Lipscomb was elected to join AAMI's board of directors in 1968, where he served for several years. Lipscomb was chairman of the department of biochemistry at Baylor University College of Medicine.

W. Gerald Rainer, MD

W. Gerald Rainer attended many of AAMI's earliest meetings and began his service on the Board of Directors in 1969. He served as AAMI's president from 1972 to 1973. He played a role in the passage of the 1976 Medical Device Amendments, actively lobbying Congress on AAMI's behalf. He was also involved in AAMI's very early standards work serving as a member of AAMI standards committees and attending the first European Congress on standards in 1972 and an early International Organization for Standardization meeting in London. He serves as chair of the Harken Memorial Awards Committee today. A thoracic and cardiovascular surgeon, Rainer is a distinguished clinical professor of surgery at the University of Colorado Health Sciences Center.

Charles D. Ray, MD

Charles D. Ray served as chair of AAMI's first standards board starting in 1966. In that role, he led efforts to define AAMI standards activities and set program policies. He also published many articles in AAMI's journal, *Medical Instrumentation*. Ray was an assistant professor of neurological surgery at the Johns Hopkins University School of Medicine.

Mike Miller

Mike Miller has served as AAMI's CEO since 1969. He has overseen AAMI's efforts in the development of medical device legislation, standards, and regulations. He also has been substantially involved with the development and management of nonprofit association education, communications and standards, business strategies, and programming for more than 35 years. Miller, who holds a law degree from George Washington University Law School, came to AAMI with an association management background and experience in lobbying and legislation.

Over the last four decades, under Miller's leadership, AAMI has grown into a thriving association—a successful alliance of nearly 6,000 diverse members united by the common goal of increasing the understanding and beneficial use of medical instrumentation. Today, Miller oversees a staff of 40 who manage AAMI programs and membership services that have blossomed under his leadership. He also enjoys the support of an 18-member Board of Directors, and the commitment of dozens of dedicated professionals in the medical technology industry who volunteer their time and resources.

"AAMI has been blessed with great staff and volunteer leaders who have contributed greatly to medical device standards development; standards-based educational programs; and medical technology management forums, education, and recognition programs."

Sylvia Chandler

While not a founder, Sylvia Chandler has been AAMI's longest-serving staff member, second only to Mike Miller. Chandler joined AAMI in October 1978 as an assistant to the Executive Director. She now serves as AAMI's Vice President, Administration, overseeing the association's general office and human resources administrative functions and a three-person accounting department.

"It's been exciting and satisfying to work with so many dedicated, hard-working employees and AAMI leaders over the years and to be involved with such a vibrant, quality-driven organization."

Pioneers in Medicine Lend AAMI a Helping Hand Early On

Earl Bakken

Earl Bakken, the founder of Medtronic, played an active role in AAMI's early days, often providing financial support to the young organization and served on AAMI's Board of Directors in the early 1970s.

Bakken won the AAMI Foundation Laufman-Greatbatch Prize in 1998 in recognition of his unique and significant contribution to the advancement of medical instrumentation. He developed one of the first wearable, external, battery-powered, transistorized pacemakers in 1957. Bakken lives in Hawaii today where he is pursuing efforts to link high-tech with high-touch medicine.

Michael E. DeBakey

Michael E. DeBakey, a pioneering cardiovascular surgeon and researcher, served on AAMI's Board of Directors for several years starting in 1966, and frequently published articles in AAMI's journal, *Medical Instrumentation*. DeBakey was one of the first to perform coronary artery bypass surgery, and in 1953 he performed one of the first successful carotid endarterectomies. He was an innovator in developing an artificial heart. In 2006, at the age of 97, he underwent heart surgery using a procedure that he had pioneered and has now returned to good health.

Wilson Greatbatch

Wilson Greatbatch, an electrical engineer and inventor, invented one of the first implantable cardiac pacemakers. In recognition of his work, he won the AAMI Foundation Harold Laufman Award in 1982. Later in that meeting, he made a generous gift to AAMI of stock in his corporation. That same award now bears his name, the AAMI Foundation Laufman-Greatbatch Prize, and honors those who make unique and significant contributions to the advancement of medical instrumentation. Greatbatch subsequently developed advanced pacemakers and pacemaker power sources and started several companies. Wilson Greatbatch, Ltd., today manufactures lithium iodide batteries for the pacemaker community; Mennen-Greatbatch Electronics markets hospital medical monitoring equipment that evolved from astronaut physiological instrumentation originally invented for the first U.S. monkey space shots. Greatbatch Gen-Aid, Ltd., provides genetic assistance to medical and agricultural professions, and Greatbatch Enterprises, Inc., is pursuing nuclear power generation and the design of an MRI-compatible pacemaker.

Adrian Kantrowitz, MD

Adrian Kantrowitz, a pioneering cardiac surgeon and inventor, has been an active participant in AAMI meetings through the years and has published articles in AAMI's journal, *Medical Instrumentation*. More recently, Kantrowitz presented the Dwight E. Harken Lecture at AAMI's Annual Meeting in 1998, speaking about "Mechanical Devices to Aid the Failing Heart."

Photo courtesy of the Bakken Library and Museum.

Pioneering inventors Earl Bakken and Wilson Greatbatch at a medical meeting in the early 1970s.

Edward Duffie's major contributions to the 1991 AAMI reorganization helped refocus the association's strategic priorities and position it for major growth. Also, he is recognized for his leadership in helping to reposition the association's standards program to respond to the globalization of the medical device industry, the increasing role of standards in international regulation, and the need for the international harmonization of standards and regulations. These two leadership roles were pivotal to AAMI success during the last 15 years.

Mike Miller, AAMI chief executive since 1969

Kantrowitz, founder and scientific leader of L-VAD Technology, Inc., performed the first implantation of a left ventricular assist device intended to remain in the body for congestive heart failure treatment in 1966. He performed one of the first heart transplants in the United States and was the first in the world to perform a heart transplant in an infant. He developed an early implantable cardiac pacemaker and developed and introduced the first practical intraaortic balloon pump.

John P. Merrill, MD

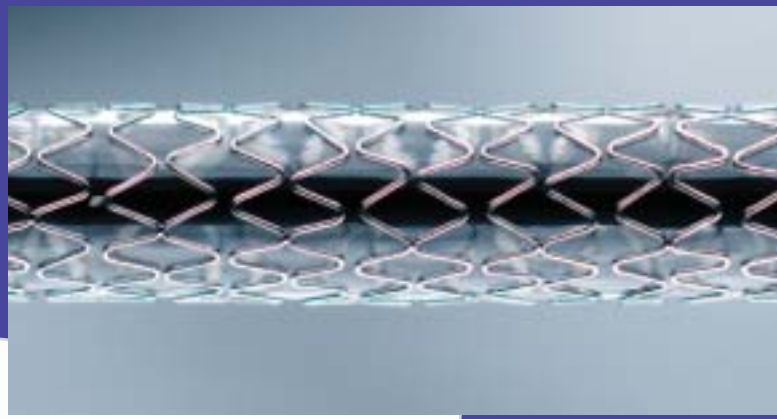
John Merrill, the kidney transplant pioneer, lent his name and his prestige to AAMI as early as 1965 as chairman of the association's Medical Advisory Board. He also served on AAMI's Board of Directors for several years. A nephrologist and surgeon at the Peter Bent Brigham Hospital, Merrill and his colleagues performed the first successful human kidney transplant in 1954 on identical twins.

Edward R. Duffie, Jr., MD

Edward R. Duffie, Jr., MD, spent 20 years taking care of infants and children with heart disease as a pediatric cardiologist before moving on to Becton Dickinson and Co. as the medical device manufacturer's corporate medical director. It was at BD that Duffie would hone the management and strategic planning skills that he would bring to AAMI in 1982. As chairman of AAMI's Strategic Planning Committee beginning in 1985, Duffie introduced a way of thinking about the future that was markedly different from the strategic and financial planning model the organization had used throughout its early years. As a direct result of Duffie's leadership, AAMI adopted a governance and management model that resulted in a new organizational structure that continues to this day. For his efforts on behalf of the organization, Duffie received the AAMI's Leadership Award in 1994.

Renowned surgeon Michael DeBakey debated possible artificial heart designs with Adrian Kantrowitz, MD, at AAMI's first meeting, called MEDAC '66.

Inventor Wilson Greatbatch in a 1991 *AAMI News* clipping. He built a solar-powered canoe and celebrated his 72nd birthday by traveling a record-setting 142 miles in it. "I spent $3,000 on the parts for this canoe, and added 300 pounds to its weight, to get a craft which doesn't go quite as fast as the Indians did 200 years ago," he said. Isn't progress wonderful?



AAMI's founders worked to ensure that legislation would not hamper development of new devices, such as Medtronic's Endeavor drug-eluting stent, shown here.

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION

9865 Rockville Pike, Bethesda, Maryland 20014
Telephone: (301) 530-2800

January 15, 1970

The Honorable Donald D. Clancy
U.S. House of Representatives
208 Cannon House Office Building
Washington, D.C. 20515

Dear Mr. Clancy:

The enclosed report of the deliberations and recommendations of a National Conference on Medical Devices held on September 6th and 7th, 1969, in Bethesda, Maryland, represents a unique contribution by prominent representatives of government, industry, engineering, and medicine to the health of all citizens of the United States of America as it relates to medical devices.

The participation of these persons, expert in diverse fields, was necessary and desirable to further the public interest in development of effective and safe medical devices. This conference was sponsored by the Association for the Advancement of Medical Instrumentation with financial support from the National Heart Institute. As Conference Director, I take great pride in presenting to you this report representing a milestone in cooperative effort to assure our Nation the best in health care devices.

The Association for the Advancement of Medical Instrumentation is a non-profit, professional organization of physicians, engineers, representatives of industry and members of diverse scientific fields pertaining to the development, evaluation and utilization of medical devices. The Association was founded in 1965.

The Medical Profession is now confronted with an estimated 5,000 medical instruments and devices produced by over 1,300 manufacturers. New devices are appearing on the market in increasing numbers. Understandably, this progressive advancement of medical instrumentation presents a complex problem which must be solved if all patients are to receive the best available medical care.

Page 2

One of the areas in which great progress must be made in the near future is that of device legislation. You will notice a section of this conference was devoted to that topic. Critical to the development of useful legislative proposals is the development of accurate terminology. Particularly, the definition of devices (as opposed to drugs) and further refinement of this to specifically include a classification of types of devices is an absolute necessity.

In the public interest, I respectfully suggest that you carefully consider the contents of this Devices Report. Progress must certainly be made in medical instrumentation. Great care must be exercised on the part of all concerned to ensure that we do not deprive the patient of the benefit of scientific advancement either by strangling initiative in development or by crippling the mechanisms for widespread utilization of effective methods and mechanisms.

Thank you very much for your service to us all. Please let us know wherever we can be of assistance to you and, through you, to our patients.

Sincerely yours,

Dwight E. Harken

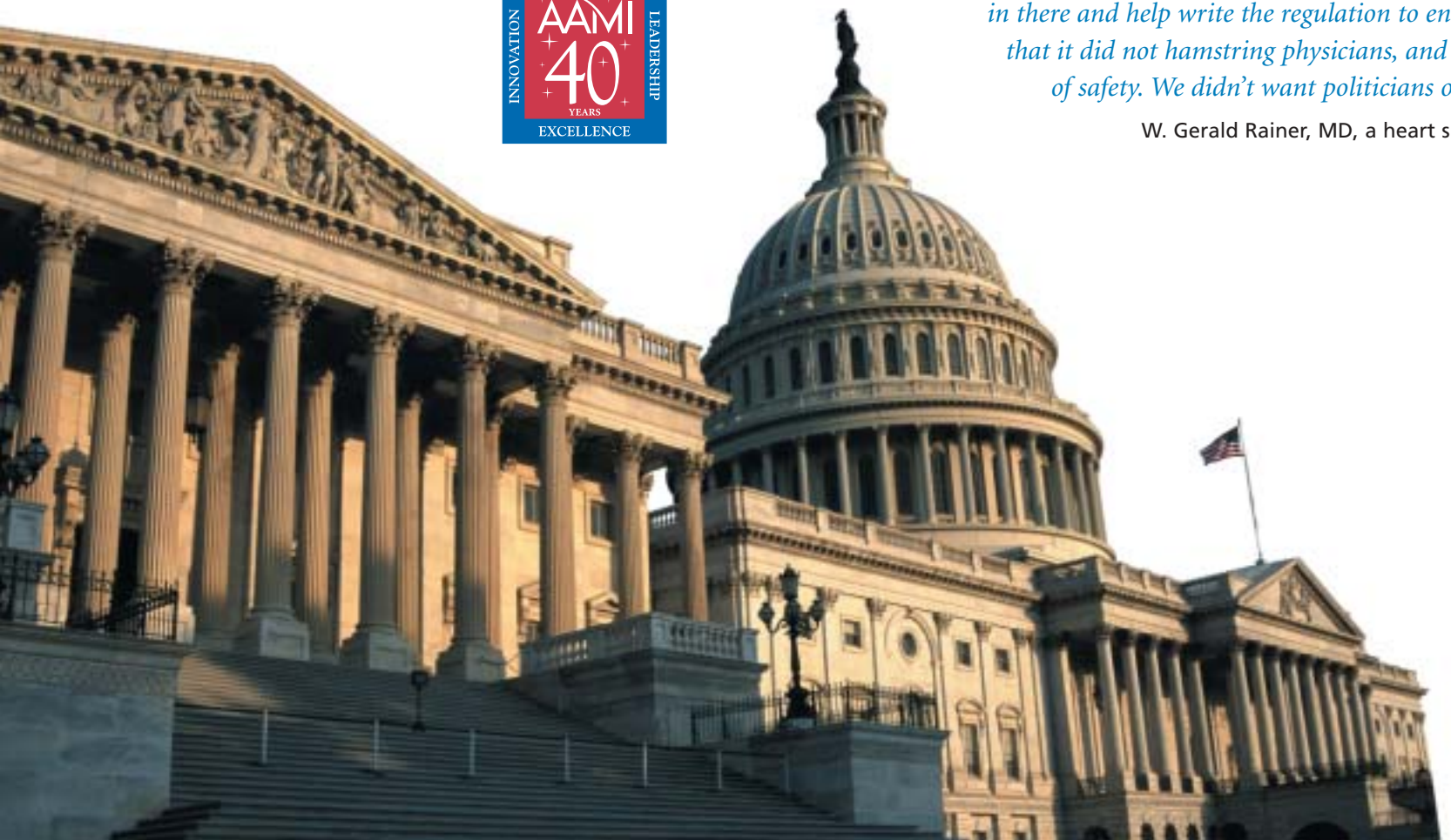
Dwight E. Harken, M.D.

A letter to Congress from Dwight Harken sharing the results of AAMI's 1969 National Conference on Medical Devices.

AAMI's Role in Medical Device Regulation

We doctors knew that regulation was inevitable. We wanted to get in there and help write the regulation to ensure that it was sensible, that it did not hamstring physicians, and that it spoke to the issue of safety. We didn't want politicians or bureaucrats writing it.

W. Gerald Rainer, MD, a heart surgeon and AAMI founder



1960s Bring Mounting Pressure for Device Regulation

In the 1960s, the specter of government regulation of medical devices was looming over the medical community. While FDA had been actively regulating drugs since 1906, it rarely exercised its power in the field of medical devices.

By the late 1960s, though, the agency was seeking authority to regulate medical devices the way it did drugs. Concern about device safety was prompting Congressional leaders to introduce bills on device regulation, and both President Johnson and President Nixon called for device regulation in messages to Congress.

Key Milestones in Device Legislation

1906 • Federal drug legislation first enacted.

1931 • The Food, Drug, and Insecticide Administration, which was formed in 1927, is renamed the Food and Drug Administration.

1938 • The Food, Drug and Cosmetic Act introduces the concept of premarket clearance of drugs for safety and extends coverage to devices, making it illegal to sell therapeutic devices that are dangerous or marketed with false claims.

1962 • The Kefauver-Harris Amendment first requires proof of drug efficacy.

1967 • President Lyndon B. Johnson includes a call for medical device legislation in his message to Congress.

1968/1969 • In two legal cases, the AMP case and the DIFCO case, the courts establish a basis for treating conventional medical devices as drugs, opening the door to subjecting many devices to drug preclearance.

1969 • President Richard M. Nixon delivers a special message to Congress on consumer protection calling for regulation of medical devices.

President Nixon's 1969 Call for Device Regulation

"Another important medical safety problem concerns medical devices—equipment ranging from contact lenses and hearing aids to artificial valves which are implanted in the body. Certain minimum standards should be established for such devices; the government should be given additional authority to require premarketing clearance in certain cases. The scope and nature of any legislation in this area must be carefully considered, and the Department of Health, Education, and Welfare is undertaking a thorough study of medical device regulation. I will receive the results of that study early in 1970."

—Richard M. Nixon in his October 30, 1969, Special Message to Congress on Consumer Protection

1969

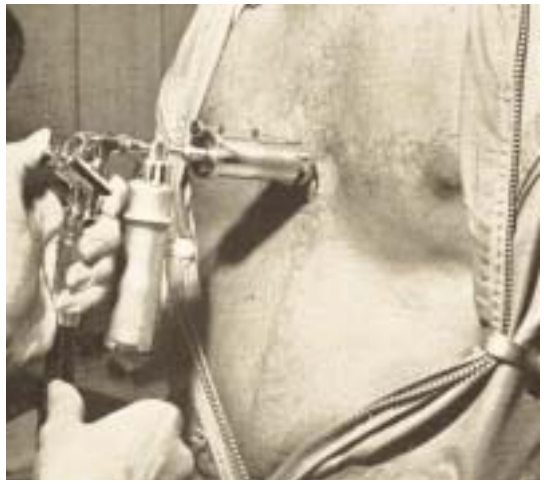
AAMI holds "A National Conference on Medical Devices," supported through funding from the National Institutes of Health. This conference led to the release of the Cooper Report, which outlined a practical context and framework for legislation that was ultimately approved in the 1976 medical device law.

AAMI should not become involved in the impending controversy associated with federal legislation, but instead assert its policy of being a fact-finding, impartial, expert, objective, but active organization.

AAMI Policy on Government Legislation, 1967

To put the subject in perspective, it has been pointed out that toilet valves must undergo several preclearances before they can be used. Yet a pacemaker inserted in the body to regulate the heart need not be tested or examined at all.

Virginia Knauer, special assistant to President Nixon for consumer affairs, opening the meeting with remarks that highlighted the government's concerns over device safety



Device photos from early issues of Medical Instrumentation.

Two Legal Cases in the Late 1960s Threatened Drug-Like Regulation for Devices

AMP Case. The company brought suit against FDA in 1967 when the agency sought to classify its device—a nylon locking disc used to tie off or ligate severed blood vessels during surgery—as a drug. AMP lost its case and the Supreme Court declined to hear its appeal.

DIFCO Case. Also known as the Bacto-Unidisk case, it concerned a cardboard disc impregnated with antibiotics for use as a laboratory testing device. The government condemned the product from interstate commerce in 1968, contending it was a drug and therefore misbranded. The Supreme Court did agree to hear an appeal in this case, concluding that FDA does have the power to regulate that product as a drug.

1972

First AAMI/FDA conference on medical device regulation held.

1974

AAMI board member David Link appointed head of FDA's Bureau of Medical Devices and Diagnostic Products.

AAMI Organizes 1969 National Conference on Medical Device Regulation

AAMI, under Dwight Harken's leadership, organized a conference in Bethesda, MD, in 1969 to address device safety concerns of the medical community and the government. The National Institutes of Health (NIH) offered start-up funding for the conference, giving AAMI a grant of $20,000. Harken authored a letter to the AAMI membership and industry outlining the importance of the event and raised an additional $100,000.

Manufacturers saw AAMI and its physician members as a means of helping to secure constructive legislation and were eager to sign on to support the conference. Doctors, heavily dependent on devices and afraid that their promise could be throttled by government regulation, were also eager to participate.

Leaders from all sectors were pulled into the conference—people from the highest levels of government, industry, and medicine. The 1969 conference had an impact on device regulation like no other meeting before or since. The report from AAMI's conference was published simultaneously in many major engineering, medical, industrial, nursing, and other journals and trade publications. The report included task force recommendations on device regulation that outlined the framework of the legislation that was ultimately adopted in 1976.


A NATIONAL CONFERENCE
ON
MEDICAL DEVICES
Bethesda, Maryland
September 6-7, 1969

A detailed report of discussions at AAMI's 1969 Bethesda conference was published in the Nov/Dec 1969 issue of AAMI's journal, Medical Instrumentation*, and simultaneously in every major medical journal of the time, along with engineering, industrial, nursing, and other journals and trade publications.*

This conference was a huge event. It was the first time that the presidents of every American Medical Association-recognized society were present in one room.

John Abele, AAMI founder and Board member


JAAMI: Journal of the Association for the Advancement of
medical instrumentation
Contents

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1976

Medical Device Amendments to the Food, Drug & Cosmetic Act of 1938 are enacted to ensure safety and effectiveness of medical devices.

1978

FDA good manufacturing practices (GMP) regulations become effective.

This collection of photos was taken at the 1974 AAMI/FDA Conference on Medical Devices. AAMI sponsored such meetings frequently to provide a forum to discuss issues related to the emerging legislation and continues to hold them today as The AAMI/FDA International Conference on Medical Device Standards and Regulation.

Mort Levin, Hewlett-Packard Co.

Michael J. Miller, JD, AAMI

Herbert H. Ley, MD, Consultant

Robert J. Cangelosi, FDA

Charles A. Hufnagel, MD,
Georgetown University Hospital

Dwight E. Harken, MD,
Harvard Medical School

Great care must be exercised on the part of all concerned to ensure that we do not deprive the patient of the benefit of scientific advancement either by strangling initiative in development or by crippling the mechanisms for widespread utilization of effective methods and mechanisms.

Dwight Harken, MD, in a letter to Congress sharing the results of AAMI's 1969 National Conference on Medical Devices

1984

Medical Device Reporting regulation published requiring manufacturers to report device-related incidents to FDA.

1990

Safe Medical Devices Act requires user facilities to report device incidents to FDA.

AAMI Leadership Works to Ensure Effective Legislation

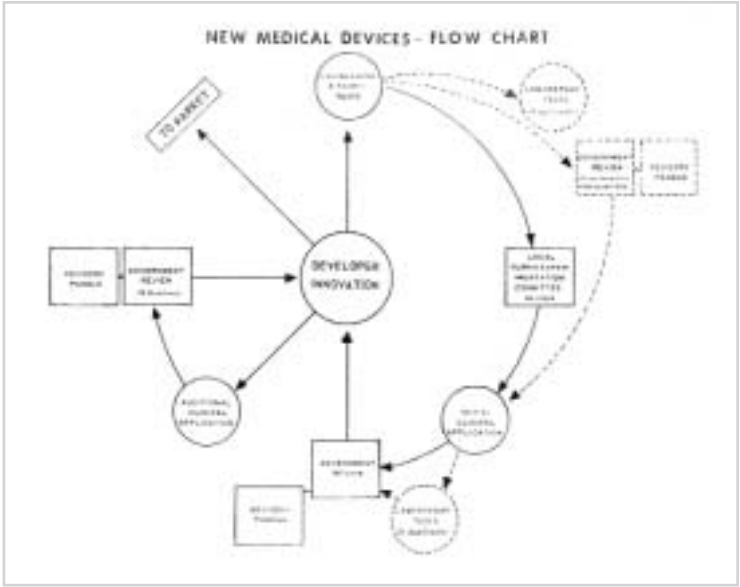
Following the 1969 conference, the Department of Health, Education, and Welfare organized the Study Group on Medical Devices chaired by Theodore Cooper, MD, director of the National Heart and Lung Institute. The group's report—known as the Cooper Committee Report—built on the AAMI report and fed directly into subsequent device-related bills introduced into Congress.

Arthur Beall, Dwight Harken, John Collins, W. Gerald Rainer, and other AAMI leaders worked tirelessly to ensure that the evolving legislation would protect patient safety without hampering innovation of medical devices. They literally wrote sections of the legislation. They worked closely with FDA executives like David Link, who would eventually become Director of FDA's Bureau of Medical Devices and Diagnostic Products and Larry Pilot, another FDA executive who wrote many of the regulations that would put the legislation into practice.

As the legislation worked its way through the halls of Congress, FDA was already beginning its implementation efforts. AAMI members were actively involved in those efforts as well.

A year-long effort was launched to inventory the medical device industry, and AAMI helped the agency gather information. In the early 1970s, a series of meetings was held to classify devices according to risk. AAMI president John Collins chaired the committee evaluating cardiovascular devices and AAMI board member Harlan Amstutz chaired the committee on orthopedic devices. AAMI also held a series of conferences to bring the diverse medical device community together to consider regulatory issues.

On May 28, 1976, Gerald R. Ford signed the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act into law and a new era in device regulation was born.



The Cooper Committee Report, published in September 1970, built on the ideas formulated during AAMI's 1969 Conference on Medical Device Regulation. This flow chart from the Cooper Report depicts the route that new devices would take to reach the marketplace.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1991

AAMI holds series of highly successful seminars on Safe Medical Devices Act of 1990 in partnership with ECRI.

1997

FDA Modernization Act signed into law; new quality systems (QS) regulation takes effect. AAMI launches successful course series based on the new QS regulation.

1976 Medical Device Amendments: Key Requirements

- Medical devices must be classified according to their comparative risk, and regulated accordingly.
- Three classes of medical devices were created, each requiring a different level of regulatory scrutiny, up to premarket approval.
- Good Manufacturing Practice regulations also were authorized—a set of procedures to ensure that devices are manufactured to be safe and effective through quality design, manufacture, labeling, testing, storage, and distribution.

Theodore Cooper, MD, for whom the Cooper Committee was named, delivers a keynote address at AAMI's 1973 Annual Meeting. Pictured listening from left are AAMI leaders W. Gerald Rainer, Mike Miller, and Arthur Beall.

It took until 1976 to pass the law because of the complexity of the process, the size of the effort, and the interruption of Watergate. The finished legislation was more extensive than any other product-type legislation passed before or since. Ultimately, the final legislation was essentially the same as that outlined at the AAMI conference and detailed in the Cooper Committee Report.

Larry Pilot, attorney and FDA executive in the 1970s

This 1972 photo shows AAMI leaders participating in an Annual Meeting session on proposed regulation of medical devices. Pictured from left are Larry Pilot, then of FDA; John J. Collins, MD, of Peter Bent Brigham Hospital; Arthur C. Beall, Jr., MD, of Baylor College of Medicine; and [standing] Earl Bakken of Medtronic.

THE WASHINGTON POST *Saturday, May 29, 1976*

Ford Signs Medical Device Bill

Associated Press

President Ford yesterday signed the first federal legislation to protect consumers against faulty or deceptive medical devices.

The law permits the Food and Drug Administration to set safety standards for thousands of medical devices, ranging from tongue depressors to artificial hearts.

Previously, the FDA "has had inadequate authority" to regulate the enormous advances that have been made in the use and manufacture of medical devices, Mr. Ford said.

The law affects about 1,300 manufacturers of 12,000 kinds of medical devices already on the market. It also gives the FDA regulatory muscle over any new products introduced.

A federal task force estimated that in 1970 medical devices caused an estimated 10,000 injuries, including 741 deaths during the previous decade.

The report attributed 512 deaths and 300 injuries to heart valves, 89 deaths and 186 injuries to cardiac pacemakers, and 10 deaths and 8,000 injuries to intrauterine devices.

Injuries and deaths from medical devices have mounted since then, authorities said.

Mr. Ford said the Medical Device Amendment of 1976 "does not represent another expansion of government into affairs we might better manage ourselves."

"Instead, this is an example of government doing for the individual what he or she cannot do unaided," he said.

A New Era in Government Regulation

With the passage of legislation, a new era in regulation of devices began. FDA had to determine how to implement the new regulation, and educate industry about its requirements. In a ten-day, ten-city blitz, Larry Pilot and two colleagues introduced the new requirements to industry and geared up for implementation.

Regulations implementing the legislation were completed over the next few years, including the Good Manufacturing Practices (GMP) regulation published in 1978. Throughout this period, AAMI maintained its neutrality, playing a nonpartisan role as the facilitator of discussions, holding frequent conferences and educational sessions and not advocating for any one position except for patient safety.

The rising importance of voluntary standards in device regulation, both in the United States and abroad, led to the explosive growth and international expansion of AAMI's standards program in the 1980s and 1990s.

In 1990, when the Safe Medical Devices Act required user facilities to begin reporting adverse events to FDA, AAMI commented extensively on the regulation and, after its passage, sponsored a series of seminars to educate the user community about the new requirements. Similarly, AAMI held a series of seminars on reuse of single-use devices when the user community was affected in the late 1990s by new FDA requirements.

The 1990s would also bring a new role for AAMI in the realm of government regulation. When FDA issued in 1996 a new GMP regulation, which laid out strict requirements for medical device manufacturers, the agency turned to AAMI to help with its implementation. In this groundbreaking effort, AAMI and others created a process where FDA and industry learned together what meeting the new regulation would require. AAMI's government education program grew out of this effort and is now a mainstay of the association.

By capitalizing on its unique membership mix—an alliance of physicians, manufacturers, engineers, and others with an interest in medical devices—AAMI was able to bring different factions together to advance the field. Through the years, AAMI would play this role again and again, laying the foundation for its success on future government programs.

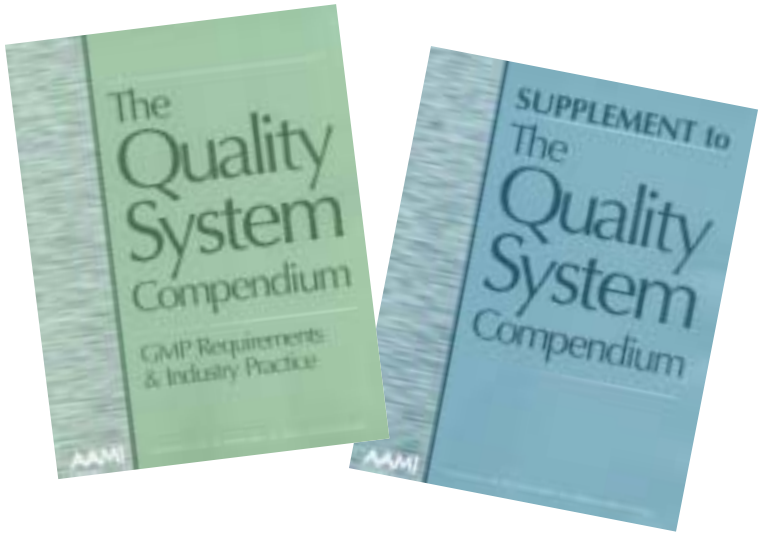
Mike Miller, AAMI chief executive since 1969

Larry Pilot

Larry Pilot joined the Food and Drug Administration in 1969. He was responsible for the development of many aspects of FDA's regulatory program for medical devices prior to and after the passage of the Medical Device Amendments of 1976. He was responsible for the development of the agency's Good Manufacturing Practice regulations in 1978. When he left FDA in 1979 to go into private practice as an attorney, he was Associate Director of Compliance, Bureau of Medical Devices. Today he is a partner with McKenna, Long & Aldridge based in Washington, DC. A longtime AAMI member, he has frequently spoken at AAMI events and written about government affairs for AAMI publications. His law firm has provided counsel to AAMI for many years.

David Link

David Link came to FDA in the early 1970s from positions in engineering and marketing with Hewlett-Packard. He managed FDA's first regulatory program for medical devices, and was appointed head of FDA's Bureau of Medical Devices and Diagnostic Products in 1974, where he served until 1980. After leaving FDA he went on to manage the regulatory affairs, quality assurance, sales, and manufacturing functions at several medical device companies and served as an industry consultant. As a member of AAMI's Board of Directors for many years, he played an active role in AAMI's standards program and chaired AAMI's government relations committee. Link is now executive vice president of Boston Healthcare Associates.



AAMI Comments on SMDA User Reporting Requirements

The Food and Drug Administration's (FDA) user reporting regulations were published on 26 November 1991 as a tentative final rule, and the comment period ended 26 February 1992. The regulations implement the requirements of the Safe Medical Devices Act of 1990 (SMDA). These regulations represent the first FDA regulatory activity directly affecting user/health care facilities.

AAMI's corporate and institutional membership reviewed the comments outlined below. The comments were also reviewed by the 1100 registrants of the eight SMDA seminars AAMI held in 1991, in conjunction with the FDA, national nursing organizations, and other health care organizations.

AAMI AND ITS MEMBERS SUPPORT THE INTENT of the regulations. Some AAMI members believe that the regulations will enhance patient care by improving internal reporting and management of medical device incidents.

AAMI urges that the regulations be developed to comply literally with the intent of Congress until it has been clearly established that more extensive regulations are required. If the regulations are carefully developed, the FDA can obtain the information it desires and Congress intended and avoid a significant number of unnecessary reports. Unfortunately, the regulations as currently drafted are likely to produce a significant number of reports, many of which will be unnecessary, burdensome, and costly.

The regulations should foster cooperation between manufacturers and the health care community if they are to accomplish the intent of Congress and if they are not to impose major resource burdens on manufacturers, health care facilities, and the Agency. The regulations as currently drafted could potentially create a conflict between manufacturers and hospitals that would not only thwart the intent of the regulations but also result in a major diversion of resources from the health care community. These costs would be in addition to the health care cost pressures being brought to bear on the domestic economy and competitive pressures affecting the ability of the industry to compete in the international marketplace.

AAMI proposes that a conference be held to provide FDA a

Continued on Page 3

Providing necessary resources for the biomed community has been a driving force behind AAMI from the outset. An early committee meeting is shown here.

A 1975 meeting of the Board of Examiners for Clinical Engineering

This 1971 photo shows the BMET Certification Program receiving approval from the AAMI Education Committee. With its certification program, AAMI helped launch the biomedical equipment technician and clinical engineering professions.

Bill Staewen's biomedical shop at Johns Hopkins Hospital, circa 1960.

AAMI and the Engineering Community

Pioneering Engineer Recalls Launch of In-House Clinical Engineering Service in 1962

Longtime AAMI member William S. Staewen tells of his experiences launching one of the first organized medical equipment programs at Sinai Hospital of Baltimore.

I was invited to establish medical engineering services at Sinai Hospital of Baltimore in 1962 after working as a medical instrumentation engineer at the Johns Hopkins Hospital for almost three years. While I had been principally involved in research projects at Hopkins, my mission at Sinai was to be intimately involved with patient care equipment. This was the vision of Dr. Bernard Tabatznik, Director of Cardiology.

This mission included not only maintaining and repairing equipment, but also operating equipment during procedures such as cardiac catheterization, open heart surgery, elective cardioversions, and cardiac pacemaker implantation. All of these medical procedures were just being developed. Not only did I have to become expert with a number of new devices, but I also had to become proficient in the basics of cardiology and electrocardiology. I was fortunate to have some very good medical mentors.

It also became immediately obvious to me that the medical, nursing, and technologist staff needed considerable assistance and training in the proper and safe use of various electromedical devices. Therefore one of my first tasks was to prepare and schedule inservice programs for the clinical staff.

Preventive maintenance, repair, and testing of the electromedical equipment presented some unique challenges. Test equipment specific to medical devices generally wasn't available. Thus I had to design and fabricate my own defibrillator, electrosurgical and pacemaker analyzers. And, of course, at this time there were no medical device standards.

In 1964 reports started to appear in the medical literature concerning electrocution hazards involving indwelling pacemaker electrodes and medical apparatus. Suddenly the whole medical engineering world changed and it was obvious that an in-house Clinical Engineering Department would be an essential part of most hospitals. So we thought!

Early AAMI Leaders Saw Need for Engineering Expertise

In the mid-1960s, the number of medical devices in hospitals was exploding, as was the complexity of those devices. AAMI's early leaders were concerned about who was watching all of that equipment. Service was provided almost exclusively by manufacturers. Hospitals struggled to get their hands on service manuals and spare parts. Few hospitals had engineers on staff, and even fewer had organized medical equipment maintenance programs.

AAMI's physician leaders knew that the engineering community was a hugely important partner in the effort to ensure the safety of medical instrumentation. Their services were badly needed in hospitals to manage these devices that were becoming so central to patient outcomes. In response, AAMI undertook several initiatives to help promote the biomedical equipment technician and clinical engineering professions.

Our concern was that we had a lot of people using this complex instrumentation, but nobody was maintaining it.

AAMI founder John Abele

I had a nagging feeling that somebody in the hospital ought to be keeping a closer eye on that equipment.

Bob Stiefel, on his first job at the University of Rochester–Strong Memorial Hospital in the mid-1960s

Hospitals Magazine Survey: Manpower Needed to Maintain Biomedical Equipment

As more sophisticated equipment becomes available to hospitals with 51 to 100 beds, the problem of maintenance of biomedical equipment will become critical because they do not have the qualified personnel necessary to maintain it. . . . There is a serious lack of manpower to maintain the biomedical equipment that is available.

—Survey reported in the June 1, 1971, issue of *Hospitals*

This pyramiding series of major responsibilities [for medical equipment] cannot be handed over to the "local handyman." . . . there is no substitute for a reliable "in-house" capability consisting of a comprehensive staff of skilled, well-informed technicians with suitable tools and adequate working facilities.

John C. Norman, MD and Lester Goodman, MD, *Medical Instrumentation* Sept/Oct 1966

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1967

AAMI helps develop the first biomedical equipment technician (BMET) training programs and studies the need for the profession in partnership with the Technical Education Research Center (TERC).

The Engineering Professions: Early Beginnings

Biomedical Equipment Technician Profession

Medical equipment maintenance programs in the armed forces became common after World War II. In the private sector, AAMI's early leaders helped develop the first training programs for biomedical equipment technicians (BMETs). In 1967, the Technical Education Research Center (TERC), an independent, nonprofit research organization based in Cambridge, MA, and funded by the U.S. Office of Education, developed a two-year post-high school curriculum for BMETs. AAMI helped the center conduct a study of the need for biomedical equipment technicians in the health field, improve the BMET curriculum, and set up pilot teaching programs. AAMI also received funding to research and promote the profession at the hospital level.

BMET Training Programs: A TERC Legacy

"When the development [of a curriculum] is completed in late 1970, it is projected that TERC will be able to provide course descriptions, laboratory guides, equipment lists, and general examinations that schools can adapt and adopt. Present indications are that the curriculum will be a two-year course of study with heavy emphasis on electronics and instrumentation and introductory work in 'biomedicine.' "

—W. D. Hubbard, "The development of educational programs in biomedical equipment technology," *Medical Instrumentation*, July 1969

An early meeting of the BMET Board of Examiners, which would create AAMI's CBET certification program.

AAMI researched the need for BMETs and sold hospitals on the idea. The hospitals had no idea how much it cost them to maintain instruments or how to do it. So AAMI told them.

AAMI founder John Abele

1967 TERC Study of the Need for BMETs

Present opportunities for adequately trained BMETs: 4600

1970 projected need for adequately trained BMETs: 10,800

Average 1967 BMET salary: $7,500 per year

BMETs Needed	Hospitals	Industry	Research Institutes	Total
1967	600	3,600	400	4,600
By 1970	1,100	8,100	1,600	10,800

By comparison, the Bureau of Labor Statistics estimates that there were 29,000 people employed as BMETs in 2004.

1969

Electrical safety scare led to a highly successful AAMI electrical safety workshop, held in New York. AAMI electrical safety exhibit created.

1971

BMET certification exam developed by Lt. Col. Burt Dodson. First AAMI Board of Examiners appointed. First exam given in the fall of this year.

Clinical Engineering Profession

In AAMI's early years, the value of engineering expertise in the healthcare environment was just being recognized. AAMI's early leaders played a major role in putting the clinical engineering profession in the spotlight. AAMI's early efforts to promote the profession included seminars, a dedicated newsletter, and the launch of the certification program. Those efforts continue today in AAMI's publications and book series, the Annual Conference, and the efforts of the Technology Management Council (TMC).

The AAMI Education Committee discusses certification of clinical engineers.


Clinical Engineering Newsletter

AAMI's *Clinical Engineering News* Launched in 1973, Distributed Nationwide

AAMI launched the newsletter *Clinical Engineering News* in January 1973. Its editor was Cesar A. Caceres, an AAMI founder and early advocate of the clinical engineering profession. In November 1973, the AAMI foundation received a $50,000 grant from the Fannie E. Rippel Foundation to provide a year's subscription of the newsletter to every hospital and hospital-related association in the U.S. in order to promote the importance and utility of clinical engineering. It was also sent to all fourth year medical students. Subsequent grants ensured the nationwide distribution of the newsletter for many years.

Robert H. Stiefel, CCE

Bob Stiefel, Chair, AAMI Board of Directors, 2006–2008, became a clinical engineer in the mid-1960s and has been involved with AAMI since the early days. He has been a leader in providing programming to the engineering community over the years, serving frequently as a course instructor, author, and committee chair. He has been the longtime chair of AAMI's Clinical Engineering Management Committee. He has also served on numerous AAMI standards committees, the *BI&T* Editorial Board, the Finance Committee, the Nominating Committee, and the AAMI Foundation. He is currently director of clinical engineering at the University of Maryland Medical Center.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1972

Eleven BMETs are the first to become certified.

1973

AAMI board approves clinical engineering certification program.

1974

Six clinical engineers selected to serve as the initial Board of Examiners for the clinical engineering certification exam.

Cesar Caceres realized that the term "biomedical engineer" did not truly describe what clinical engineers were doing in hospitals. Biomedical engineers typically work in industry, education, or government, not hospitals. Caceres felt that the hospital needed the judgment and experience that clinical engineers provided.

Tom Hargest

Cesar Caceres, MD

Cesar Caceres first joined AAMI's Board of Directors in 1969, then served as AAMI's president from 1971 to 1972. An early advocate for the clinical engineering profession, he coined the term "clinical engineer" in the mid-1960s. He organized several conferences for AAMI on topics such as clinical engineering and rising healthcare costs; won research grants for AAMI, many on topics related to clinical engineering; and edited several books on clinical engineering. He had a practice in internal medicine for 53 years and today is executive director of the Institute for Technology in Health Care in Washington, DC.

How Clinical Engineering Got Its Name

By Cesar A. Caceres, MD

In the mid-1960s, a philanthropist from New Jersey who ran the Fannie A. Ripple Foundation was interested in what could be done for elderly ladies. He had heard we were involved in electrocardiographic computerization at the Public Health Service Medical Systems Development Laboratory. When he asked me what we were doing, I told him it was Clinical Engineering: trying to put Engineering into the Clinical world of medicine, so that our various disciplines could work hand in hand to improve health care in the reality of the practicing medical world.

Through daily contact I had grown to realize that the solution to healthcare is not just in the hands of scientists doing research or academicians or physicians with hands-on medicine—it must be in Clinical Engineering with a goal-oriented, problem-solving approach combining multiple talents.

The Ripple Foundation, after visiting us, gave out several grants to intensive care units and funded several AAMI projects.

Since medicine is turning with ever increasing dependence to the engineer . . . some common understanding of the mutual problems must be sought. It is the purpose of AAMI to bring about such an understanding.

John Merrill, MD, *Medical Instrumentation* editorial, July/August 1966

1982

First AAMI Regional Meeting, later renamed the Mid-Year Meeting, held in Philadelphia, PA.

1983

International Certification Commission for Clinical Engineering and Biomedical Technology formed through merger of the AAMI Certification Commission and the American Board of Clinical Engineering. AAMI serves as secretariat of the ICC.

Electrical Safety Scare Puts Engineering Professions, AAMI in the Spotlight

The electrical safety scare of the early 1970s helped to solidify the importance of the BMET and clinical engineering professions to the hospital community. AAMI played a leading role in responding to the scare. Leaders such as John (Jack) Bruner, Dave Kelch, John Post, David Lubin, and many others helped the association respond. AAMI launched a series of electrical safety education programs and created a traveling electrical safety exhibit to educate medical audiences about the issue. In 1971, AAMI's first published standard focused on electrical safety. These efforts gained AAMI significant recognition in the hospital community for the first time.

The AAMI electrical safety exhibit was taken to many medical meetings to educate the doctors. The message was as basic as the importance of using a three-prong, grounded plug, something we all take for granted today.

John Post

Electrical Safety Scare—Real or Imagined?

While concerns about electrical safety in hospitals had been prevalent throughout the 1960s, it was not until 1969 that the concerns gained widespread attention. Dr. Carl Walter, a well-known surgeon at the time, asserted in a series of major articles and television broadcasts that 1,200 patients were being accidentally electrocuted in U.S. hospitals each year. In 1971, Ralph Nader published an exposé citing that number in the *Ladies Home Journal*, and later even inflated that number to 5,000 deaths annually. National attention focused on the issue. Many hospitals developed in-house medical equipment management programs for the first time in response to the concerns.

The base claims behind the electrical safety scare—that at least 1,200 people were being electrocuted every year in U.S. hospitals—ultimately were debunked. But the scare did focus nationwide attention on equipment safety and ensured that basic safe electrical practices were implemented nationwide.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1986

Lt. Col. Burt Dodson, Jr. receives the first AAMI Leadership Award.

1991

First annual clinical engineering management seminars held.

1992

The certification program adds a 3-year renewal process to add value and increase credibility to the CBET, CRES, CLES, and CCE programs.

It has taken a long time—over a decade after 'the slaughter in our hospitals'—to be able to say with reasonable certainty that it simply didn't happen. The 5,000 bodies were never found because there weren't any.

From *Electricity, Safety and the Patient* by John M.R. Bruner and Paul F. Leonard, page 194

John M.R. Bruner, MD

John (Jack) Bruner, an anesthesiologist at the Peter Bent Brigham Hospital in Boston, MA, played a leading role in helping AAMI respond to the electrical safety scare of the 1970s. Along with John Post and Dave Kelch, he helped design AAMI's electrical safety exhibit. He was also an active participant in standards committees related to electrical safety and blood pressure measurement over the years.

David Kelch

Dave Kelch, an electrical engineer, helped AAMI put together its electrical safety exhibit in the late 1960s. He went on to play an active role in AAMI over the years, serving in the 1980s on the publications committee that helped set up AAMI's new journal, *Biomedical Instrumentation & Technology*. He spent more than 30 years working in Hewlett-Packard's medical division.

AAMI's electrical safety committee discussing the safe current limits standard.

AAMI Took the Lead on Electrical Safety Education

March 1968 • AAMI provided members a **bibliography** on electrical hazards, injuries, and related accidents.

December 1970 • AAMI held the first **electrical safety workshop** in New York City. An audience of 200 listened to doctors, engineers, and industry representatives make practical presentations with Q&A sessions on how to use equipment safely. That workshop would grow into a successful nationwide series that helped put the young association on a firm financial footing for the first time.

February 1970 • AAMI presented its **electrical safety exhibit**, "Seven Steps to Electrical Safety," for the first time at the 1970 annual meeting of the American College of Cardiology, New Orleans. This exhibit presented seven practical steps to improve electrical safety in the hospital and demonstrated testing devices for the determination of safe or unsafe conditions. The exhibit was shown for several years at major medical meetings throughout the United States. A **brochure** by the same name was also created and distributed to great demand wherever the AAMI exhibit was shown.

September 1971 • AAMI's subcommittee on electrical safety published its **safe current limits standard**, "Recommended AAMI safety standard for electromedical apparatus, Part I: Safe Current Limits," in *Medical Instrumentation*.

December 1971 • AAMI helped develop a **film series** for nurses, technicians and physicians on electrical safety in the hospital. These films were designed to foster a clear understanding of safe conditions, and reduce the hazard of electrical shock to patients and hospital staff. Topics included "How electricity works," "Electrical safety in general care" and "Electrical safety in special care." Delmar Snider, MD, Stanford University Hospital and Dave McKinney, University of California Medical Center, worked on the films.

1997

In response to the changing U.S. environment, the United States Certification Commission (USCC) is established. The U.S. Board of Examiners, BMET and CE, report to the USCC, which in turn reports to the ICC.

2003

AAMI launches Technology Management Council, which serves the interests of and provides benefits to BMETs, CEs, and other medical technology professionals.

AAMI Certification Programs Bring Recognition, Prestige to BMET, CE Professions

AAMI's early leaders and those in the emerging engineering professions knew that a credible certification program would help the new BMET and clinical engineering professions gain recognition and acceptance in the healthcare community. Toward that end, separate efforts were launched to develop certification programs for each profession. The goals of both programs were to:

- help America's healthcare community identify qualified individuals with the skills required to support increasingly complex biomedical equipment systems;
- provide a means by which those individuals could be recognized for their unique experience and knowledge;
- provide definition to the developing profession; and
- improve patient and public healthcare safety by creating a certification of competence.

The defining factor in AAMI's relationship with and programming for BMETs was the development of the BMET certification exam by Lt. Col. Burt Dodson in the early 1970s. He had a major role in training Air Force BMETs and took his knowledge and developed and tested the first BMET exam for AAMI.

Mike Miller

The visionaries of the industry at that time saw the clearly growing need to recognize and identify individuals with the unique skills necessary to adequately support the technology-driven healthcare future they saw unfolding.

Mike Carver

Growth of the CBET Program

In the early 1970s, AAMI leaders recruited Lt. Col Burt Dodson, who had managed a successful medical equipment support operation for the U.S. Air Force, to help them develop training programs for biomedical equipment technicians and eventually institute a certification program to solidify the growth of this new profession.

AAMI facilitated the many planning sessions that followed and, in 1971, established the pioneering Certification Commission. By establishing criteria for experience, knowledge, and education, the Certification Commission defined the minimum qualifications necessary for certification of BMETs. By the fall of 1971, the commission was ready to administer the first certification examination. A predominantly military group of veteran and well-accomplished BMETs received the first examination. In April 1972, the first AAMI CBET certificates were issued to the 11 individuals who passed.

A certification program for radiology equipment specialists (CRES) was added in 1979, and another for laboratory equipment specialists (CLES) in 1981.

The title Certified Biomedical Equipment Technician (CBET) has long been the single most recognized and universally accepted credential by which BMETs can publicly demonstrate both their commitment and achievement in their chosen profession. In the credential-oriented U.S. healthcare environment, the letters CBET engender confidence, mutual respect, and acceptance by other healthcare professionals.

Mike Carver

Burt Dodson, Jr., CCE

Lt. Col. Burt Dodson, Jr., authored the first biomedical equipment technician certification exam and played a leading role in the establishment and growth of AAMI's certification programs over the years. He went on to serve as AAMI's first non-physician president from 1978 to 1979. Dodson's many contributions to the BMET profession were recognized in 1977 with the first SBET Lifetime Membership Award. From a 23-year career in the Air Force Medical Services, he joined the multi-hospital corporation Sunhealth (now Premier) and was the chief operating officer at retirement.

Michael E. Carver, CBET, CCE

Mike Carver has been involved with AAMI's certification programs for more than 20 years. He has chaired the International Certification Commission, the United States Certification Commission, and the BMET board of examiners. Carver had a 22-year career with the United States Air Force, where he directed worldwide clinical engineering operations, and recently retired from ARAMARK Healthcare Clinical Technology Services.

Burt Dodson, Jr. [left] discusses AAMI's new certification program at an AAMI annual meeting.

Two Firsts

In 1972, Herman D. Hubbard [left] of Fitzsimons Army Hospital in Aurora, CO, became the first person designated a certified biomedical equipment technician. Thomas Hargest earned the first certification as a clinical engineer in 1974.

The Only One: Virginia Biomedical Engineer Holds All Four AAMI Certifications

Christopher D. Riha of Virginia is the first and only person to earn all four certifications offered by AAMI. He earned the CBET designation in 1983; CLES in 1993; CRES in 1994, and in 1998 added the initials "CCE" to his name.

It Pays to be Certified

On average, respondents to a 2005 AAMI salary survey reported earning 5.7% more than those who were not certified.

Growth of the Clinical Engineering Certification Program

The Clinical Engineering certification program had a very different launch than that of the CBET program. AAMI began the process by working with an Engineering Foundation-sponsored study group to initiate development of a program for the certification of the qualifications of clinical engineers. In September 1974, AAMI announced that six clinical engineers had been selected for certification by eminence after acclamation and public scrutiny.

These engineers constituted the initial Board of Examiners for clinical engineering certification. Tom Hargest was elected a chairman of the Board of Examiners by the group after its first meeting. This initial board of examiners developed responsibilities, rules and regulations for the Board; reviewed and approved certification procedures; and reviewed pending applications. At AAMI's 1975 Annual Meeting, 47 clinical engineers were formally certified. Over the 25 years that AAMI ran the program, more than 400 clinical engineers were certified. The application process for the CCE program under the International Certification Commission was suspended in 1999.

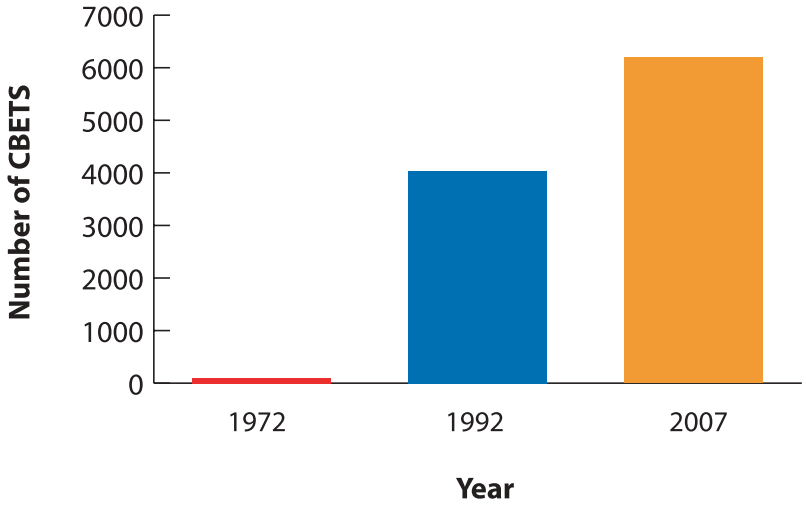
Thomas S. Hargest, III

Tom Hargest holds AAMI certificate 001 in clinical engineering and served as the first chairman of the Board of Examiners for Clinical Engineereing. He played an active role in AAMI through the years, serving as a director, vice president for clinical engineering, and chair of AAMI's Board of Directors from 1987 to 1988. He is retired from a post as director of clinical engineering at the Medical University of South Carolina.

The first six clinical engineers certified by AAMI in 1974.

Merger negotiators toast the newly formed International Certification Commission in 1983. Pictured from left are Cedric Walker, Barry Feinberg, and Gailord Gordon.

Growth in the Total Number of Certified Biomedical Equipment Technicians



Certification Milestones

- **1983 Merger Joined AAMI, ABCE Certification Programs**

In parallel with the AAMI process, the American Board of Clinical Engineering (ABCE) was also certifying clinical engineers. Having similar purposes, AAMI and ABCE were primarily differentiated by their audiences. The ABCE targeted graduating CE students, while AAMI's focus was directed toward experienced CEs and BMETs currently working in the clinical environment. A merger between these two clinical engineering certification programs became official at AAMI's 1983 Annual Meeting. The merger consolidated AAMI's Certification Commission and the ABCE into a new entity, the International Certification Commission (ICC).

- **U.S. Certification Commission Established in 1997**

By the mid-1990s, the growing complexities of certification in the U.S. environment and the expanding international focus of the ICC necessitated development of a body with a purely U.S. focus. In June 1997, the U.S. Certification Commission was established. Not only did this increase support for U.S. activities, but it further allowed the ICC to focus its efforts more equitably among international constituents.

- **The International Certification Commission Today**

Today, the International Certification Commission (ICC) consists of certifying bodies and other interested organizations from around the world and serves as an overarching framework certifying Biomedical Equipment Technicians and Clinical Engineers. A common misconception is that when an individual becomes certified as a CBET, CRES, or CLES, they are certified through AAMI. In actuality, they are certified through the ICC, of which AAMI is the Secretariat.

BMET Newsletter Launched in 1974

BMET News premiered in late 1974 to provide a forum for BMETs to comment on and discuss educational, technical, governmental, certification, and other issues for resolution by the BMET community. The newsletter was published bimonthly until 1984, when its content was merged into *AAMI News* and the AAMI journal.

A 1975 BMET organizational meeting.

BMET News

Message from the Executive Director:

Message from the Editor:

Message from AAMI President:

1975 Article Highlights Need for BMET Certification, Representation

*The following article is excerpted from "Why a BMET Society?" published in B*MET News*, May–June 1975, by David E. McCanna, CBET, Trumbull Memorial Hospital, Warren, OH.*

The BMET of the 1960s, where was he? Nowhere. Nobody recognized us except on an individual basis. Few companies supplied literature. . . . Often we had to prove to the salesman that we were qualified to repair the machine, if we could get parts lists, schematics, etc.

I was hired [by a hospital] in 1968 as a rather highly paid mechanic since "the hospital only has a few hundred of those machines, you wouldn't be doing that full time anyway." . . . After I began my present job in 1968, I found the civilian life of a BMET not so rosy. I started to look for an organization to help improve our position. I wrote dozens of organizations in the hopes of finding one that was interested . . .

Then I heard about the TERC report on the BMET career field and contacted them. They, in turn, advised me that AAMI was investigating the needs for certification. My first letter to AAMI was dated November 27, 1970 . . . I asked "are you going to open a registry?" No more than 5 days later a letter came back with the greatest news I had heard in many a day, and, I quote Mr. Miller, executive director of AAMI: "At the present time, an AAMI subcommittee is working on an examination for biomedical instrumentation technologists. . . . This examination would be the first step in an AAMI program for the certification of technologists."

. . . Where else but AAMI would we find an organization willing . . . to establish a program for us? Who else is prepared to establish meetings and seminars for the BMET? AAMI presently has had over twenty such meetings. Who else has gone to the government on behalf of BMETs? AAMI did. They went to the civil service and fought for a change in the classification of the BMET to a professional.

AAMI is the best organization to represent us, and they are the only one who cares about us. . . .The reason they do it: "to improve the health care industry."

Society of Biomedical Equipment Technicians (SBET) Launched in 1976

The Society of Biomedical Equipment Technicians was officially launched in March 1976 at AAMI's 11th Annual Meeting. Through the late 1990s, SBET worked to advance the training of BMETs and to promote the profession. That role within AAMI is played today by the Technology Management Council.

SBET Presidents

1976	Joe Squatrito	1986	Terrance C. Clemans
1977	Charles Pavesi, Jr.	1987	Jessie F. Williams, Jr.
1978	Barry Altman	1988–89	Terrance C. Clemans
1979–80	John W. Cates	1990–95	John Koberstein
1981	Vincent Rauscher	1995	Robert Hugh Larkin
1982	James Wallace	1996	Steve Haupt
1983–85	Raymond E. Walroff		

Charles A. Rawlings, PhD, CCE

Charles A. Rawlings, AAMI's president from 1982 to 1984, played an active role in developing AAMI's certification program, eventually heading up both the BMET Board of Examiners and the Certification Commission. He designed and directed the Seminar in Biomedical Instrumentation, an intensive short-course for BMETs and CEs that would be presented for 34 years at various universities in the United States. He was recognized in the 1980s for his service to the BMET community with a lifetime membership in the Society of Biomedical Equipment Technicians. He was also Editor-in-Chief of *Medical Instrumentation* from 1987 to 1989, and served on the AAMI Foundation. He is professor emeritus of electrical and computer engineering at Southern Illinois University, where he directed biomedical engineering for 33 years.

The Professions Today

What do BMETs do?

Biomedical equipment technicians (BMETs) are responsible for servicing and maintaining medical equipment and technology for hospitals and other healthcare facilities, manufacturers, and third-party service organizations around the world. Skilled technicians help acquire, install, use, maintain, and train healthcare personnel to use cutting-edge medical equipment. BMETs also coordinate contracts and play a key role in investigating device-related problems.

Employment Projected to Grow

The long-term employment outlook for BMETs is strong. The U.S. Department of Labor projects that the number of jobs in the U.S. will increase between 21 and 34 percent through 2010. With the rapidly expanding elderly population, demand for healthcare professionals will remain high. As medical equipment becomes increasingly complicated, the need for highly trained technicians will be a necessity for hospitals and healthcare facilities in all parts of the world.

This job is a perfect fit—working with people, managing projects, troubleshooting equipment repair, and knowing what we do makes a difference.

Vickie Snyder, Fairview Southdale Hospital

AAMI's Technology Management Council (TMC) Supports BMETs, Clinical Engineers

In December 2003, AAMI announced that it would create a new Technology Management Council, or TMC, to better serve the interests of biomedical equipment technicians, clinical engineers, and others who provide management and support services related to medical technology. The idea for the committee grew out of a study of AAMI's technology management members which showed that new services were needed.

The council is designed to provide the clear focus necessary to enhance the recognition and services that technology managers need and deserve. It includes 21 AAMI members and a five-member Executive Committee.

The TMC's goals are to:

- Work to increase the recognition of technology managers and their important role in health care.
- Serve as a focal point for formulating AAMI policies and programs for technology managers.
- Assist staff and the AAMI Board with the development of strategic and business plans.
- Work to optimize communications between this segment of the membership and other members of the healthcare community.

This is a great step forward, and will serve as an important avenue to advance the interests of BMETs and clinical engineers.

TMC chair
Ray Laxton

To Provide a More Focused Voice . . .

AAMI Launches New Technology Management Council

The AAMI Board of Directors has approved the creation of a new Technology Management Council to better serve the interests of biomedical equipment technicians, clinical engineers, and others who provide management and support services related to medical technology.

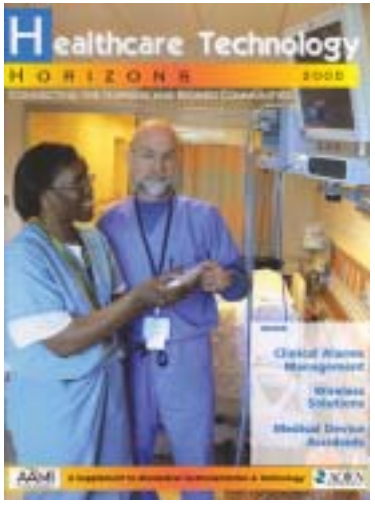
Earlier this year, AAMI conducted a study of its technology management members to determine their perceptions about AAMI in general, and current and potential ways that technology managers could best interact with AAMI, other members, and the health care community (the results of this study are posted at www.aami.org/resources/BMET/news.html).

As a result of the study and the perceptions of AAMI staff and leadership that new services were needed to be responsive to the needs of technology managers, a 15-member BMET Task Force was created to review the study results and develop recommendations on existing and new services.

The BMET Task Force has completed its work and has made a number of recommendations, including a recommendation for the creation of a new Council and Technical Management Executive Committee that will provide a more focused voice for technology managers.

The Council and its Executive Committee would work to increase the recognition of technology managers and their important role in health care, serve as a focal point for formulating AAMI policies and programs for technology managers, assist staff and the

CONTINUED ON PAGE 2



The TMC has launched a series of supplements to AAMI's journal, Biomedical Instrumentation & Technology. Healthcare Technology Horizons *focuses on issues of interest to the nursing and biomed communities;* IT Horizons *has explored information technology issues in healthcare.*

In Response to Member Needs . . .

AAMI Launches Major Benchmarking Project, ECRI Assigned a Lead Role

AAMI has selected health research agency ECRI to conduct the first phase of a benchmarking project designed to help clinical engineering departments evaluate their performance, procedures, and policies in a standardized manner.

The ambitious project is a top priority for AAMI's Technology Management Council (TMC), which was formed in 2004 to help AAMI better serve the interests of biomedical equipment technicians, clinical engineers, and other managers of medical technology.

According to Ray Laxton, TMC chair, "this is a groundbreaking endeavor, because reliable benchmarks for clinical and biomedical engineering simply do not exist. The project has the potential to make an enormous contribution to our field."

For years, benchmarking has posed a challenge in the clinical/biomedical technology field, in part because responsibilities and data vary so significantly from one facility to the next. As a result, it has been difficult to develop benchmarks to measure the value of technology management and hospital departmental and employee performance.

Nonetheless, hospitals and the clinical engineering and biomedical technology engineering community are constantly seeking information to assist them in benchmarking certain practices—on issues ranging from a department's costs to the number of devices the typical technician maintains at a given facility.

CONTINUED ON PAGE 5

This Council is an important mechanism for AAMI to get a new perspective on the needs of technology managers and provide a means for addressing those needs.

TMC member Steve Yelton, PE, of Cincinnati State Technical and Community College

Ray Laxton

Ray Laxton currently chairs the Technology Management Council (TMC). He was previously a member of the BMET Task Force and serves on AAMI's Board of Directors. He is director of clinical engineering with Clarian Health Partners/Aramark CTS.

A survey of AAMI members helped the TMC identify the priorities and projects that we needed to tackle; and I'm happy to say the TMC has delivered more than was promised.

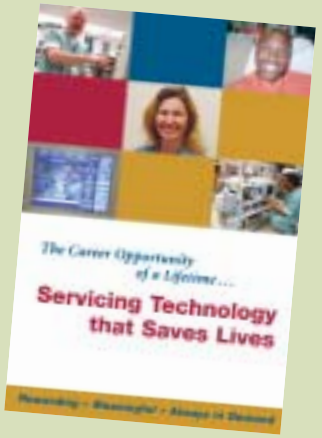
TMC Executive Committee member Dave Francoeur, TriMedx Healthcare Equipment Services

TMC Accomplishments

In its first three years, the TMC has implemented a number of important new benefits and services for BMETs, CEs, and other medical technology professionals. Among them:

AAMI's TMC
Advancing Your Career in Medical Technology

- **Joint Commission Guidance**—Access to Joint Commission officials through a Q&A column and appearances at the Annual Conference. Plus, a new online community where AAMI members can share Joint Commission news and experiences.
- **New Career Resources**—Salary and fringe benefit surveys, a new CD filled with career tools and tips, a job fair at the Annual Conference, and free resume postings.
- **Increased Outreach to Biomedical Societies**—An online speaker's bureau to help societies find speakers for their meetings, a special new membership category for biomedical societies, and guidance to help societies organize and grow.
- **IT Resources**—The publication of three editions of a special IT-focused magazine and a new CD featuring useful IT articles and other resources.
- **Promotion of the Field**—The distribution of more than 7,000 brochures to attract new biomeds to the field.
- **Best Practices**—A new "best practices" column in AAMI's journal, a "Best Practices" award at the AAMI conference, and a major ongoing project to develop benchmarking data for CE departments.
- **Outreach to Nurses**—The development of two special editions of a publication focused on issues of mutual interest to biomeds and nurses.



Engineering/Technician Tools

In this shot of Bill Staewen's biomedical shop in 1960, the equipment rack with an empty panel is an electromyograph he was building. It is used to analyze nerve and muscle activity.

Test Equipment in the Early Days of Clinical Engineering

by William S. Staewen

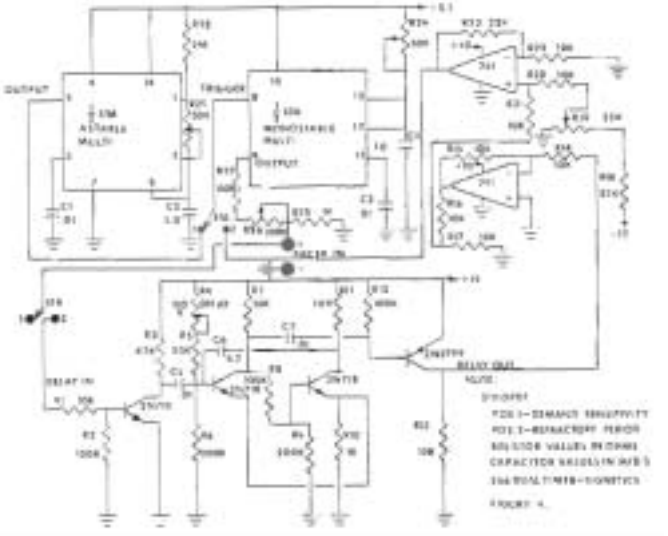
When I first started practicing medical engineering at Johns Hopkins Hospital in 1960 and later at Sinai Hospital of Baltimore in 1962, there was no commercially available test equipment for patient care devices such as defibrillators, patient monitors, electrosurgical machines, and blood pressure monitors. This pretty much held true into the 1970s. My colleagues in the field and I had to improvise most of the test equipment we used to evaluate and repair clinical instrumentation.

Most of the test devices I had to fabricate were very simple. To test electrosurgical units (ESU), for example, I used a voltage divider consisting of high wattage, non-inductive resistors in series with a light bulb. The values of the resistors were selected to cause the light bulb to be lit at specific output levels of the ESU. Occasionally we had to evaluate specific characteristics or effectiveness of the ESU simulating actual conditions. We would get the hospital kitchen to donate a steak that we used as a simulated patient. Of course, the steak was never wasted!

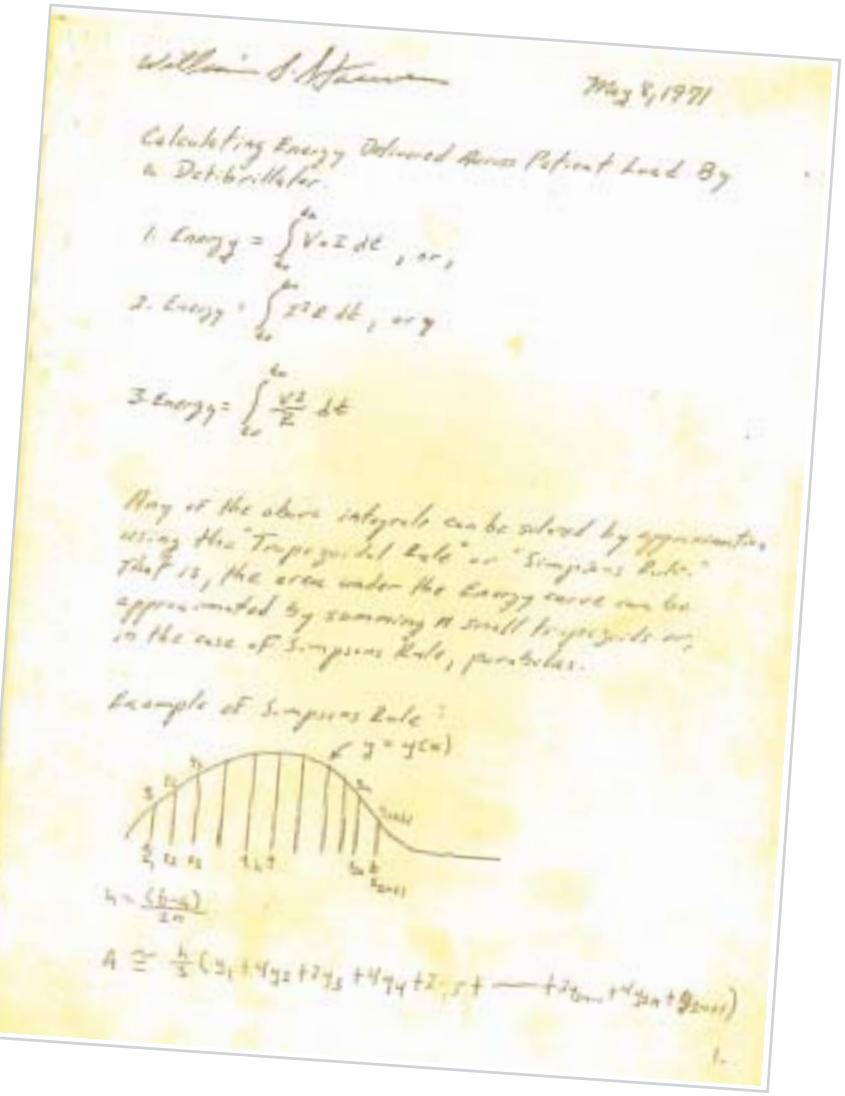
My home-grown defibrillator analyzer also consisted of a high wattage voltage divider that included a 1 ohm resistor across which I connected an oscilloscope to analyze the I = E/R waveform. DC defibrillators were introduced around 1960 with their characteristic damped sinusoidal waveform. I would photograph the waveform and compute the area under the curve to determine the energy in watt-seconds.

I also designed and built my own external demand cardiac pacemaker analyzer. This instrument would measure the pulse rate, current amplitude, pulse width, demand sensitivity, refractory period, and sine wave frequency response. I still used this analyzer well into the 1990s.

We had to rely greatly on conventional test equipment to facilitate testing of medical devices. In Baltimore, we were able to obtain oscilloscopes, various test meters, waveform generators and electronic components at very low cost from a local prison. This military "surplus" equipment was sold through the prison to nonprofit organizations such as hospitals.



Schematic for Bill Staewen's external demand pacemaker analyzer.



May 8, 1971

Calculating Energy Delivered from Patient Lead By a Defibrillator

1. Energy = $\int_{t_0}^{t_n} V \cdot I \, dt$, or,

2. Energy = $\int_{t_0}^{t_n} I^2 R \, dt$, or,

3. Energy = $\int_{t_0}^{t_n} \frac{V^2}{R} \, dt$

Any of the above integrals can be solved by approximation using the "Trapezoidal Rule" or "Simpsons Rule." That is, the area under the Energy curve can be approximated by summing N small trapezoids or in the case of Simpsons Rule, parabolas.

Example of Simpsons Rule:

$h = \frac{(b-a)}{2n}$

$A \cong \frac{h}{3}(y_1 + 4y_2 + 2y_3 + 4y_4 + 2y_5 + \cdots + 2y_{2n-1} + 4y_{2n} + y_{2n+1})$

Bill Staewen's notations on his methodology to compute defibrillator energy.

Hickok Tube Tester

By Bob Stiefel

For a number of years after transistors were introduced, many devices still used vacuum tubes. It took many years before solid state electronics could match the characteristics of some vacuum tubes. One of many serious drawbacks of many vacuum tubes is that they wear out relatively quickly. When a device stopped working properly, one of the first things we would test would be the vacuum tubes—in particular, vacuum tubes in amplifier circuits.

Photo courtesy of Brent Jesse of audiotubes.com

Eventually, solid state electronics improved to the point that pretty much all applications for vacuum tubes were replaced by transistors and then integrated circuits. Gradually, the old ECG recorders and electrosurgical units that used vacuum tubes were replaced with solid state equipment. In some cases, we had to wait for some old physicians to retire before we could retire the cath lab system that they swore gave the only valid results.

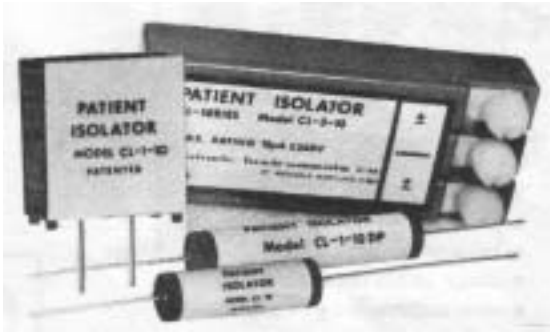
Bob Stiefel in a 1970s photo.

Photo courtesy of Brent Jesse of audiotubes.com

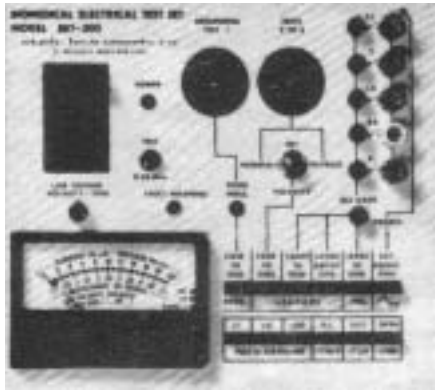
The CS-45 Conductive Shoe Tester was used to check safe shoe conductivity before entering an operating room.

Early Devices for Medical Safety

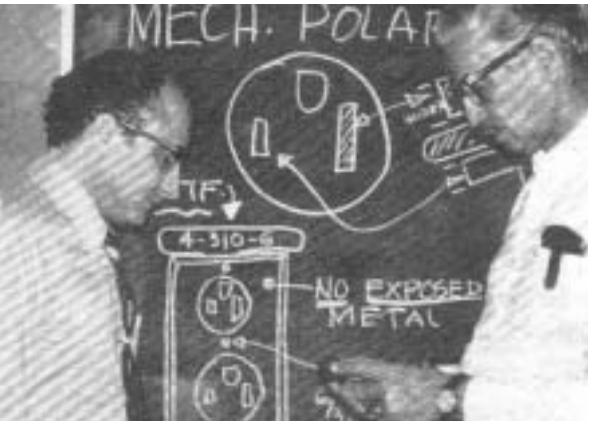
Denes Roveti helped form Ohmic Instruments Co. in the fall of 1969 at the request of David Lubin, who was the electrical safety officer at Sinai Hospital in Baltimore, MD. Lubin, a pioneer in electrical safety, was the first to use x-ray photos to show the defects in power line plugs used on medical equipment. He was the major catalyst and contributor to high reliability hospital-grade plugs and receptacles, and served for several decades on code committees. Ohmic was among the earliest companies to make electrical safety devices, and was an early exhibitor at AAMI annual meetings.



In 1971, a patient isolator called the Shock Eliminator was patented. They are placed in series with every lead and are designed to open to avoid electrical shock during an EKG.



The rugged BET-200 Biomedical Electrical Test Set has changed little over the years and is still in production today.



This 1970 photo shows Denes Roveti [left] and David Lubin discussing electrical safety.

The RIN Receptacle Interrogator was introduced in 1974 to check the electrical safety of receptacles by ensuring proper wiring.

The LR-200A was a leakage resistance meter made to meet the NFPA and NEC 1971 standards. This unit became the SI-100, which is still in production.

Photos this page courtesy of Ohmic Instruments Co.

Technician Tools Then and Now

Fluke Biomedical, a division of Fluke Corporation, has been serving customers of biomedical test equipment for more than 30 years, and has witnessed the steady evolution of the tools of the trade. The most obvious change from the old units to today's devices is the change in size. The early equipment was much heavier and more awkward. New technologies have reduced the overall size and made the units easier to use with simpler interfaces, better displays, and streamlined operations. **Here, photos of old devices (on left) are coupled with today's versions (on right).**

International Electrical Safety Analyzer

The ISA470 uses an analog meter and has only five lead jacks, whereas the ESA601 has a digital display and can accommodate 10 leads. The ISA470 is built into a heavy Formica case, making it a cumbersome unit for onsite testing. Alternatively, the ESA601 comes in a smaller, lighter, and more durable package, ideal for portable testing.

ECG Simulator

The ECG-II is a large, heavy unit with many buttons, creating a burdensome manual user interface. The PS400 is small and easy to use with autosequencing capabilities, allowing users to perform ECG and QA testing more quickly.

Electrosurgery Analyzers

The RF301B is a large and bulky ESU analyzer with an analog meter to measure current and power. The new RF303$_{RS}$ boasts a higher quantity of test loads, digital display, and simple interface, packaged in a more lightweight and compact case.

Ventilator/Gas-Flow Analyzer

The old ventilator tester weighed nearly 40 lbs, vs. the VT MOBILE, which weighs approximately 1 lb. The VT MOBILE is a small, battery-operated unit that can perform bidirectional flow, volume, pressure, and oxygen concentration measurements.

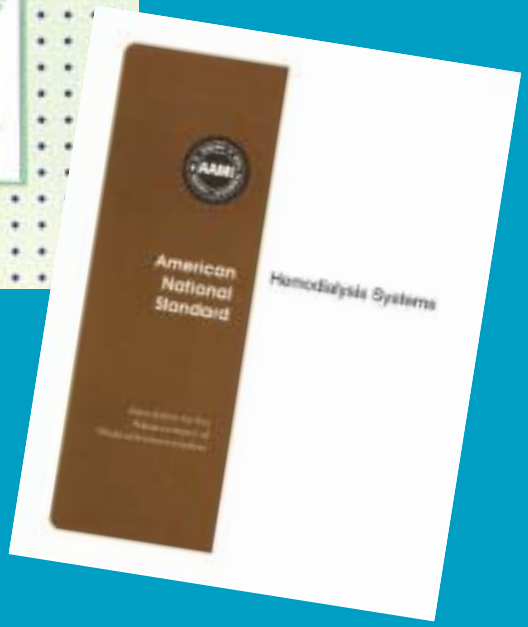
Ultrasound Wattmeter

The UW-1 was housed in a heavy wood case and used a latex membrane which was permanently filled with a water/antifreeze solution. This technology was inferior to today's technology because air would diffuse through the membrane, providing unstable and inaccurate readings if not regularly calibrated. The UW5 accepts ultrasound signals up to 10 MHz vs. the UW-1, which was capable of accepting signals up to only 1 MHz.

Defibrillator Analyzer

The QED-IIIS was a large unit that used an analog meter and was not capable of testing external pacemaker functionality. The QED 6$_H$ is lightweight and uses a digital display to play back the output waveforms. In addition to standard defib testing, the QED 6$_H$ has extended ECG simulation capability, programmable autosequences, and can also test transcutaneous pacemakers.

Photos this page courtesy of Fluke Biomedical

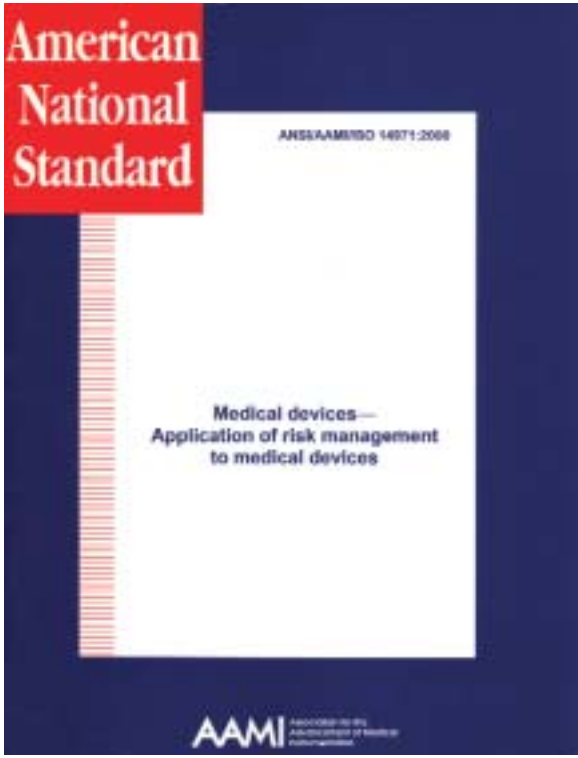


FDA's Carol Herman [center] joins [from left to right] AAMI's Betsy Bridgman, Theresa Zuraski, Mike Miller, and Joe Lewelling. "AAMI's standards committees have accomplished a great deal, and much of the credit should go to Betsy, Theresa, and Joe," says Miller. "They have been the backbone of AAMI's standards program since its major expansion in the late 1980s through today."

AAMI's Standards Program

Standards, when needed and relevant, are an important way for industry, through collaboration and consensus, to serve its customers: health care professionals, regulatory bodies, and patients.

—AAMI Standards Philosophy



The Footsteps of 21st Century Medical Engineering

When AAMI was first conceived, cardiac pacemakers were just beginning to excite hearts across the country, fetal monitoring was in its infancy, and CPR was just being pressed into action. Lithotriptors had yet to send a shock wave through the industry and opthalmic lasers were not even yet a vision. There were few coronary care units in which to defibrillate or rehabilitate the heart, or electrophysiology labs in which to ablate them.

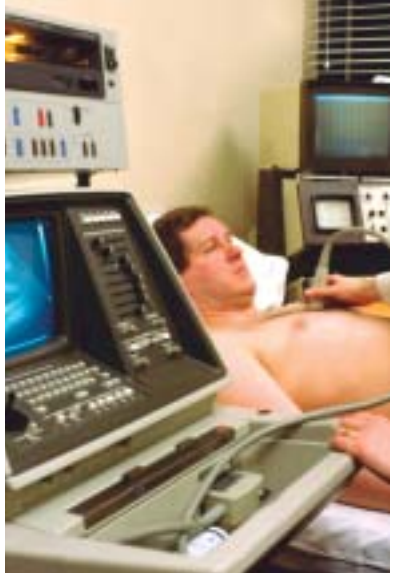
Congress had not yet determined (or decided) for FDA whether devices were the same as drugs, and the Joint Commission only accredited hospitals, not healthcare organizations. And, Hill-Burton was the hospital's best federal friend.

There was no coronary bypass surgery, and CAT scans and PET scans were skills used only by veterinarians. It would now be politically incorrect to call magnetic resonance imaging by its original name, "nuclear magnetic resonance," but it hadn't been invented yet anyway. And, the implantable cardiac defibrillator, when it was invented several years later, was considered a dangerous folly by some prominent cardiologists.

There wasn't an "echo" of ultrasound in cardiology and parents had to wait until birth to get a picture of their baby. Ventilators were called respirators by most and still are by many. The NICU was barely a reality. The need to establish patient electrical safety standards was only a whisper in the background. And, clinical engineers and BMETs were not yet called clinical engineers and BMETs.

AAMI, through its organization, programs, and members, has been a major factor in promulgating the progress of medical instrumentation over the past 40 years. And personally, it feels nice to have been a part of ancient medical history.

—William S. Staewen

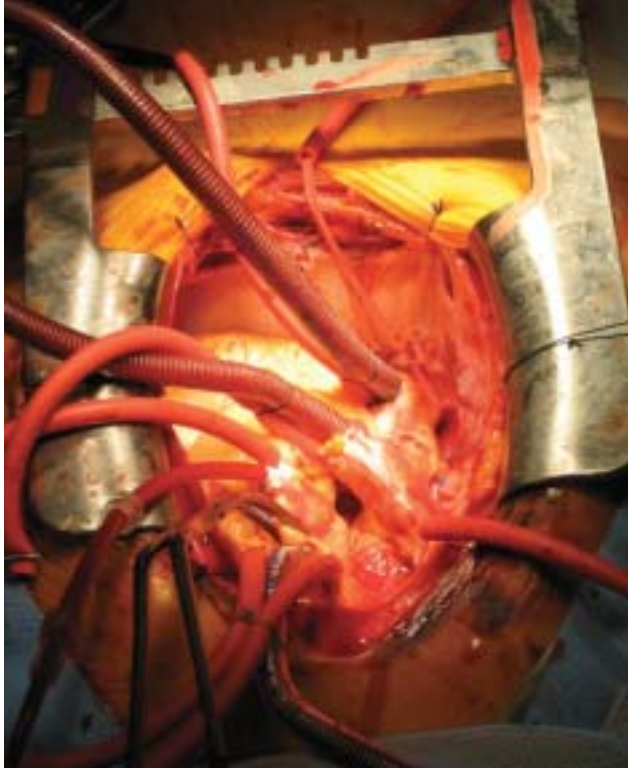


40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

Cardiovascular

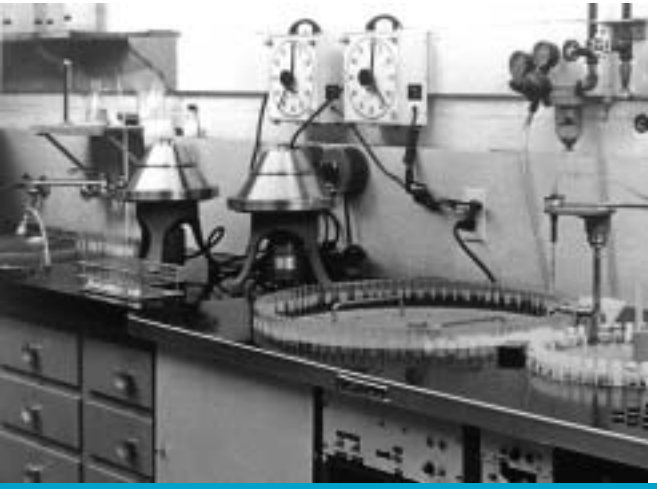
One of the most intellectually satisfying aspects of working with AAMI was my opportunity to interact with scientists, engineers, and medical folks in developing voluntary standards. I believe lots of good stuff resulted from input from individuals with backgrounds in industry, government, and academic research.

Alan S. Berson, PhD



Stanton P. Nolan, MD

Stan Nolan has been a mainstay of AAMI's standards program since the early 1970s. He was the cochair of AAMI's Cardiac Valve Prostheses Standards Committee for an astounding three decades, and has also served in leadership roles on AAMI's Committee on Standards Strategy, Board of Directors, and Executive Committee.



Electrical Safety

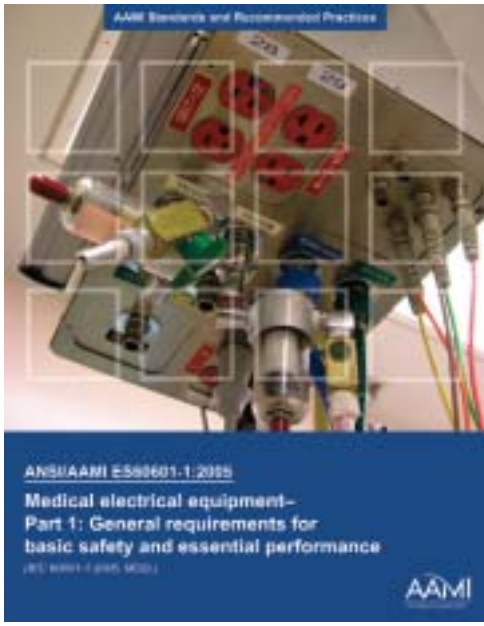
As early as 1968, AAMI's Electrical Safety Subcommittee had begun addressing the potential hazards associated with the increasing use of advanced diagnostic and therapeutic electromedical equipment in hospitals. This work would culminate with the official approval (June 1971) and publication (September 1971) of AAMI's very first standard: *Recommended AAMI Safety Standard for Electromedical Apparatus—Part 1: Safe Current Limits*. The document recommended minimum design and construction methods for electromedical equipment and established "safe current limits" for the "risk currents" that may flow to or from electromedical equipment.

In the 35 years since its initial publication, AAMI has taken on a larger role in the development of international standards. AAMI's Chair-Elect Charles Sidebottom is the secretary of the IEC's medical electrical equipment subcommittee 62A and led the development of IEC 60601-1, 3rd edition. In the U.S., the standard is available as ANSI/AAMI ES60601-1, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*, which supercedes, with greatly expanded scope, the AAMI safe current limits standard. At more than 300 pages, it is often referred to as "the bible" by medical electrical equipment professionals, and is seen as a major step forward in patient safety.


Association for the Advancement of Medical Instrumentation
Subcommittee on Electrical Safety

Recommended AAMI safety standard for electromedical apparatus

Part 1: safe current limits



Electrical patient safety is now a given. That wasn't always the case, and AAMI has played a key role in making equipment safer and more reliable.

Mort Levin

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

MILESTONE—1974

AAMI is appointed administrator of its first international standards secretariat, ISO TC 150/SC2, Cardiovascular implants.

The third edition of 60601-1 will be Chuck Sidebottom's legacy—not only with AAMI but to the whole medical electrical equipment standards family, nationally and internationally.

Nick Tongson, AAMI senior director of standards

Charles Sidebottom

The driving force behind the latest revision of IEC 60601-1, Sidebottom has guided the development of this key international standard for medical electrical equipment for a decade as secretary for IEC/SC 62A, Common Aspects of Electrical Equipment Used in Medical Practice. Sidebottom and his employer, Medtronic, were also instrumental in establishing ISO/TC 150/SC 6, the international subcommittee on active implants, largely due to Sidebottom's work with implantable pacemakers and defibrillators. In 2007, he was recognized as one of four recipients of the inaugural AAMI Standards Developer Award.

"One of the things that got me into standards work was the idea of a single set of technical criteria that could be used worldwide to judge the safety and, to a degree, efficacy of medical devices. Although we still have a long way to go to reach that goal, we have made substantial progress with our standards being recognized by many regulatory agencies around the world."

William S. Staewen, CCE

A key contributor in many different program areas, Staewen worked in standards, certification, publications, and educational programming. He was vice president from 1977 to 1978, served on the Board of Directors from 1978 to 1981, and was a member of the Standards Board from 1979 to 1989.

"I enjoyed every minute of it because I was involved during the 'glory' years . . . the growing years, during which we saw significant progress in patient electrical safety, medical device standards, and innovative electromedical technology. I have always cherished the memories of the wonderful people I was privileged to work with through my association with AAMI."

AAMI President-elect Mort Levin, President Dennis Stupak, Executive Director Michael J. Miller, and Cochair of the Standards Board Robert C. Flink represented AAMI at the NIST hearings on the development of international standards in 1990.

Mort Levin presents 1991 AAMI Foundation Laufman-Greatbatch Prize to Allen Latham, Jr.

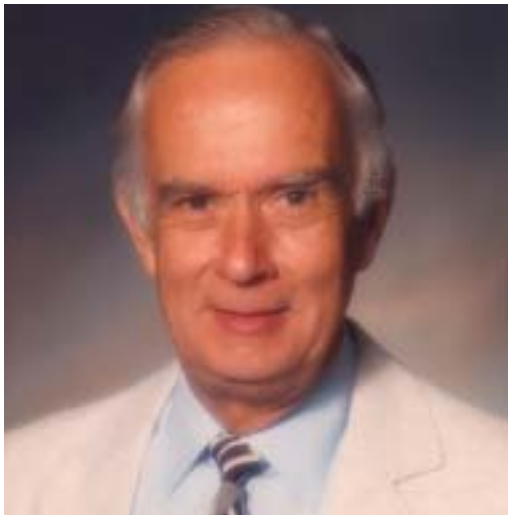
AAMI has 20 committees and working groups in the electromedical area that have published 69 general and device-specific American National Standards and AAMI Technical Information Reports over the years.

Sterilization

The success and growth of AAMI's sterilization program over the last 30 years reflects the work of literally hundreds of volunteers who participated in developing the standards, but it also stems from the good fortune of having such dynamic leadership of the AAMI Sterilization Standards Committee, in people like Carl Bruch, Bob Ernst, Neal Danielson, Virginia Chamberlain, Victoria Hitchins, Bill Young, Darlene McLeod, Bertha Litsky, Judy Veale, Jan Schultz, and Colette Keyser.

Joe Lewelling, AAMI vice president
for standards development

An early AAMI standards committee meeting. AAMI would go on to become an international leader in medical device standards.



Much of AAMI's success in sterilization standards comes from the fact that, from the very beginning, industry and hospital people worked side by side on the committee. With the marriage of the industrial side and the hospital central service personnel, we had a cross fertilization that amazed me. We produced documents that had real substance, that gained recognition from the healthcare community, and that established AAMI's role as a leader in the field.

Carl Bruch, Cochair of AAMI's Sterilization
Standards Committee from its
inception in 1974 through 1998

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

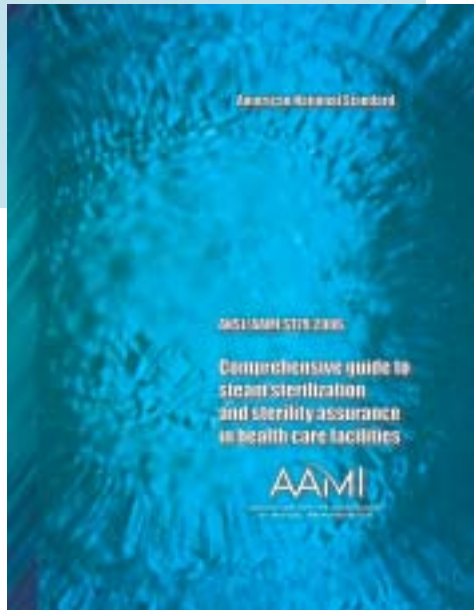
MILESTONE—1974

The AAMI Sterilization Standards Committee is founded. The committee is cochaired by Robert Ernst and Carl W. Bruch, and will go on to become AAMI's most prolific standards committee, with more than 30 affiliated working groups publishing nearly 80 nationally recognized documents since the committee's inception.

I can't think of anyone who has contributed more to the AAMI standards program, both as the tireless chairman of several working groups and as a committed member of many others, than Neal Danielson. He has truly dedicated himself to the advancement of sterilization practice in healthcare facilities, to the benefit of AAMI, the central service profession, and, most importantly, the patients.

Judith Veale, former AAMI director of standards

AAMI's 2006 guidance for hospital steam sterilization carries the legacy of cooperation between industry and hospital professionals to the present.



Virginia C. Chamberlain, PhD

Virginia Chamberlain began her involvement with AAMI in 1983 when she became the CDRH, FDA representative on the Sterilization Standards Committee (SSC) and several of its working groups. In 1988, she was named cochair of the committee, and two years later was named chair of the newly formed ISO/TC 198, Sterilization of Healthcare Products, holding the position until 1999.

"The SSC presented the opportunity for contact with a network of sterilization experts from industry, healthcare, academia, and government. This network provided a chance to learn from others more actively involved in actual sterilization of products and a chance to bounce ideas off each other in a respectful, non-threatening atmosphere. The ISO Technical Committee gave the opportunity to network with experts from around the world. I know that, as a result of my involvement with the SSC, I was better able to perform my job at FDA in protecting the public health."

Neal E. Danielson

During his years on AAMI's Hospital Practices Working Group on Steam Sterilization, which he chaired for nearly 20 years, Danielson was a driving force behind the AAMI standards that have had a profound positive effect on patient safety. AAMI's newest hospital steam sterilization guidance draws heavily from the standards he helped develop in the 1980s and 1990s. Danielson also assumed a leading role in defending the continued practice of ethylene oxide sterilization in healthcare facilities.

"I'm proud to see that AAMI still has a strong voice in the continued progress of improving the medical device industry. Having the opportunity to be a part of bringing together different disciplines for consensus in the area of sterilization of medical devices is one of my most satisfying memories."

AAMI standards committee meeting.

MILESTONE—1977

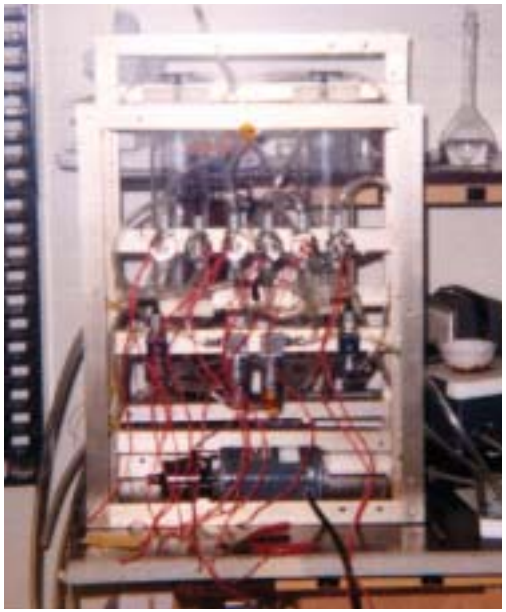
AAMI is accredited by ANSI as a National Standards Organization and, a year later, publishes its first ANSI-recognized American National Standard, *Safe current limits for electromedical apparatus*.

Matthew Weinger, George Hutchinson, Peter Carstensen, Michael Wiklund, and Charles Sawyer at the 11th Annual AAMI/FDA International Conference on Medical Device Standards and Regulation (2001), where they participated in a discussion on human factors in medical device design.

Dialysis

Working on the AAMI Renal Disease and Detoxification Committee was a great privilege. We wrote standards that helped improve practice, reduce conflicts, and establish an effective understanding with patients and government agencies. Even today, the committee continues to be active in these ways and others. I am proud that in all my years, we never took a vote—we acted on consensus.

John H. Sadler, MD, AAMI RDD Committee Chair, 1982–2002



Renal Systems prototype dialysis machine (inside)

Today, more than 20 million Americans have chronic kidney disease and another 20 million are at an increased risk.

Approximately 350,000 Americans are currently being treated with kidney dialysis.

The federal government pays 80% of all dialysis costs for most patients. Private health insurance or state medical aid also help with the costs.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

MILESTONE—1980

The first AAMI sterilization recommended practice is published. *Good hospital practice: Steam sterilization and sterility assurance* marks the beginning of a long history of AAMI guidance for hospital sterile processing departments and operating rooms to enhance patient safety.

Federal government policy for hemodialysis relies heavily on AAMI standards.

"This final rule contains standards and conditions for safe and effective hemodialyzer reuse and reprocessing, enforceable as Medicare conditions for coverage. It incorporates by reference voluntary guidelines and standards adopted by the Association for the Advancement of Medical Instrumentation in July 1986 (i.e., "Recommended Practice for Reuse of Hemodialyzers"). . . . failure of facilities to comply with these conditions could result in suspension of payment or removal of the facility from coverage under the Medicare program."

—Medicare program; standards for reuse of hemodialyzer filters and other dialysis supplies. HCFA. Final rule.

Nathan W. Levin, MD

Dr. Nathan Levin, medical and research director at the Renal Research Institute and professor of clinical medicine at Albert Einstein College of Medicine and former National Kidney Foundation board member, has made significant contributions to the renal community for more than 25 years, having served as a clinician, researcher and volunteer. Levin has a long history as an advocate for water quality standards in hemodialysis treatment and has been at the clinical forefront in the areas of hemodialysis adequacy and dialyzer reuse.

"I believe the effects of the AAMI Renal Disease and Detoxification Committee and its recommendations for increasing quality in dialysis are impressive. The acceptance by the Health Care Financing Administration and later the Centers for Medicare and Medicaid Services of various recommendations and standards is testimony to this. I joined the committee due to my interaction with Ronald Easterling, MD, then head of dialysis at the University of Michigan. He was a hands-on dialysis doctor of a type that has largely disappeared, and was an early leader in setting standards in dialysis."

LeRoy J. Fischbach

After joining Minntech (then known as Renal Systems) in 1973, his vast knowledge of equipment and the industry quickly earned him an international reputation as a technical expert in dialysis, blood filtration, and water treatment, which in turn led to his involvement as member and chairman of numerous technical standards committees with AAMI and ISO. As a longtime cochair of AAMI's Renal Disease and Detoxification Committee, he was an accomplished consensus builder, making certain that all stakeholders were part of the standards development process and doing all that he could to ensure that patient safety and quality of care were always the priority. In 2007, he was recognized (posthumously) as one of four recipients of the inaugural AAMI Standards Developer Award.

AAMI's participation and contributions in the hemodialysis arena go beyond standards-setting to providing an open forum for discussion and policymaking.

MILESTONE—1990

AAMI is named secretariat for a new ISO committee on sterilization. As administrator of ISO/TC 198 (and the related U.S. TAG), AAMI will go on to play a key role in the development of important sterilization standards and their worldwide acceptance.

Globalization of Standards

AAMI's Committee on Standards Strategy (CSS) came into existence in the late 1980s as AAMI embarked on a major expansion of its international standards program. AAMI had been a player in international standards since the early 1970s when the International Organization for Standardization (ISO) decided to develop standards for surgical implants and AAMI undertook responsibility for cardiovascular implants. As Europe moved toward a standards-based regulatory system a decade and a half later, AAMI's corporate members—especially those interested in selling their products worldwide—envisioned an important new role for the organization. International standards were becoming the gateway to the global market for medical devices, and AAMI would seek key leadership roles in ISO and the International Electrotechnical Commission (IEC) for its members and itself. Today AAMI serves as secretariat for most of the ISO and IEC committees that develop standards applicable to broad categories of medical devices—so-called "horizontal standards." These cover such topics as sterilization, quality systems, biological evaluation, risk management and electromedical safety. The European Commission and FDA have recognized these standards as suitable for demonstrating compliance with regulatory requirements. This serves both manufacturers and regulators, who now can rely on a single consistent set of international standards.

Robert C. Flink

Flink was director of standards for Medtronic, Inc. from the 1970s until his retirement in 2000. During that time, he took an active role in encouraging U.S. government and industry participation in medical device standards worldwide.

He has a long and distinguished record of contributions to ISO and IEC standards as well as AAMI standards committees, and also served on the AAMI Board of Directors and AAMI Standards Board. "Earl Bakken took me to a meeting of AAMI's Pacemaker Committee in the early 1970s. I made the 'mistake' of offering some comments on how to proceed, and the rest is history. AAMI participation allowed me to see a very broad picture of medical devices including clinical use issues, regulatory concerns, and technology past and future. This is largely due to the quality of AAMI membership and staff as well as the give-and-take between the disciplines present in the membership."

The International Standards Conference has been a mainstay of the AAMI–FDA relationship. Pictured: The 1992 conference [left], and Joe Tsiakals (Baxter), John Gams (Medtronic of Canada), Kim Trautman (CDRH), and Victor Dorman-Smith (Abbott Ireland) at the 2002 conference.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

MILESTONE—1991

AAMI assigned secretariat for IEC/SC 62D, Electromedical Equipment.

MILESTONE—1993

AAMI is named secretariat for a new ISO committee on quality management. AAMI's leadership of ISO/TC210 has helped usher in a new era of medical device manufacturing that helps define important processes, supports the regulatory framework, and results in safer devices and better patient care.

Betsy Bridgman

After a decade in progressively responsible positions with the American National Standards Institute (in both New York and Washington offices), Bridgman joined AAMI in January 1984 as manager of the standards program and in 1991 was appointed Executive Vice President. During her career at AAMI, she has at one time or another had supervisory or direct management responsibility for every programmatic and administrative department.

"The successful implementation of the international standards strategy is certainly one of the highlights of my tenure at AAMI. The support of AAMI's corporate members—both financial and technical—enabled the success of our strategy. FDA support was likewise crucial. Also very satisfying to recall is the formation of two new ISO technical committees under AAMI leadership—ISO/TC 198 on sterilization and TC 210 on quality management. The paths to creation of these committees through both national and international political quagmires and procedural bureaucracies were at times tortuous, to say the least. I admit there were times I doubted a favorable outcome, but TC 198 held its inaugural meeting in 1990 and TC 210 followed in 1994. Both committees have benefited from visionary leaders and contributed substantially to worldwide harmonization of medical device regulation.

Many of my most treasured memories involve the people I worked with—committee members and leaders, board members, staff colleagues—knowing these people and their dedication to a better, safer healthcare environment has enriched my life."

Theresa Zuraski

Zuraski joined the AAMI staff in 1988 as Director of Standards and is currently Senior Vice President of Standards Policy and Programs.

"My favorite memories involve all the great people on our technical committees as well as on staff whom I've had the fortune to meet and work with. I think the members and staff are all very dedicated people and it's always satisfying when one's work relates to such important goals as patient safety and improved patient outcomes. It was exciting to be part of the tremendous growth that AAMI underwent back in the early 1990s when we became much more involved in international standards. I remember all the meetings to discuss strategy and lay the groundwork for starting new international technical committees for sterilization (ISO/TC 198) and quality systems (ISO/TC 210), and the early years of our involvement in IEC when the secretariats of the two major subcommittees for medical devices covering common aspects of electromedical equipment (IEC/SC 62A) and electromedical equipment (IEC/SC 62D) were transferred to AAMI. Each of these presented their own challenges but, through the combined efforts of U.S. experts and AAMI staff involved in leadership roles internationally, AAMI managed to quickly develop new relationships and trust with the international medical device standards community. That foundation is what has enabled us to complete so many documents at the international level and to achieve one of the main goals set for us by the members—global harmonization of medical device standards."

Donald E. Marlowe

With nearly three decades at FDA and on AAMI standards committees, Marlowe has played a major role in raising the visibility and conveying the importance of standards within FDA, the industry, and the worldwide medical device community. Colleagues praise Marlowe as an exceptional leader in the area of biological evaluation of medical devices. He has made profound changes in the direction of laboratory research, focusing on integrating laboratory work with the needs of device reviews, enhancing the laboratory's investigative capabilities to deal with compliance problems, and championing the active participation of both laboratory and review scientists in consensus standards development.

"Biocompatibility standards have come a long way. When AAMI became active in the development of standards for biocompatibility, the idea was very tenuous. Today, standards for assessing biocompatibility of materials and devices are understood and appreciated by the global community."

MILESTONE—1996

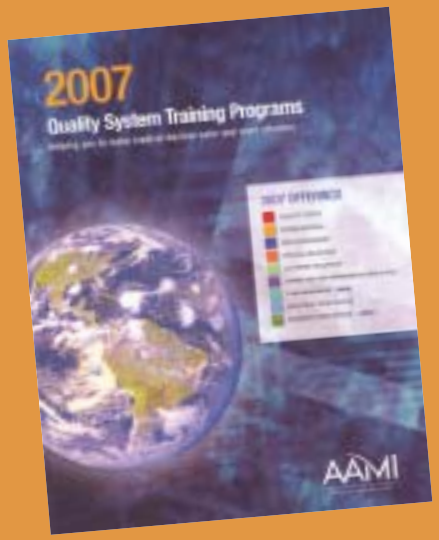
AAMI assigned secretariat for IEC/SC 62A, Common Aspects of Electrical Equipment Used in Medical Practice.

MILESTONE—1998

AAMI assigned secretariat for new ISO/TC 150/SC 6, Active Implants.

MILESTONE—2007

Current AAMI standards exceed the 150 mark. Over 50 percent are adoptions of ISO and IEC standards—one of the major goals of the 1990 program expansion to international standards.



AAMI
Q SOURCE

- Quality Systems
- Design Control
- Human Factors
- Software Validation

Includes key standards, guidance documents, and other resources medical technology developers need for product development and regulatory compliance.

Participants in an AAMI course gain insights on risk management from expert panel.

Panelists Kimberly Trautman, Alfred Dolan, Ed Kimmelman, and Paul Brooks discuss risk managment at the 2006 AAMI/FDA International Conference on Medical Device Standards and Regulation.

Ed Israelski discusses human factors engineering at an AAMI webinar.

Employees from ConMed Corp. [left above] were among the 450 medical technology professionals who participated in a 2005 webinar at 79 sites across the country. Presenters included Deb Yoder and Vickie Schmid [left, left to right].

GMPs and Quality Systems: A New Role for AAMI

The mid-1990s brought a new revision of FDA's good manufacturing practice (GMP) requirements, and with it came a new role for AAMI. When FDA began revising the original 1978 regulations in the mid-1990s, the agency turned to AAMI for help. In a groundbreaking effort, AAMI and others created a process where FDA and industry learned together what meeting the new regulation would require. For AAMI, it established the organization as the leader in quality systems education for the medical device industry. AAMI's government education programs grew out of the effort and are now a mainstay of the association.

AAMI's educational programs present the state of the industry practice in implementing regulations and standards. AAMI's approach is unique in the industry: current regulations, up-to-date industry practices, diverse faculty backgrounds and perspectives.

Tammy M. Pelnik, The St. Vrain Group, Inc., AAMI course instructor

AAMI was one means by which FDA offered training on the new regulation and what meeting it required. FDA chose AAMI, working in partnership with others, to create a process where FDA and industry would learn together.

Kathy Warye, former AAMI vice president of education and government programs

What are GMPs?

The good manufacturing practices (GMP) regulations outline a set of procedures to ensure that devices are manufactured to be safe and effective through quality design, manufacture, labeling, testing, storage, and distribution.

Interplay Between Standards, Regulation Gave AAMI Central Role

The worlds of medical device regulation and international trade had changed significantly since the first GMP regulation was published in 1978. The 1980s saw the coming together of the European Community, which emphasized voluntary standards as a form of regulation of medical devices. It became essential that regulators remove barriers to trade by harmonizing medical device regulatory requirements wherever possible, including in the area of GMPs—or quality systems as it was known internationally.

By the early 1990s, AAMI recognized the importance of international harmonization of standards and had taken a leadership role in many key international standards-writing efforts. This included TC 210, the International Organization for Standardization (ISO) committee that handles standardization of requirements and guidance in the field of quality management for medical devices. FDA was involved in these international committees and actively worked to harmonize the requirements of the new GMP regulation and international standards like ANSI/AAMI/ISO 13485, *Medical devices—Quality management systems—Requirements for regulatory purposes*.

The current GMP regulation took effect on June 1, 1997.

Working through AAMI committees, leaders like industry's Ed Kimmelman [below left] and FDA's Kim Trautman [below right, pictured with Victor Dorman-Smith of Abbott Laboratories, Ireland] played major roles in the creation of international standards for quality systems for medical devices. Here, both are shown at a meeting of ISO/TC 210.

Global Harmonization Task Force (GHTF)

Representatives from the United States, the European Union, Canada, and Japan created this global consultative partnership in 1992 in order to harmonize medical device regulatory practices, including GMPs. This voluntary group includes representatives from national medical device regulatory authorities and the regulated industry. It aims to encourage convergence in regulatory practices by publishing and disseminating harmonized guidance documents on basic regulatory practice that can then be adopted or implemented by member national regulatory authorities.

As Secretariat of ISO/TC 210, AAMI established a Memorandum of Understanding with the GHTF. TC 210 has incorporated GHTF guidance into its standards and the two organizations have frequently held joint working group meetings aimed at harmonizing their documents related to quality systems.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

1997

FDA Modernization Act signed into law; new quality systems regulation takes effect.

1997

AAMI launches Quality Systems course and exam, March 17–21.

1998

AAMI launches Design Control course.

Materials, Course Development Use Consensus Process

In May 1995, AAMI—with FDA's support—announced that it would launch an education program for GMP consultants, auditors, and corporate regulatory affairs professionals. The goal of the program was to establish a common body of knowledge of GMP requirements, bringing greater uniformity, consistency, and correctness to the interpretation and application of the medical device GMPs.

To help develop content for the courses, AAMI hired the consulting team of Ed McDonnell and Fred Hooten, both former FDA staffers. Following its standards model, AAMI formed a committee made up of representatives from industry, government, and private consulting that used a consensus process to interpret the emerging regulation. A two-year effort resulted in the course materials that would help both FDA and the industry understand and interpret the new GMP regulation.

In December 1996, their efforts resulted in the publication of *The Quality System Compendium*, the definitive desk reference on the new regulation. Each chapter includes a restatement of the relevant portion of the regulation, interpretations of the provision, and relevant industry practices.

In 2005, a supplement to the *Compendium* was published that included updated information about FDA's quality system regulation.

Content development was a considerable project given that FDA and industry participants were not just writing content but really working out interpretations of the regulation. In many ways, the content of the courses drove interpretation.

Kathy Warye

The advantage is that the materials we developed were not one person's opinion, but rather involved a collective effort that was constantly updated.

Vera Buffaloe

1999

AAMI invited by FDA to hold GMP/QS courses for European conformity assessment bodies.

1999

AAMI launches process validation course.

2000

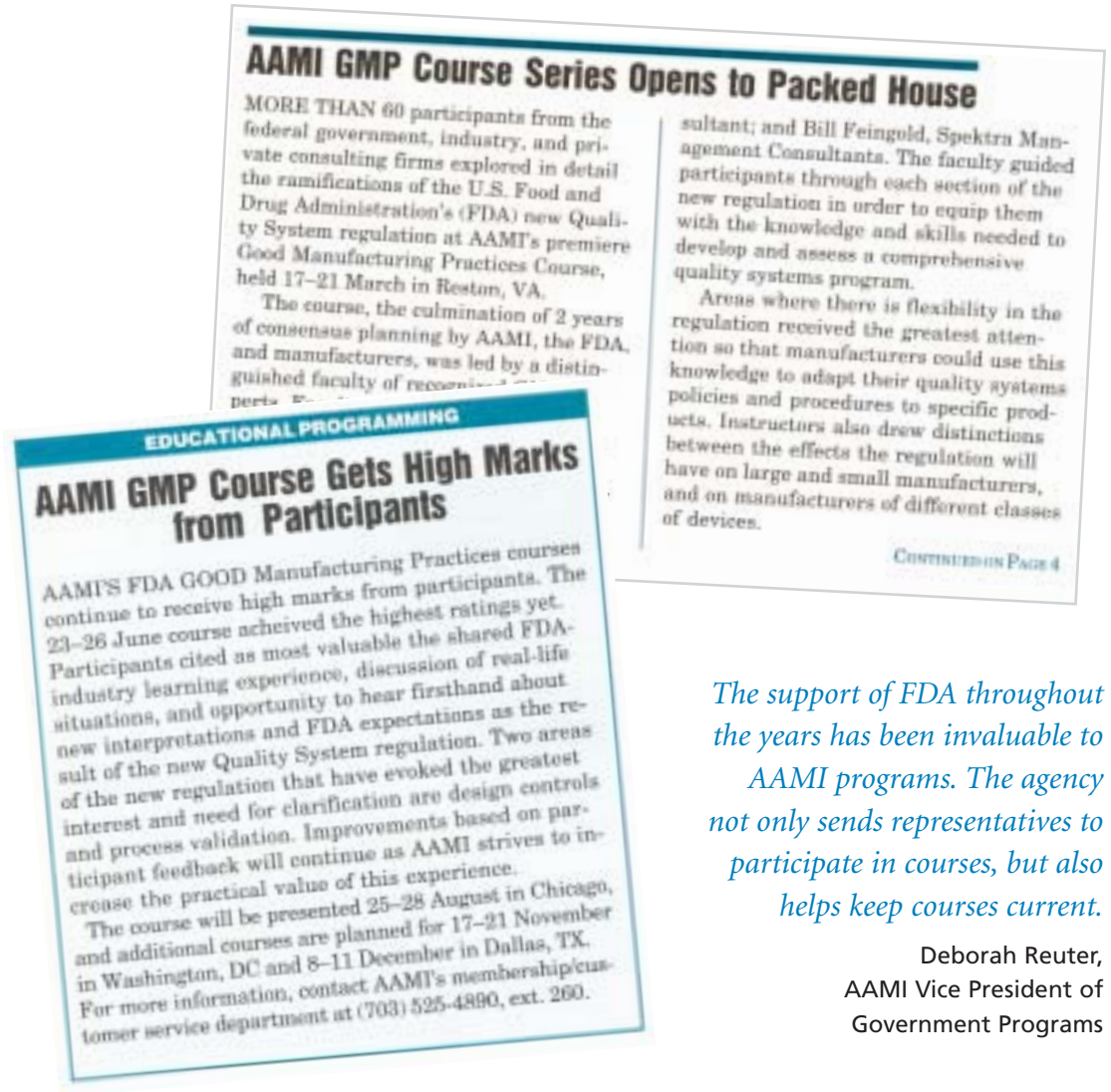
AAMI and FDA hold seminar on reuse of single-use devices.

Quality Systems Course Premieres in 1997 to Packed House, Sees Continued Growth

The first Quality Systems course premiered in January 1997 to a packed house. It offered four days of intensive, interactive instruction that stressed strategies participants could employ to implement the new requirements. A half-day examination followed the course, giving participants a chance to gauge their mastery of the materials presented. Faculty members were drawn from industry, consulting, and government. Attendees included both industry representatives and FDA professionals, all of whom needed to learn about the new regulation.

It received high marks from participants, who cited as valuable the shared FDA-industry learning experience, discussion of real-life situations, and the opportunity to hear firsthand about new interpretations and FDA expectations as the result of the new Quality Systems regulation.

AAMI's programs sell out on a regular basis. A core group of 24 industry representatives do the actual training for the courses. Perhaps most importantly, FDA also supplies a representative to attend each course. FDA involvement in the courses is an immense benefit to attendees and contributes to the popularity of the courses.



AAMI GMP Course Series Opens to Packed House

MORE THAN 60 participants from the federal government, industry, and private consulting firms explored in detail the ramifications of the U.S. Food and Drug Administration's (FDA) new Quality System regulation at AAMI's premiere Good Manufacturing Practices Course, held 17–21 March in Reston, VA.

The course, the culmination of 2 years of consensus planning by AAMI, the FDA, and manufacturers, was led by a distinguished faculty of recognized [illegible] experts. [illegible] sultant; and Bill Feingold, Spektra Management Consultants. The faculty guided participants through each section of the new regulation in order to equip them with the knowledge and skills needed to develop and assess a comprehensive quality systems program.

Areas where there is flexibility in the regulation received the greatest attention so that manufacturers could use this knowledge to adapt their quality systems policies and procedures to specific products. Instructors also drew distinctions between the effects the regulation will have on large and small manufacturers, and on manufacturers of different classes of devices.

Continued on Page 4

EDUCATIONAL PROGRAMMING

AAMI GMP Course Gets High Marks from Participants

AAMI'S FDA GOOD Manufacturing Practices courses continue to receive high marks from participants. The 23–26 June course achieved the highest ratings yet. Participants cited as most valuable the shared FDA-industry learning experience, discussion of real-life situations, and opportunity to hear firsthand about new interpretations and FDA expectations as the result of the new Quality System regulation. Two areas of the new regulation that have evoked the greatest interest and need for clarification are design controls and process validation. Improvements based on participant feedback will continue as AAMI strives to increase the practical value of this experience.

The course will be presented 25–28 August in Chicago, and additional courses are planned for 17–21 November in Washington, DC and 8–11 December in Dallas, TX. For more information, contact AAMI's membership/customer service department at (703) 525-4890, ext. 260.

The support of FDA throughout the years has been invaluable to AAMI programs. The agency not only sends representatives to participate in courses, but also helps keep courses current.

Deborah Reuter,
AAMI Vice President of
Government Programs

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

2001

AAMI launches software validation course.

2002

AAMI receives funding from FDA to educate hospitals on the regulation for reprocessing SUDs, which results in AAMI's first live webinar.

2002

AAMI introduces courses on Industrial Sterilization and Risk Management.

AAMI course instructors John Sawyer [left], Vera Buffaloe, and Dan Weese at a 1999 course.

Vera Buffaloe

Vera Buffaloe is an author of AAMI's *The Quality System Compendium* and led the development of content for the Design Control and Process Validation courses launched in 1998 and 1999, respectively. She has served as an instructor for AAMI's quality systems, design control, process validation, and CAPA courses since 1997. Currently president of Buffaloe Consulting, Inc., she has more than 25 years of experience as a regulatory and quality professional in the medical device industry.

Most companies want to understand what is required, and word has spread about the quality of these programs that set the standard for the industry.

Vera Buffaloe

Whatever Happened to GMP Certification?

AAMI originally envisioned the program to be a certification program, but the concept of certification was scuttled because of industry concerns over threshold requirements, retesting, and recertification. In a compromise, an exam is now offered upon completion of a course without formal certification attached to it. Ironically, today the course and the exam are so well thought of by both the industry and FDA that many consider passing the exam a requirement that carries almost the weight of a certification. In the end, the importance of the program was clear even without a certification requirement, through quality and impact on the community.

2003

AAMI launches Corrective and Preventive Action (CAPA) course.

2005

AAMI begins offering educational programming on the updated quality system standard, AAMI/ANSI/ISO 13485:2003.

2006

AAMI adds radiation sterilization course to educational offerings.

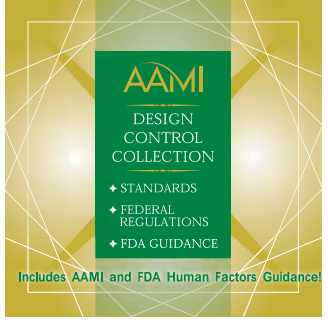
Courses, Materials Added In Response to Requests

Quality Systems course attendees consistently gave the course high ratings, but frequently requested more in-depth information on various subsystems of the regulation. In response to these requests, AAMI undertook new content development efforts and rolled out a series of short courses on specific topics starting in 1998. These short courses concentrated on specific sections of the GMP regulation:

- Design Control course, 1998, developed by Vera Buffaloe
- Process Validation course, 1999, developed by Vera Buffaloe
- Software Validation course, 2001, developed by Alan Kusinitz
- Corrective and Preventive Action (CAPA) course, 2003, developed by Vera Buffaloe and Ken Peterson
- Risk Management course, 2002, with 2005 revisions led by Tammy Pelnik, provide an in-depth examination of its role in the GMP regulation.

In addition, a new book, *Supplement to the Quality System Regulation*, was published in 2004 to keep manufacturers current on new strategies for compliance with the regulation and key areas that have experienced significant change in the years since the Compendium was first published. This project was led by Tammy Pelnik.

All of AAMI's courses and materials were developed with a consensus approach. Both industry representatives and FDA were involved in providing information and reviewing each course to make sure it included accurate interpretation of the regulation and reflected industry practice.



AAMI to Introduce Design Controls Course this Spring

IN RESPONSE TO numerous requests from participants in AAMI's comprehensive course, *GMP/QS Requirements and Industry Practice*, AAMI will introduce a short course on design controls this spring. This course is the first in a series of short courses concentrating on specific sections of the U.S. Food and Drug Administration's (FDA's) Quality System regulation. The first short course will build on the foundation of the design controls content from the original GMP/QS course, which was developed in collaboration with FDA and industry experts.

The program will consist of 3 days of intensive coverage of the elements of design control. Content will be targeted toward quality assurance staff, such as RA/QA, research and development, design engineering, and manufacturing professionals. Upon completion of the course, participants will be able to evaluate the degree of compliance of a design control system including identification of noncompliance issues and improvements needed to bring practices into c
sions of the FD
will be based p
Guidance for M
sign Control In
mid-year evalu
ducted by FD
team, will als

AAMI Launches New Process Validation Course, Developed Jointly with FDA

A NEW EDUCATIONAL TOOL designed to help manufacturers comply with the FDA's GMP/Quality System regulation and bring them up to date on the Global Harmonization Task Force's (GHTF) guidance on process validation was introduced by AAMI last month. "Process Validation Requirements and Industry Practice," a three-day course held in Washington, DC, is the latest addition to the growing family of quality systems-related products developed by AAMI over the past three years.

Like the first two courses, "Design Control Requirements and Industry Practice" and "GMP/Quality Systems Requirements and Industry Practice," this third course was developed with the shared-learning formula that continues to be well-received by both government and industry. Unique in the medical devices industry, this consensus approach is intended to promote in-

"This consensus approach promotes interaction and open dialogue."

teraction and open dialogue among regulatory affairs experts, quality systems professionals, manufacturing and process development engineers, and FDA staffers.

With 22 participants from industry and 12 from FDA's Center for Devices and Radiological Health participating in the course, this goal was met, according to Kathy Warye, AAMI's senior vice president, Education and Government Programs. "Process validation has been an

CONTINUED ON PAGE 2

After the initial courses, surveys indicated overwhelming requests for more courses. We added new topics in response to requests from participants.

Vera Buffaloe

AAMI-FDA Relationship Brings Agency Benefits

Starting in 2004, FDA has brought AAMI's Design Control, CAPA, and Process Validation courses in-house to train their Office of Compliance personnel. And, with FDA losing personnel due to retirements, the agency is having new staffers teach AAMI courses to gain exposure to industry.

AAMI and the Japanese Society of Medical Instrumentation (JSMI) have been collaborating for more than 30 years. At right, Masakazu Tsuzuki, MD [center], who first made contact with AAMI in 1974, is pictured with former AAMI Chair Stanton P. Nolan, MD [left] and Mike Miller.

Here, Harold Laufman is pictured with Masakazu Tsuzuki and other representatives from the JSMI during the 1982 AAMI Annual Conference.

Quality Systems Work Only One Aspect of Important Relationship with JSMI

When AAMI's quality systems course traveled to Japan, it was only one more example of an important collaboration between AAMI and the Japanese Society of Medical Instrumentation (JSMI) that began more than 30 years ago.

In 1974, Masakazu Tsuzuki, MD, who was chairman of the international liaison committee of JSMI (then known as MISJ) began corresponding with then-AAMI president Harold Laufman, MD, PhD. He visited Laufman in America and then attended the 11th AAMI Annual Meeting in 1976 in Atlanta, GA. This was the first of 25 consecutive AAMI Annual Meetings that Tsuzuki would attend.

Over the years, JSMI has sponsored many educational programs at AAMI's Annual Conference. Since 1992, they have organized and supported joint JSMI–AAMI scientific sessions, and a special lunch for AAMI board members. They have invited many AAMI officers and staff to speak in Japan on many subjects. "We will continue to support this joint program, and we are also interested in expanding our international cooperation in the field of medical device regulations and R&D and also in the field of international telemedicine," says JSMI international committee chairperson Kenichi Matsumoto.

The following individuals deserve special recognition for their leadership in collaborative efforts between AAMI and JSMI:

- Masakazu Tsuzuki, MD. He is today an honorary member of JSMI, and is chairman of the board of directors of the International Medical Device Society of Japan
- Kenichi Matsumoto, chairman, International Liaison Committee, JSMI
- Masaki Takashina, MD, of the Surgical Center at Osaka University Hospital, Japan.
- Masako Kaufman, Liaison, JSMI

New Formats Broaden Course Accessibility, Tailor Content

Webinars

In response to demand, AAMI began bringing programs to its audience by holding webinars, or web-based seminars. These popular online sessions typically offer two-hour programs that focus on specific aspects of standards, regulation, procedures, or policies. Webinars allow thousands of people to participate. For example, almost 2,000 listeners tuned into AAMI's online seminar on the topic of the ISO 13485 standard, held in December 2003.

In-House Training

In-house training is another popular format increasingly being requested by program participants. Attendees impressed by the quality of AAMI's programs went back to their companies and encouraged management to bring AAMI training in-house. From four programs held in-house in 1999, the program has now grown to 26 programs held in-house in 2006.

European Notified Bodies

In 1999, the AAMI GMP/Quality Systems course and exam were selected by FDA as a component of the training curriculum for notified bodies and conformity assessment bodies (CABs).

A scene from AAMI's first webinar.

AAMI's quality systems courses have also made an international impact, with tailored programs being offered since 1997 in countries such as Germany, Japan, and Sweden. Here, a shot from a program held in Japan.

Each course incorporates hands-on exercises, so when participants return to their jobs, they are ready to use the tools and methods presented. As courses include both industry experts and FDA employees on the faculty, participants receive a breadth of perspectives.

Tammy M. Pelnik, The St. Vrain Group, Inc.,
AAMI course instructor

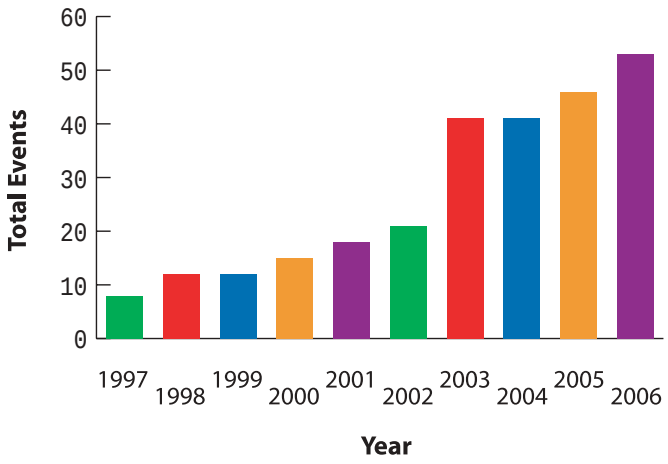
Consensus, Training Success Opens New Opportunities for AAMI

Building on the success of the AAMI–FDA collaboration in the GMP arena, AAMI will be seeking new areas of collaboration with FDA, working with other interests, to achieve consensus on quality systems and other important areas of regulation. While AAMI has always served as an important neutral third party, its role as facilitator of consensus was heightened by the success of the GMP programs. AAMI has since played a leading role in questions like whether third party servicers would be regulated and resolving electromagnetic compatibility concerns. AAMI also had the opportunity to hold conferences and other consensus building activities in contentious areas such as the reuse of single-use devices.

In addition, the success of the standards-to-training-course format has resulted in the addition of new training courses based on AAMI standards documents. The last few years have seen the premier of three standards-based education programs:

- Building a Quality Management System in a Regulated Environment: a 13485 Workshop
- Industrial Sterilization for Medical Devices
- Radiation Sterilization for Medical Devices
- Risk Management for Medical Devices

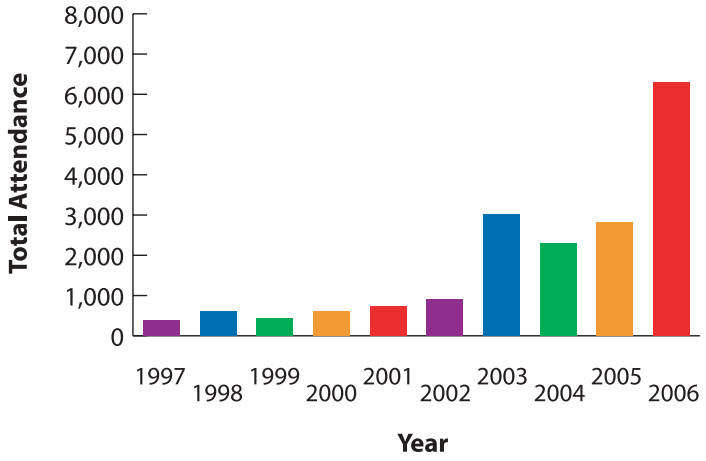
Growth in Government Programs Offerings



Leah Lough

Leah Lough joined AAMI in 2001 as the senior vice president of education and government programs. During her tenure, the number of government programs and standards-related programs tripled. She is now AAMI's executive vice president for education and membership services.

Growth in Quality Systems and Standards-Related Program Attendance

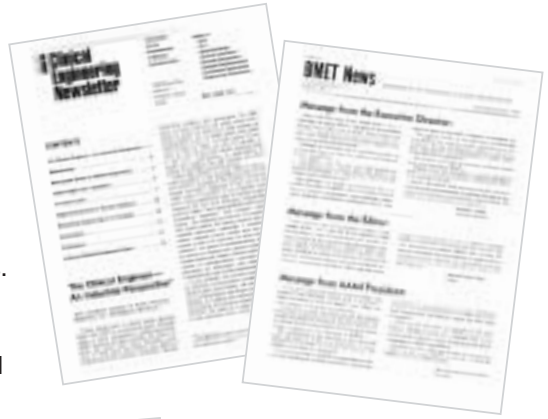


AAMI Services and Recognition

Publications

AAMI Newsletters Keep Members Informed

Several AAMI newsletters have come and gone over the years, including *Clinical Engineering News*, *BMET News*, and *Medical Device Research Report*. But *AAMI News*—which premiered in September 1965—is still going strong after more than 40 years.



As the association's official newsletter, *AAMI News* has undergone several design changes in the last four decades and grown significantly in size to support an increase in editorial and advertising content. Published 11 times each year, the newsletter strives to cover the diverse interests of AAMI members and provide a mix of timely news about industry events and updates on AAMI's own products and services.

In recent years, a "Tech World" column has been added to the newsletter to provide a voice for the technician segment of AAMI's membership; other sections have been expanded to recognize the achievements of AAMI members. In surveys, *AAMI News* consistently ranks as a top membership benefit.

AAMI Clinical Engineering Publications

AAMI has been providing technical and professional resources for the engineering community since the early days. From the *Electrical Safety Manual* to the *Medical Equipment Management Manual*, the *BMET Study Guide* and the *Clinical Engineering Management Collection*, these resources give biomedical equipment technicians and clinical engineers the information they need to be successful.

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY

Journal Serves as Flagship Publication

AAMI's first journal, *Medical Instrumentation*, premiered in 1965 and quickly became the leading journal of the medical device community. In 1985, *Biomedical Technology Today* premiered, and three years later the two journals merged to form *Biomedical Instrumentation & Technology* (*BI&T*).

As AAMI's peer-reviewed flagship journal, *BI&T* places a heavy emphasis on articles of practical use for biomedical equipment technicians, clinical engineers, and other medical technology professionals. In recent years, columns have been added to focus on IT issues, certification, career guidance, best practices, Joint Commission news, and troubleshooting expertise. In 2006, AAMI launched the online edition of *BI&T*, which enables members to view and search through current and archived editions. Today, the journal—which is mailed to more than 6,000 members and other subscribers—is distributed in 52 countries around the world.

In recent years, a series of *BI&T* supplements to the journal, called *Horizons*, have been published to address specific topics and niche audiences, including dialysis, IT issues, and issues of mutual interest to biomeds and the nursing community.

Website Premieres in 1997

AAMI's website added a new dimension to the communications program with its launch in 1997. Over the years, the website has grown significantly to include specialized and popular sections on standards, educational issues, and publications. AAMI's online Career Center—which helps to match employers with qualified job applicants—is consistently one of the most visited areas of the site. Each month, www.aami.org attracts nearly 70,000 visitors.

Annual Conference

Since 1966, AAMI's annual conferences have brought together professionals who share a common interest in the advancement of medical instrumentation. By giving members a forum to educate one another, build consensus on important issues, recognize leaders in the field, and even showcase new products, the annual meeting is key to AAMI's success every year.

1972

Program Committee Continually Updates Content, Presents Broad Spectrum of Ideas

The content of AAMI's Annual Conference is developed by a program committee that meets each year to lay out the framework for the program and then works for several months developing educational sessions. They not only develop the content but also recruit speakers and moderators for each session.


1983

Topics change each year and range from business management to patient safety to new technologies to information technology. With presenters ranging from senior management at medical device manufacturers to astronauts to FDA officials to pioneering physicians, AAMI attendees hear from a broad spectrum of leaders to help enhance their knowledge base and better understand their current role and what the future may hold for their field.


1993


1973

The Annual Conference is constantly evolving to meet the needs of the field. From adding topic areas such as information technology to the program to providing unfettered access to Joint Commission officials, the Program Committee ensures that the knowledge gained at the conference is timely and relevant to attendees and changes with industry demands.

Chris Dinegar, AAMI
vice president of education

Over the years, the AAMI Annual Conference has evolved to meet the dynamic needs of the AAMI membership, technology, and the overall healthcare delivery system. This progress has been possible because of the partnership between AAMI staff and members as well as the professional commitment of individuals.

Carol E. Davis-Smith, CCE, Premier Consulting Solutions, Inc., former AAMI Annual Conference Cochair


1979

1997

In my experience attending the AAMI annual conference over the past 29 years, plus having participated in its planning over the past six years, the clinical engineering community as a whole has been well served by the conference's fresh content and found the venue to be a focal point for professional development.

Mark E. Bruley, CCE, ECRI, 2007 AAMI Annual Conference Cochair

Expo Hall Makes AAMI Conference a Premier Event

The Expo Hall has grown significantly over the years and new companies are purchasing booth space each year. New opportunities exist for exhibitors to provide educational sessions at the conference through breakfast symposia and through special showcase sessions in the exhibit hall. In 2007, more than 160 companies will be participating in the Expo.


2000

Partnerships Enhance Content, Highlight Partnerships

In an effort to get varying points of view on the topics being covered, AAMI continues to develop relationships with organizations including the Healthcare Information Management Systems Society (HIMSS), the American College of Clinical Engineering (ACCE), and the Japanese Society of Medical Instrumentation (JSMI) and works with them in providing education from their areas of expertise.

Conference Offers Unique Access to Joint Commission

A unique partnership with the Joint Commission begun in recent years offers conference attendees rare access to Joint Commission officials. The AAMI conference is one of the only places that biomedical technology managers and clinical engineers get to discuss Joint Commission requirements and where Joint Commission requests input from biomeds and CEs.

Local Biomed Groups Play Key Role

AAMI partners with local biomedical associations across the country in an effort to provide exposure to these organizations on a national scale as well as incorporate their issues into the educational program. Their involvement highlights these groups and allows their members to participate at a discounted rate.

International Flavor Adds to Annual Conference

International attendance at AAMI's conference has increased over the years. A special reception is now offered for international attendees. They come from Europe, Canada, Mexico, South America, and Asia.

AAMI Award Winners

From the young investigators just launching their careers, to mid-career professionals looking to further their education, to the giants in the field, AAMI's awards program has brought recognition to medical device professionals at every stage of their careers.

Clarence Dennis and Dwight Harken present the 1982 Laufman Award to Wilson Greatbatch [right].

AAMI Foundation Laufman-Greatbatch Prize

Honors an individual or group that has made a unique and significant contribution to the advancement of medical instrumentation.

1975	Barouh V. Berkovits
1976	Robert F. Rushmer, MD
1977	Willem Johan Kolff, MD, PhD
1978	Godfrey N. Hounsfield
1979	Norman J. Holter, DSc
1980	Martin H. Wilcox
1981	Reginald C. Eggleton
1982	Wilson Greatbatch, PE
1983	Charles A. Mistretta, PhD
1984	Clarence Dennis
1985	Dwight E. Harken, MD
1987	Leslie A. Geddes, ME, PhD
1988	Michel Mirowski, MD
1989	Paul C. Lauterbur, PhD
1991	Allen Latham, Jr.
1992	Otto Herbert Schmitt, PhD
1993	Craig J. Hartley, PhD
1994	Robert Arzbaecher, PhD
1995	John Watson, PhD
1996	John G. Webster, PhD
1997	Alan Berson, PhD
1998	Earl E. Bakken
1999	Adrian Kantrowitz, MD
2000	Thomas Fogarty, MD
2001	Huntly D. Millar
2002	David E. Flinchbaugh, PhD, PE
2003	David Hood, Steve Alexander, Matthew Hanson, Todd Kneale, and Terry Domae
2004	Dr. George J. Magovern, Sr., MD
2005	Maynard Ramsey, III, MD, PhD
2006	Nathaniel Sims, MD
2007	Willis A. Tacker, Jr., MD, PhD

Harold Laufman, MD, PhD, presents the 1979 AAMI Foundation Harold Laufman Award to Norman J. Holter, DSc, for the development of biotelemetry of biological phenomena.

Paul C. Lauterbur, PhD, a pioneer in the development of magnetic resonance imaging, won the AAMI Foundation Laufman Prize in 1989. He would later be recognized with the 2003 Nobel Prize in Physiology or Medicine for his work.

Harold Laufman, MD, PhD

Harold Laufman, MD, PhD, for whom the AAMI Foundation Laufman-Greatbatch Prize is named, served as AAMI's president from 1974 to 1976. He is emeritus professor of surgery at Albert Einstein College of Medicine and director emeritus, Institute of Surgical Studies, Montefiore Medical Center in New York. He is a surgeon renowned for his work in operating room sepsis, and designed the first prototype operating room in which mechanical and electric services and all surfaces and fixtures were easily adjustable and changeable to accommodate new technology safely, efficiently, and economically. At age 84, after a pioneering career in vascular surgery and research, he formed a new company, HLA Systems, and he and his biomedical engineering partners have consulted on design, construction, renovation, and operation of more than 300 hospitals and healthcare institutions all over the world.

AAMI Leadership Award

This award, given only three times in AAMI's history, recognizes AAMI leaders who have made an extraordinary contribution to the growth of the association and the advancement of medical instrumentation.

1986

Lt. Col. Burt Dodson, Jr., for his development of AAMI's certification program for biomedical equipment technicians in the 1970s, which became the defining factor in AAMI's relationship with and programming for BMETs.

1994

Edward R. Duffie, Jr., MD, for his driving role in the 1991 AAMI reorganization that helped refocus the association's priorities and position it for major growth.

2001

Robert C. Flink, for his visionary leadership in standards.

Clinical/Biomedical Engineering Achievement Award

Recognizes individual excellence and achievement in the clinical engineering and biomedical engineering fields.

1980	David J. Lubin, CCE
1983	Thomas S. Hargest, CCE
1984	Jonathan Newell, PhD
1985	Thomas J. Bauld, III
1990	Emanuel Furst, PhD
1991	Dwayne R. Westenskow, PhD
1992	Alfred M. Dolan, CCE
1993	James P. Keller
1994	Larry Fennigkoh, CCE
1995	Michael Van Lysle
1996	Gailord Gordon, CCE
1998	William Betts, CCE
2000	Robert H. Stiefel, CCE
2001	Malcolm G. Ridgway, PhD, CCE
2002	J. Tobey Clark, CCE
2003	Eric Rosow
2004	Ted Cohen, CCE
2005	Joseph F. Dyro, PhD, CCE
2006	Alan Lipschultz, CCE
2007	Larry Hertzler, CCE

Alan Lipschultz [left] receives the 2006 Clinical Engineering Achievement Award from Bob Stiefel.

Becton Dickinson Career Achievement Award

Identifies and encourages outstanding achievement(s) by a promising health care professional in the development or improvement of medical devices, instruments, or systems that will help all people live healthy lives.

1977	William Schuler Pierce, MD
1979	Dwayne R. Westenskow, PhD
1980	Deane B. Jacques, MD
1981	Anthony M. Albisser, PhD
1982	William D. Ensminger, MD, PhD
1983	Perry J. Blackshear, MD
1984	Robert A. Kruger, PhD
1985	Stephen C. Jacobsen
1986	Donna Bourgelais
1988	Kenneth R. Hogstrom, PhD
1989	George Kondraske, PhD
1990	Michael J. Kallok, PhD
1991	Neal E. Fearnot, PhD
1992	Rebecca Richards-Kortum, PhD
1993	Dwight Nishimura, PhD
1994	Deborah Burstein, PhD
1995	Ira Tackel, CCE
1996	Arun Gulani, MD
1997	Suresh Gurunathan
1999	John D. Hughes, Jr.
2000	Rabih O. Darouiche, MD
2001	Jeffrey I. Joseph, DO
2002	John W. Gosbee, MD
2003	Becki E. Harter
2004	Vinay Shah, MD
2005	Rebekah Drezek, PhD
2006	A. Ray Dalton
2007	Marvin Shepherd, PE

In this 1989 photo, George Kondraske [left] receives the Becton-Dickinson Career Achievement Award from Edward Duffie Jr., MD.

AAMI/GE Healthcare BMET of the Year Award

Recognizes a biomedical equipment technician for individual dedication, achievement, and excellence in the field of biomedical equipment technology.

1981	Edwel W. Butler, CBET
1989	Charles Connor, CBET
1990	Gail Seput
1991	Lance Martucci
1992	Jahangir Azizi, CBET
1993	Michael P. Myatt, CBET
1994	Benjamin Ethridge, CBET
1995	David Houge, CBET
1996	Roger Zielinski
1997	Terrence D. McCartney
1998	John Thomas
1999	Michael R. Kauffman, CBET
2000	David E. Francoeur, CBET
2001	Dennis Cox, CBET, CRES, CLES
2002	Dennis R. Edwards, CBET
2003	Gregory S. Duncan, CBET
2004	Theresa Gorski
2005	Glen L. Wolfe, CBET
2006	Dustin Telford, CBET, CRES, CLES
2007	W. Glenn Scales, CBET

Charles Connor [left] receives the BMET of the Year Award from SBET president Terry Clemans.

AAMI Foundation/ACCE Robert L. Morris Humanitarian Award

In honor of Robert Morris, recognizes individuals whose humanitarian efforts have applied health technology to improving global human conditions.

2001 Robert Morris, CCE PE
2002 Herman R. Weed, PE
2003 George I. Johnston, CCE
2004 Alfred Jakniunas
2005 Dave Harrington
2006 Robert Pagett
2007 Louis M. Schonder, CBET

Clinical engineer Robert Morris was remembered with the creation of an award in his honor in 2001. Here, his daughter Julie is shown accepting the award given to her father posthumously. Pictured from left are Antonio Hernandez, Andrei Issakov, Julie Morris, Elliot Sloane, William Betts, and Joe Welsh.

AAMI Foundation/Institute for Technology in Healthcare Clinical Application Award

Recognizes a clinical engineer for an innovative solution that shows how to solve a clinical patient care problem through the use of computers or other technology.

2005 Antonio Hernandez
2006 Thomas M. Judd, CCE

AAMI Foundation Educational Advancement Award

Recognizes a mid-career biomedical professional who seeks to advance his or her career by pursuing an undergraduate or advanced degree or completing training at an appropriate technical school.

1999 Randolph J. Cremer, CBET
2000 Reynaldo Banasijan
2001 Ray Laxton
2002 Chris Edward Peters, CBET
2003 Glen L. Wolfe, CBET
2004 Ed Snyder, CBET
2006 Dennis B. Cox, CBET, CRES, CLES
2007 Wade E. Blessing, CRES

AAMI Standards Developer Award

Recognizes major contributions to the development or revision of a specific AAMI standard or international standard or ongoing contributions toward notable advances in standards development.

2007 Ronald E. Easterling, MD *(posthumous)*
LeRoy J. Fischbach *(posthumous)*
Charles B. Sidebottom
James L. Whitby, MD, MB, FRCP

AAMI Technical Committee Award

Recognizes AAMI technical committees for benefits resulting from a standard or a group of standards.

2007 AAMI Renal Disease and Detoxification Committee
AAMI Steam Sterilization Hospital Practices Working Group

Young Investigators Competition

From 1995 to 2004, the Whitaker Foundation provided grants to help support this award. It promoted outstanding research in the fields of medical instrumentation, medical devices, clinical outcome studies related to application of technology, and innovative management strategies for clinical engineering or medical equipment quality assurance/risk management programs.

1995 Donald E. Chickering, III, PhD
1996 David H. Liang
1997 Jeffrey Bishop
1998 Chih-Cheng Lu
1999 Shyam Srinivas
2000 Elaine W.M. Liow
2001 Suresh A. Atapattu
2003 Eugene D. Boland
2004 Zhifei Wen

Donald E. Chickering [right] won the first Young Investigators Competition in 1995. Here, he receives a plaque from A. William Paulsen.

Past Presidents and Board Chairs

J. Scott Butterworth, MD
1966–1967

Arthur C. Beall Jr., MD
1967–1969

Dwight E. Harken, MD
1969–1970

John J. Collins, Jr., MD
1970–1971

Cesar A. Caceres, MD
1971–1972

William C. Beck, MD
1978–1980

Clarence Dennis, MD, PhD
1980–1982

Charles A. Rawlings, PhD, CCE
1982–1984

Clark Watts, MD
1984–1985

Willis A. Tacker, Jr., MD, PhD
1985–1986

Alan S. Berson, PhD
1991–1993

Laurence A. Tanner
1992–1994

William A. Short, PE, CCE
1994–1996

Ronald H. Abrahams, PhD
1996–1998

Stanton P. Nolan, MD
1998–2000

W. Gerald Rainer, MD
1972–1973

William G. Malette, MD
1973–1974

Harold Laufman, MD, PhD
1974–1976

Charles A. Hufnagel, MD
1976–1977

Lt. Col. Burt Dodson, Jr.
1976–1979

Richard E. Clark, MD
1986–1987

Thomas S. Hargest, CCE
1987–1989

Kenneth L. Mattox, MD
1988–1990

Dennis R. Stupak
1989–1991

Mort H. Levin
1990–1991

William F. Betts, PE, CCE
2000–2002

Frances R. Koch, RN
2002–2004

Alfred M. Dolan, CCE
2004–2006

Robert H. Stiefel, CCE
2006–2008

NOTE: AAMI's senior volunteer officer has been called at various times either President or Board Chair. In AAMI's 1991 reorganization, that title officially became Board Chair.

AAMI would like to thank the following sponsors for their financial support of this special 40th anniversary publication:

40 YEARS OF PEOPLE, PROGRESS, AND PATIENT SAFETY