

AAMI @ Work

For Health Care
Professionals



For Medical
Equipment
Managers



For Patient
Safety



Volunteers Make AAMI Thrive

During my 35 years as CEO at AAMI, the medical device field has experienced extraordinary changes, challenges, and innovations. Technology has driven many advances and made so much possible.

But one thing hasn't changed over the last three decades: AAMI has always attracted the most dedicated professionals in the industry who volunteer their time and resources to increasing the understanding and beneficial use of medical instrumentation.

Today, many of the faces have changed and the numbers have increased ten-fold, but the commitment of the members is just as passionate—whether it is a commitment to develop the most comprehensive sterilization or dialysis standards or a commitment to produce the most useful benefits to clinical engineers or biomedical equipment technicians.

Many of their accomplishments are highlighted in the following pages. We hope this report will not only showcase the many successes of AAMI committees, but also the challenges that lie ahead. I extend a heartfelt “thank you” to those who have made AAMI what it is today, by leading and participating in these worthy AAMI programs.



Michael J. Miller, JD
AAMI President

See inside to learn more about these important AAMI committees:

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WHAT DRIVES VOLUNTEERS?

Different Perspectives, Common Goals, and Lifelong Rewards

The hours can be long, the work slow and often tedious. Financial reward? Better look somewhere else. With a recruiting pitch like this, how is it that AAMI is able to attract some of the most intelligent and talented people in the medical device field to its committees?

“I’ve learned a tremendous amount and met some great people,” says Matthew Weinger, MD, professor of anesthesiology at Vanderbilt University Medical Center. “I’ve made some lifelong friendships even, and that’s what keeps me going—the camaraderie, the feeling that we’re making a difference.” Weinger is a cochair of AAMI’s Human Factors Committee, which is responsible for developing standards and other guidance on the design of medical device user interfaces. In this role he sets meetings, agendas, and deadlines for work products; responds to inquiries; conducts media interviews; and works in the trenches with the other members on standards.

A balance in membership interests, perspectives, and expertise is sought in the composition of every AAMI committee.

When a typical AAMI technical committee or working group convenes to begin drafting a new medical equipment safety standard, a quick look around the table reveals the diversity that makes for a true consensus standard. Representatives from the medical equipment manufacturing sector sit side by side with device users, researchers, regulatory officials, and other technical specialists—all with the shared goal of producing a document that will make medical equipment better and safer.

Michael Scholla, PhD, senior consultant with Dupont Nonwovens, says “the people who are involved in AAMI, both the staff and those who serve on committees, are just really good people.” He adds that although your colleagues may be from competing companies, “you get to be friends with them.” Scholla serves on the Sterilization Standards Committee, which is charged with developing standards for sterilization of medical devices and related equipment. He became involved in the committee about 12 years ago, when it started a working group on medical packaging. He’s now involved in



Matthew Weinger, MD



Michael Scholla, PhD

other sterilization subcommittees and serves on the Executive Committee of AAMI’s Board of Directors, as well as the AAMI Committee on Standards Strategy and the board of the AAMI Foundation. He estimates that he spends about four to six weeks per year on AAMI standards development and another three weeks on other AAMI work. Scholla adds that his work is made easier by AAMI staff. “They do an excellent job of running the organization, in keeping us informed of issues that arise, and taking our input and putting it into the path forward.”

In addition to bonds forged with other volunteers, AAMI committee members find the work gratifying. “When there’s a need for a standard, one that needs to be harmonized on a global scale, it may take a while, but you finally get it done,” says Scholla, who represents the producer perspective. “Finishing a standard and seeing that it’s useful” is very rewarding, explains Weinger, who says he spends about nine or 10 days a year with the Human Factors Committee. He still recalls with pride the work he completed several years ago on HE74, which describes the process a company should go through in designing a device interface. “It’s had a big impact in that it was picked up as part of a larger standard, IEC 60601-1-6,” he explains, adding that the FDA has used that to “substantially increase their oversight of human factors engineering of medical devices.”

Committee work is not without its frustrations, though. Because an accord must be reached before a standard can be

completed, the process can take years, or even decades. The AAMI Protective Barriers Committee last year finished the PB70 standard for barrier performance of drapes and gowns, a classification scheme based on the level of protection provided. Scholla estimates that the entire process took perhaps 20 years. “It was difficult to reach a consensus,” he notes somewhat understatedly.

According to Weinger, one of the biggest challenges of his work is attracting and keeping more medical device users on committees. “If they’re not working, they’re not making money,” he explains. Whereas for most industry and government people, participation in



standards development is part of their job. “Clinicians are a critically important voice, because you need to see how the design of a device will affect them.” People try to do committee work “in their discretionary or uncompensated time, when they could be with their families or doing other things,” Weinger says, adding, “there’s not a good solution to that.”

Although serving on committees may involve sacrifices, users, producers, and government representatives find satisfaction in their belief that their work

further the overall goal of patient safety. For example, Scholla explains that because medical packaging must maintain the sterility of the product, standards help ensure that medical devices remain uncontaminated. Likewise, many medical errors occur with medical devices that lead to patient harm, Weinger notes. “The majority of those are because the design does not support the user’s needs for a variety of reasons, and many of those are because of poor interface design,” he says, adding, “to the extent that our standards get companies to pay more attention to interface design, we reduce the number of errors and the resulting patient injury.” These are just two examples of how AAMI standards, which cover a wide range of medical device products and processes, relate to patient safety. ●

The FDA’s Voice in the AAMI Standards Program

Carol Herman doesn’t require FDA staff to do committee work—because they participate willingly.

“It makes our job easier if we know that we have a good standard that contributes to the development of good quality medical devices,” says Herman, who is director of FDA’s Medical Device Standards Program.

Herman, who serves on AAMI’s Symbols & Nomenclature for Medical Devices Working Group (under the Committee on Quality Management and Corresponding General Aspects for Medical Devices), an ISO working group with a similar name and scope (ISO/TC 210/WG 3), as well as the AAMI Committee on Standards Strategy and the AAMI Standards Board, is one of numerous FDA professionals who participate in the AAMI standards program. The open-to-all-parties, public nature of AAMI standards development creates transparent, inclusive guidance that allows device developers and regulatory officials to clearly see what the rules are and how they came to be. As a result, this helps get devices through the regulatory

approvals process smoothly and ensures that there will be fewer adverse effects, Herman explains.

Another reason FDA representatives are eager to serve is that it helps them “keep abreast of the new technology involved in their area of biotechnology. It’s an educational venue for our staff,” says Herman, who spends 20 percent

of her professional time on AAMI committees.

As with volunteers who represent the producer and user perspective on AAMI committees, those serving on behalf of FDA find satisfaction in the work they do. “It’s rewarding to see that

finished product, knowing that we helped draft a standard that will be useful to FDA, and to medical device manufacturers marketing their products in the U.S.,” Herman says. And like her colleagues, Herman sometimes finds it frustrating to reach a consensus in an increasingly global marketplace. “It can be extremely difficult at times, but I’m proud of the fact that we do find common ground and build from that,” she says. “We’re helping to raise the bar on safety and efficacy.”

It can be extremely difficult at times, but I’m proud of the fact that we do find common ground and build from that. We’re helping to raise the bar on safety and efficacy.

Carol Herman, FDA

BOARD OF DIRECTORS

Expanding Services and Advancing Interests of AAMI Members

In 2004, AAMI and its members accomplished a number of important goals, which AAMI's Board and staff are building upon this year. Significant achievements in program areas such as standards development, services and resources, and education were nearly upstaged by a rejuvenated Annual Conference & Expo and a new initiative, AAMI's Technology Management Council, which hit the ground running in 2004 and already has a number of successful projects to its credit and more on the way.

Strong programs such as these don't come out of thin air—they are the product of a great deal of care, planning, foresight, and discussion that takes place within and under the guidance of AAMI's Board of Directors, whose challenge is to ensure that AAMI meets the needs of a diverse but united collection of medical equipment professionals.

Understanding AAMI's diverse membership is paramount to enhancing member benefits. Increasingly, AAMI's

membership and customers fall into three groups:

- Managers of health care technology, including clinical engineers, biomedical equipment technicians, and other professionals who are employed by hospitals and health care institutions.
- Members who develop and are served by standards and other technology-oriented consensus programs. Although all members reap the benefits of standards, government and manufacturing members hold a particular interest, since they rely on both regulatory and standards consensus to ensure that products meet both governments' and customers' thresholds for safety and efficacy.
- The third category includes members who are seeking to enhance their knowledge and skills and, as a result, use AAMI's many educational services and resources, including the AAMI Annual Conference, seminars, teleseminars, and publications.

To maintain and expand member services, AAMI needs substantial resources, which are provided by members and customers. AAMI is a catalyst for these services. In 2004, the association had an excellent year in terms of financial performance, which enables the association to expand services.

All programs achieved important goals. The Annual Conference, for example, experienced very strong member and exhibitor participation. A number of new education programs and mediums were successfully introduced in 2004 and more are planned for 2005. These programs help generate ideas for new ones, as AAMI strives to deliver timely and topical programming to more than 5,000 people each year.

In 2004, AAMI leaders took advantage of an opportunity to attend a major international workshop (scheduled to evaluate the need for more coordination of international medical technology standards) to outline how standards can best serve the health care community and patient safety. Some within the Interna-

tional Organization for Standardization (ISO) believe that better coordination of standards is needed, along with a new coordinating body. But AAMI and its allies are insisting on a clear demonstration of need before members' resources are expended on yet another level of coordination.

As AAMI President Mike Miller reported to this workshop audience, *"In a relatively short period of time, the world community, working through ISO and IEC, has developed a comprehensive body of medical device standards that serves the world public and economy. All involved should be commended for this tremendous undertaking and result. This has been a uniquely successful process and outcome."*

AAMI's members have made this success possible.

In 2004, AAMI reached an important compromise with the American National Standards Institute (ANSI) on royalties charged to AAMI on the sale of international standards adopted by AAMI. This new arrangement will maintain financial support for the AAMI standards program, reducing the need for membership dues increases.

It is also worth noting that AAMI has not implemented an increase in its basic price structure for the standards it sells since 1999. AAMI staff has played a key role in developing and instituting efficiencies in standards development and production, and has taken advantage of new technologies to enable it to "do more with less."

Also in 2004, a 21-member Technology Management Council (TMC) was formed to provide a clear and focused voice for all members interested in and affected by technology management in health care facilities. The TMC has a number of important projects underway, including building strong working relationships with state and local biomedical societies,

benchmarking technology management services, and collaborative efforts with nurse societies and the Joint Commission (JCAHO).

The TMC is more than a medium for improving services; it's also a resource for promoting the value of the technology management membership of AAMI.

In 2004, the new Institutional Membership concept continued to attract an increasing number of new hospitals and other institutional members—with 51 new



Alfred Dolan, CCE-C

Mission: To increase the understanding and beneficial use of medical instrumentation through effective standards and educational programs, and publications.

Leaders: Members of the AAMI Executive Committee are Alfred Dolan of the University of Toronto's Institute of Biomedical Engineering, chair; Robert Stiefel of the University of Maryland Medical System, chair-elect; Mike Scholla of DuPont Nonwovens, treasurer; Mike Miller, AAMI president; and Chuck Sidebottom of Medtronic, Inc.

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For more information: www.aami.org/about

members joining to take advantage of a membership category that offers a more flexible dues schedule to fit the needs and resources of the institution.

2004 also marked continued growth in our publications department, with the release of a second edition of *IT Horizons*, which explored the information technology developments in health care; as well as new editions of two popular clinical engineering books—the *Medical Equipment Management Manual* and the *Electrical Safety Manual*.

In 2004, AAMI launched a new online newsletter; *AAMI News Extra*, e-mailed to members each month; added four new practical columns to AAMI's journal, *Biomedical Instrumentation & Technology*; and launched a new online Career Center, which in 2004 attracted several hundred jobs and resumes.

For 2005, a number of new and exciting projects are already underway.

A consultant is being retained to define important benchmarks for successful technology management departments in hospitals and other health care institutions. These benchmarks will help managers better understand the characteristics of successful departments

and how departmental performance can be compared and improved.

Under the TMC's guidance, AAMI has also teamed up with the Association of periOperative Registered Nurses (AORN) to release a special publication called *Healthcare Technology Horizons*, a publication devoted to issues of mutual interest to biomed and nurses. The publication will be mailed to all AAMI members this summer.

The benchmarking survey and nursing outreach are two of the many projects that the Board has authorized to increase services to the technology management segment of the membership.

AAMI will also explore its role in a number of new areas in 2005 and, as a result, likely will create online forums by which members can interact with other members and experts on issues such as:

- Information technology integration in hospitals
- Best practices and achieving consensus on ways to promote the development and utilization of technology
- Quality system concepts as a means of improving medical technology use and management and patient safety

- Joint Commission standards and guidance, and
- Recognition of technology managers and the important work that they perform.

AAMI's standards program continues to expand services to members in a number of contexts. One challenge is the convergence of technologies (biotechnology, medical technology, pharmacology, etc.) and how this convergence can best be managed by standards developers.

At this time, 2005 looks as auspicious for member service as 2004. The bottom line is that:

- Programs are strong and well received.
- Members provide strong program leadership.
- The three areas of customers and programming outlined earlier are generating new programming, membership, and necessary resources.
- Membership satisfaction is strong and the membership is growing. AAMI's success in 2004 and the opportunities the association will pursue for its members in future years must continue to be grounded in a goal of the highest quality of services to its members. ●

TECHNOLOGY MANAGEMENT COUNCIL

Benchmarking, Outreach, and JCAHO News Top the Priority List

It's only been a year since the members of AAMI's Technology Management Council (TMC) met for their first time, yet the council has already embarked on a number of major projects and challenges that could have a beneficial impact for years to come.

In its first year, the TMC has served as an important resource in developing benefits for biomedical equipment technicians, clinical engineers, and other managers of medical technology—the group's main mission.

For example, TMC members decided in 2004 to take steps to improve the relationship between biomedics and nurses by developing a publication that would examine issues of mutual interest to professionals in both fields.

So over the last year, TMC members and AAMI staff have teamed up with leaders of the Association of periOperative Registered Nurses (AORN) to develop *Healthcare Technology Horizons*, which is being launched in May and distributed to nearly 20,000 AAMI members, nursing managers who belong to AORN, and others in the field.

The publication examines such topics as bedside technology management, wireless

systems, asset tracking, medical simulation, medical device incident investigations, equipment reliability, knowledge sharing, alarm management, and more.

Over the last year, TMC members have also played an integral role in developing the second edition of AAMI's *IT Horizons* publication, which examines information technology issues in health care; and revised a helpful guide for local biomedical societies, called "How to Establish and Maintain a Local Biomedical Association."

During a public forum of biomedics attending AAMI's Annual Conference in Boston in

2004, attendees suggested that they share "best practices" and other information through AAMI's Web site. That suggestion has become a reality.

The new area of the Web site—www.aami.org/tmc—features useful tools such as brochures on how to promote patient safety and the benefits of a clinical engineering department. There are also flyers on how to improve communication and



Ray Laxton

Mission: Formed by the AAMI Board of Directors, this 21-member council serves the interests of biomedical equipment technicians, clinical engineers, and others who provide management and support services related to medical technology.

Leaders: Ray Laxton of Clarian Health Partners/ARAMARK CTS and Carol Davis-Smith of Premier, Inc.

Highlights: Benchmarking, JCAHO educational resources, outreach to biomedical societies and nurses.

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For more information: www.aami.org/tmc

samples of equipment management plans and job descriptions. This area is fast becoming a clearinghouse of information for the field.

Although the TMC has had a strong start, the council's most ambitious projects are yet to come.

The TMC is working with a qualified consultant to develop benchmarking resources that would enable hospitals and clinical engineering departments to evaluate their performance, procedures, and policies.

The consultant will evaluate the feasibility of the benchmarking project and identify practices that could or should be benchmarked, and identify measurable indicators for these practices. If the benchmarking project is determined feasible, the consultant will then develop and conduct a benchmarking survey in the second phase. This major undertaking could have a meaningful and long-lasting impact on the field.

Another ongoing TMC project is to increase educational material available to AAMI members about Joint Commission (JCAHO) activities. To accomplish this, AAMI is creating a new online community, where biomedics can share information about Joint Commission news and experiences.

Under an agreement reached with JCAHO officials, the new online area will include a question-and-answer section, where AAMI members can ask questions about JCAHO standards and JCAHO will provide official responses. JCAHO and AAMI leaders are also discussing other possible collaborative efforts.

Over the next year, the TMC will tackle these and a number of other issues. The plate is full and the momentum is strong as the council members embark on these projects and others in the interest of health care technology managers around the world. ●

TMC Achievements

- Developed and published *Healthcare Technology Horizons*.
- Revised *How to Establish and Maintain a Local Biomedical Association*, now available at www.aami.org/tmc.
- Created a new area of the AAMI Web site, www.aami.org/tmc/resources.html.
- Launched a benchmarking project to develop resources to enable evaluation of performance, procedures, and policies.
- Improved access and information about the Joint Commission by partnering on a column that will feature questions from AAMI members and responses from JCAHO officials.
- Provided guidance on the revision of AAMI's BMET Study Guide and the development of educational programs at AAMI's Annual Conference & Expo.

- Helped develop *IT Horizons*, 2nd Edition, which explored IT issues facing the medical technology field.

TMC Ongoing/Upcoming Projects

- To publicize the profession to attract new technicians and engineers and to help demonstrate the value of the profession to top health care executives.
- To launch an online community where AAMI members could access and discuss current JCAHO issues.
- To develop an online speaker's bureau to help local societies identify speakers for their local and regional meetings.
- To conduct a benchmarking survey and publish results.
- To conduct a new employment/salary survey to help medical technology professionals benchmark their salaries and benefits.

STANDARDS BOARD

Objective Oversight of AAMI's Technical Committees

AAMI's vision statement is a fairly straightforward concept: To be the leading source of high-quality, timely information, collaboration, services, and consensus standards and guidelines that will expedite and enhance the development, management, and use of medical technology. But a great deal of activity takes place between where that statement ends and where delivering safer health care to patients across the U.S. and throughout the world begins. Much of that activity takes place under the administration of the AAMI standards program.

The purpose of the AAMI standards program is to assist the health care professions, industry, and governments in the U.S. and abroad with the use, acceptance, and advancement of medical technology. This is accomplished by AAMI technical committees, which develop consensus recommendations on medical device safety, performance, and use.

In addition to writing AAMI technical documents, most of which are approved as American National Standards, AAMI also operates a number of U.S. Technical Advisory Groups and sub-groups (TAGs), which coordinate participation in assigned committees of the International Organization

for Standardization (ISO) and the International Electrotechnical Commission (IEC), and develop U.S. positions on international standards.

The AAMI Standards Board, currently co-chaired by Alan Lipschultz of Christiana Care Health Services, was formed early in the program's history to direct and supervise all AAMI technical committee activities. Originally responsible for all aspects of AAMI's national standards program,

including funding, strategy, and process, today the Standards Board is primarily responsible for providing objective oversight of committee and TAG operations, including approval of new AAMI standards projects, final approval (based on a procedural



Alan Lipschultz, PE, CCE

Mission: Assist healthcare professions, industry, and governments with the use, acceptance, and advancement of medical technology.

Leaders: Alan Lipschultz of Christiana Care Health Services; industry co-chair position vacant

Highlights: In 2004, AAMI completed 20 American National Standards and other AAMI technical documents. New work approved in 2004 included five new AAMI-authored documents, four new adoptions, as well as a number of revisions, bringing the total active domestic project list to 84 at the beginning of 2005. (This is in addition to 76 active international projects that AAMI is involved with, either as the secretariat for the international committee, administrator of the U.S. TAG, or both.)

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For more information: General: www.aami.org/standards

Information about specific committees: www.aami.org/committeecentral

review) of all AAMI technical documents and international adoptions, and serving as an appeals board when disputes arise within a technical committee.

In the 1990s, AAMI began to defer more of its standards development work to the international arena, either by providing its standards as the basis for new international standards and then adopting them back, or deferring drafting from the outset to international committees and concentrating in the U.S. on providing national input and ultimately U.S. adoption. As the line between AAMI's "national" and "international" standards strategies became more and more blurred by this sharing of AAMI and international technical content, the AAMI leadership concluded that, from a strategic and financial perspective, AAMI had a single standards program. Therefore, strategy and funding issues for all standards activities (national and international) were delegated to the Committee on Standards Strategy (formerly International Standards Committee), while the Standards Board retained its previous function as an objective procedural and judicial oversight body for technical committee and TAG operations.

Since the 1990s, one of the goals of the program has been to work toward international product standards that are adopted and used worldwide. Part of

achieving this goal is for the U.S., through AAMI, to offer its documents as "points of departure" for the development of international standards, and to in turn adopt international standards as new or revised AAMI standards "to the extent

possible." Ultimately, the AAMI technical committee determines whether an international standard is suitable for adoption "as is" or with national deviations, or the committee should instead pursue its own course. ●

DID YOU KNOW?

- The AAMI standards program consists of 103 technical committees and working groups that produce standards, recommended practices, and technical information reports for medical devices, and/or serve as U.S. technical advisory groups and subgroups to 97 related international standards committees and working groups. Collectively, committee membership includes 1,013 people.
- AAMI also administers two ISO technical committees, two ISO subcommittees, and two IEC subcommittees, which have a combined total of 72 active working groups and maintenance teams. In addition, AAMI provides secretariat service to another nine working groups of international committees administered by other countries. Collectively, 793 experts from 33

countries participate on these committees, including 176 U.S. experts who fill over 38 (out of 75) leadership positions as committee chair, committee secretary, or working group convener, and 171 (out of 1,180) working group membership positions.

- There are many ways to become involved. You can:
 - Submit a new work item proposal
 - Join a technical committee
 - Submit comments on public review drafts
 - Attend open meetings of AAMI committees and working groups (all international meetings are closed)

For more information, visit www.aami.org/standards, e-mail standards@aami.org, or call the AAMI Standards Department at 703-525-4890, ext 250.

BI&T EDITORIAL BOARD

Expanding Editorial Content and Outreach Remain Priorities

Developing relevant editorial content for AAMI's journal, *Biomedical Instrumentation & Technology (BI&T)*, is a challenging task, since the interests of AAMI's diverse membership are very broad, even though they have a shared interest in the safe development and application of medical technology. But it's a mission that the 25 members of *BI&T*'s Editorial Board tackle with enthusiasm throughout the year.

Since the journal was first published in July 1966, it has strived to serve AAMI's membership by "bringing about better understanding between the medical profession and its engineering allies," as John P. Merrill, MD, wrote in the inaugural editorial of *BI&T*—originally named the *Journal of the Association for the Advancement of Medical Instrumentation*.

While *BI&T*'s mission has remained the same for nearly 40 years, the journal has undergone major changes under the guidance of Editorial Board members, who help shape the direction of the publication, recruit authors and reviewers, and write and review articles throughout the year.

In recent years, Editorial Board members have refocused the publication to include more relevant articles for biomedical equipment technicians, clinical engineers, and other managers of medical technology who count on *BI&T* as a top educational resource.

Five years ago, *BI&T* featured three regular "tools and techniques" columns. Now, there are 14 columns that provide medical technology professionals with practical information and guidance on information technology, patient safety, troubleshooting, best practices, careers, certification, Joint Commission (JCAHO) news, quality assurance and regulatory affairs matters, and numerous others.

These new columns have prompted the journal to expand from 64 to 80 pages per issue. In addition, to cover some important topics in greater detail in recent years, *BI&T* Editorial Board members have helped create three special supplements, which have been distributed to all AAMI members.

There have been two special editions of *IT Horizons*, which have examined information technology trends and emerging issues in health care, with specific



Carol Davis-Smith, CCE

Mission: Published bi-monthly, a premier journal for clinical engineers, biomedical equipment technicians, and other medical technology professionals.

Leader: Carol Davis-Smith of Premier, Inc., Editorial Board chair

Highlights: Fourteen practice "tools and techniques" articles; plus technology trends, product news, peer-reviewed research, and more.

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For more information: www.aami.org/publications/BIT

articles focused on topics such as electronic data storage, real-time decision support systems, hackers, and IT and clinical engineering mergers.

“The ‘Horizons’ publications give us an opportunity to cover specific topics in more depth than we can in the normal context of *BI&T*,” said Steve Campbell, AAMI’s vice president of communications and marketing. “With an entire issue devoted to a single theme, such as information technology, we’re able to pull together a significant resource that can be used as a reference tool for years to come.”

The newest supplement, *Healthcare Technology Horizons*, published in May 2005, explores topics of mutual interest to biomed and nurses, with topics ranging from bedside technology management and asset tracking to device incident investigations and knowledge sharing. The publication was produced by AAMI in cooperation with leaders of the Association of periOperative Registered Nurses (AORN.)

BI&T’s expanded content has prompted AAMI to share the journal with an international audience as well, by launching the AAMI Educational Outreach Program. Under the program,

BI&T is mailed to medical technology professionals around the world who are in need of educational material but may not have the financial resources to purchase such publications. ORBIS International—a non-profit, humanitarian organization—helped launch the program by sponsoring copies of the journal to medical technology professionals in 23 countries. The program could not have been possible

without the support of Editorial Board member, Antonio Hernandez.

As the *BI&T* Editorial Board prepares to develop the 2006 Editorial Calendar, its mission will be to continue to provide AAMI members with timely and practical educational resources to remain at the forefront of medical technology. Your input and involvement in continuing to enhance the journal is encouraged. ●

Share Your Expertise and Resources . . .

HOW YOU CAN GET INVOLVED IN *BI&T*

Submit articles and research papers on topics relevant to clinical engineers and biomedical equipment technicians. Topics may include equipment acquisition and repair, information technology, training, and management strategies. Visit www.aami.org/publications/BI&T to access the author guidelines and see a list of potential topics.

Posing questions to authors and writing letters to the editor help expand the dialogue in the clinical engineering and biomedical equipment technician communities. *BI&T* readers have helped bring to the forefront such issues as wireless medical telemetry systems and frequencies of preventive maintenance. Submit questions and queries to May Piotrowski at mpiotrowski@aami.org.

Sponsor *BI&T* subscriptions through AAMI’s Educational Outreach Program. As a sponsor, an organization provides educational materials to medical technology professionals around the world who lack the financial means to purchase the resources. Contact Steve Campbell at scampbell@aami.org to learn more about the program.

STERILIZATION STANDARDS COMMITTEE

Legacy of Leadership is Prolific and Far-Reaching

It's a fairly simple exercise to count off the number of documents the AAMI Sterilization Standards Committee has published over the decades, or list the many working groups that operate under its auspices. Those kinds of numbers, however, don't really tell the story in this case.

Instead, consider this fact: Anyone who has been treated in a U.S. hospital over the last 30 years, or used a consumer product that has the word "STERILE" in a rectangular box on the product wrapper has benefited from the work of the AAMI Sterilization Standards Committee. The bandage you put on your child's cut was likely processed and packaged according to AAMI sterilization guidelines. The instruments used in the surgical suite or by your dentist were likely cleaned and sterilized according to the recommended practices set forth by AAMI. The examples go on and on, but the point is clear: AAMI's Sterilization Standards Committee is the foremost developer of sterilization-related standards, recommended practices, and technical information reports in the world, and the guidance it has produced has played a key role in the health and safety of millions of people throughout the world.

Since its inception in 1974, the committee has supervised the development of nearly 60 nationally recognized documents. Through the efforts of more than 30 working groups, AAMI's sterilization-related documents address both equipment—such as steam sterilizers, ethylene oxide sterilizers, dry heat sterilizers, biological indicators, and chemical indicators—and how that equipment is put to use in health care and industrial settings. In addition, the committee spearheaded the formation of the international technical committee, ISO/TC 198, Sterilization of Healthcare Products, in the early 1990s, and had been responsible

for U.S. participation in that committee's international standards-development work.

Among the first documents developed under the auspices of the committee were a standard for hospital steam sterilizers and a recommended practice for steam sterilization—the latest editions of which are ANSI/AAMI ST8:2001 and ANSI/AAMI ST46:2002, respectively. (The recommended practice on steam sterilization, formerly designated "AAMI SSSA," was actually the second document produced by the AAMI standards program as a whole, the first being the AAMI Electrical Safety Committee's *Safe current limits for electromedical devices*,

Mission: To provide guidelines that assist manufacturers and health care personnel in the sterilization of medical devices and other health care products.

Leaders: Victoria M. Hitchins, PhD, of the U.S. Food and Drug Administration and William E. Young of Deer Park, IL

Highlights: Foremost developer of sterilization standards and guidance worldwide for application in health care facilities, equipment manufacturing, and industrial sterilization process control.

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For more information: www.aami.org/standards

published in 1978.) Another early focus for committee work was the safe use of ethylene oxide, a subject of much concern and debate in the industry and the health care community in the late 1970s and early 1980s. The committee later branched out into the areas of dry heat sterilization and radiation sterilization.

AAMI standards and recommended practices have had a profound impact on the development and use of sterilization technology. Today, AAMI recommended practices for sterilization in health care facilities are widely recognized as “the gold standard” and are cited by the Centers for Disease Control and Prevention (CDC), the Association of periOperative Registered Nurses (AORN), central service professional societies, and other organizations. At least one of these recommended practices has even been adopted as a state regulation (the state of New Jersey has made compliance with the AAMI recommended practice on flash sterilization mandatory).

Many AAMI standards, recommended practices, and technical information reports related to sterilization equipment and to industrial sterilization processes are recognized by the U.S. Food and Drug Administration (FDA); and some have formed the basis for FDA guidance docu-

ments. A manufacturer’s conformance to these documents can facilitate FDA clearance of new and modified sterilization equipment and demonstrate a manufacturer’s compliance with elements of the Quality System regulation. AAMI sterilization-related documents are all developed with the close involvement of FDA.

Today, AAMI recommended practices for sterilization in health care facilities are widely recognized as “the gold standard” and are cited by the CDC, AORN, central service professional societies, and other organizations.

The committee also serves as the U.S. Technical Advisory Group (TAG) for the International Organization for Standardization (ISO) Technical Committee 198, Sterilization of Healthcare Products, administered by AAMI. Through this leadership role, AAMI also has a liaison relationship with the European Committee for Standardization (CEN) Technical Committees 102, Sterilizers for Medical Purposes, and 204, Sterilization of Medical Devices. TC 198 has been a real success story, both in terms of the number of standards it has produced, the speed with

which they have been completed, and the worldwide acceptance the documents have received. For example, in the early years of TC 198, the U.S. and Europe had their own separate versions of standards for industrial sterilization using EO, steam and radiation. When the first editions of the ISO standards for these processes were completed, the U.S., through AAMI, adopted the ISO documents as “revisions” of the AAMI standards. Several other major markets adopted the ISO standards, while Europe maintained their own editions. Today, ISO is nearing completion of the second editions of these standards, all of which are undergoing parallel adoption in CEN as well as the U.S., In fact, all 22 of the projects currently on the CEN/TC 102 and 204 work programs that are within the scope of ISO/TC 198 are parallel adoptions of the ISO projects.

Like CEN, AAMI sterilization working groups responsible for standards intended primarily for industry are deferring development of new and revised standards to ISO/TC 198. However, AAMI also remains an active developer of consensus standards and other documents for hospital sterilization practices. In addition, while the relationship of standards to government regulation tends to mean that documents, in addition to being based on sound sterilization science, are also

conservative reflections of current practice, some of the industrial sterilization working groups have used the AAMI technical information report to publish ground-breaking work that advances the state-of-the-art. For example, work by AAMI committee members in radiation-dose setting has provided guidance on the validation of lower than conventional doses in radiation sterilization for use by manufacturers who wish to use radiation sterilization for a broader range of products.

The preeminence of the AAMI Sterilization Standards Committee and its astounding productivity over the years would not have been possible without the contributions of many health care professionals, industry scientists, regulatory representatives, and professional organizations. The first co-chairs of the committee were nationally recognized scientists Robert Ernst and Dr. Carl Bruch, who was then with the FDA and who participates in the committee to this day. Later co-chairs of the committee were Col. Collette Keyser and Dr. Virginia Chamberlain. Today, the committee is ably led by Dr. Victoria Hitchins, representing FDA, and Bill Young, representing industry.

The scientific and professional expertise of its members has long been an important component of the committee's prestige and credibility. In addition to Dr. Bruch and Mr. Ernst, sterilization scientists who served on

the committee during its early years, some of whom continue to be active, included Dr. Robert Morrissey, Dr. John Masefield, Dr. James Whitby, Dr. Bertha Litsky, Dr. Leslie Rendell-Baker, and Dr. Frank Engley. User expertise has been provided over the years by Col. Darlene McLeod, Neal Danielson, Janet Schultz, Barbara Goodman, Marimargaret Reichert, Sandy Lee, Zoe Aler, Peggy Ryan, and many others. FDA scientists have included Dr. Chamberlain, Dr. Hitchins, and Donald Marlowe.

The committee has also benefited immensely from the participation and support of professional organizations, including AORN, the American Society for Healthcare Central Service Professionals, the International Association of Healthcare Central Service Materiel Management, and the Association for Professionals in Infection Control and Epidemiology. And, of course, AAMI corporate members have been most generous in contributing the expertise of their sterilization validation and process control scientists.

The committee grows more prolific every year. In 2004 alone, the following documents were completed:

- ANSI/AAMI ST40: *Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities*. American National Standard.

- ANSI/AAMI/ISO 15882: *Sterilization of healthcare products—Chemical indicators—Guidance on the selection, use, and interpretation of results*. American National Standard.
- ANSI/AAMI ST81: *Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices*. American National Standard.
- AAMI TIR12: *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*. AAMI Technical Information Report.
- ANSI/AAMI/ISO 11737-3: *Sterilization of medical devices—Microbiological methods—Part 3: Guidance on evaluation and interpretation of bioburden data*. American National Standard.

Expected to be completed in 2005 are a comprehensive guideline for steam sterilization in health care facilities, a recommended practice on chemical sterilization and high-level disinfection in health care facilities, a standard for containment devices used in reusable medical device sterilization, and a number of new and revised guidelines for industrial sterilization. ●

RENAL DISEASE AND DETOXIFICATION COMMITTEE

Patient Safety Is the Driving Force Behind Committee Efforts

The AAMI Renal Disease and Detoxification (RDD) Committee and the standards and guidance documents it produces are probably unknown to the more than 280,000 Americans who undergo hemodialysis treatment every year, while in fact the work of this committee has a direct and significant effect on patient safety and quality of life.

“It feels never-ending sometimes,” says Richard Ward, PhD, RDD Committee co-chair and professor of medicine at the University of Louisville’s Kidney Disease Program, “but this work really does help protect our patients. That’s the only reason I do it.”

Improving the safety and quality of dialysis care has been the goal of the AAMI RDD Committee since its first published standard, ANSI/AAMI RD5, *Hemodialysis systems* in 1982. Currently, the committee is responsible for seven American National Standards and one technical information report that touch the lives of dialysis patients and caregivers throughout the world, and serves as the U.S. technical advisory sub-group

(sub-TAG) for national positions on eight international renal disease and detoxification standards developed by ISO/TC 150/SC 2/WG 5 and IEC/SC 62D/WG 7. The AAMI committee, which includes 26 members (and seven alternates) divided roughly equally between users, industry and government/general interests, has established itself as a world leader in the field.

It feels never-ending sometimes, but this work really does help protect our patients. That’s the only reason I do it.

Richard Ward, PhD,
University of Louisville

Recently, the RDD Committee published the new standard ANSI/AAMI RD52, *Dialysate for hemodialysis*, a recommended practice that provides clinicians with clear guidelines for the preparation and monitoring of dialysate, the fluid against which a patient’s blood is balanced in hemodialysis. RD52 “fills the gap” between

the 1992 edition of RD5 which addressed the equipment needed to prepare dialysate, and the need of the user of that equipment for guidance on the day-to-day preparation of dialysate at an individual dialysis facility. This includes guidance on the use, maintenance, and monitoring of equipment for purification and distribution of water, the preparation of hemodialysis concentrates, and the handling of dialysate. The new recommended practice also updates recommendations on the quality of the final dialysate.

In its role as a U.S. sub-TAG to relevant international standards activities, the RDD Committee has taken an active stance and proposed RD52 to ISO as the basis for an international standard on dialysate. As globalization reaches the dialysis field, the RDD Committee plans to propose its standards as the basis for international standards on concentrates, water, and water treatment equipment, with the long-term objective of harmonized world standards. This is the foremost challenge facing the RDD Committee today.

One area the committee has standardized for many years that is unlikely to move to the international arena anytime soon is reuse of hemodialyzers, a practice that is for the most part confined to the United States.

Although the principal mission of the RDD Committee is the development of standards, it has also been active in critical regulatory issues as they affect the safety of dialysis patients and patient care. The RDD Committee recently petitioned and received a favorable ruling from the U.S. Food and Drug Administration regarding the installation of backflow prevention devices in dialysis facilities and on the materials of construction of dialysis water distribution systems, and is working with the International Association of Plumbing and Mechanical Officials (IAPMO) to revise the Universal Plumbing Code (UPC) on these matters. In addition, over the years committee members have assisted the AAMI Education Department in conducting numerous courses on reuse of hemodialyzers and water quality for hemodialysis, with typical attendance between 250 and 350 registrants per course. In keeping with the goals of the committee, the intention of

these “extra-curricular” activities is to improve the safety and quality of patient care.

While the RDD Committee divides its standards between specifications for manufacturers of dialysis equipment and recommended practices for users of the equipment, a hallmark of the RDD Committee publications is the detailed explanatory material in informative annexes that highlight the rationales for requirements and recommendations. These informative annexes allow manufacturers and users alike to understand the thought processes that contributed to the development of the final requirements to



Richard Ward, PhD



LeRoy J. Fischbach

better understand their application. It is this commitment to patient safety through education and standards that characterizes the work of the RDD Committee. ●

Mission: To improve the safety and quality of hemodialysis (first use and reuse).

Leaders: LeRoy J. Fischbach of Minntech Corporation and Richard Ward, PhD, of the University of Louisville Kidney Disease Program

Highlights: Foremost developer of dialysis standards worldwide, including ANSI/AAMI RD52, *Dialysate for hemodialysis*, ANSI/AAMI RD61, *Concentrates for hemodialysis*, and ANSI/AAMI RD62, *Water treatment equipment for hemodialysis*.

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ELECTRICAL SAFETY COMMITTEE

Taking On a Monumental Task

Nearly 10 years in the making, with more than 200 technical experts from close to 20 countries contributing, and countless meetings all over the globe, the third edition of IEC 60601-1, *Medical electrical equipment—Part 1: General requirements for safety and essential performance*, which is expected to be published at the end of 2005, is one of the most anticipated medical device standards to be developed worldwide. The journey of the third edition of IEC 60601-1 has been long, but AAMI and its Electrical Safety Committee have been there every step of the way.

The goal of the IEC 60601 series of standards is to improve safety in the use of medical electrical equipment by providing a body of standards that assist manufacturers in designing and assembling safe medical electrical equipment and systems; aid manufacturers, test houses, and regulatory authorities in assessing compliance with requirements set forth in the standard; and help health care professionals in managing the risks associated with the use of these products.

The 60601-1 document, or General Standard as it is sometimes called, is so massive that it pushed to the limit the word processing capabilities of Microsoft Word. About 350 pages long, the General Standard is also the basis for over fifty Particular Standards that set out additional requirements that are unique to the specific medical electrical equipment that each covers. With the anticipated publication of the third edition of IEC 60601-1, which reflects some major changes in approach as well as a complete restructuring, all of the Particular Standards must be aligned to the new third edition to stay current. The bulk of this project is in SC 62D (Electromedical Equipment) with more than 30 Particular Standards needing revision.

AAMI plays a critical role in the development of these international standards by administering the secretariats for SC 62A, *Common Aspects of Electrical Equipment Used in Medical Practice*, which is responsible for the General Standard, and SC 62D. Most of the U.S. experts participating in these two subcommittees

are drawn from AAMI committees. In addition, the AAMI Electrical Safety Committee has played a crucial role as the lead committee for the U.S. adoption of the third edition. While the proposed U.S. adoption includes a few national deviations to align the U.S. version with the National Electrical Code (NEC), this is a major breakthrough in harmonization between the IEC standard, which has been adopted throughout the world, and the U.S. Other AAMI committees, which serve as U.S. Technical Advisory sub-Groups to SC 62D, will soon push forward with helping revise the Particular Standards. With the adoption by AAMI of 60601-1, it is likely that AAMI committees will increasingly adopt IEC Particular Standards as revisions of AAMI documents up for periodic review.

According to IEC/SC 62A Secretary Charles Sidebottom of Medtronic, “Such a massive effort would not have been possible without the dedication and hard work of the experts drawn from the national mirror committees such as the AAMI Electrical Safety Committee.” ●

CLINICAL ENGINEERING MANAGEMENT COMMITTEE

Developing Resources and Advancing the Field

They have developed and published the most successful books in the clinical engineering field.

They have advanced proposals that have enhanced the use and maintenance of medical equipment.

And they have lectured and authored articles that have improved medical equipment management practices around the world.

Over the last 15 years, members of AAMI's Clinical Engineering Management Committee (CEMC) have played a vital role in advancing the professional interests of clinical engineers, promoting the importance of the field, and serving as an important resource to AAMI staff to support numerous member benefits.

Formed in 1987 by the AAMI Standards Board, the CEMC was initially organized to evaluate the efficiency and productivity of clinical engineering departments. But over the years, the CEMC has assumed a much broader role, tackling issues such as effective preventive maintenance practices.

One of its chief accomplishments has been the development of books and other educational resources that have remained

among AAMI's best-selling publications for years. Now in its 5th edition, the *Medical Equipment Management Manual* has a long history of providing essential guidance to clinical engineering departments to comply with the requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The book—authored by Robert H. Stiefel, MS, CCE, the chair of the CEMC—has served as a practical guide to help a hospital's medical equipment management program remain in complete and continuous compliance with the JCAHO standards.

The 5th edition of the manual was released in 2004. This year, a 17-page update has been added to the book to reflect the JCAHO's

many revisions to their 2004 standards. In addition, for the first time, the manual is being offered in CD format.

Another publication produced by the CEMC, the *Electrical Safety Manual*, has also been a mainstay in the clinical engineering field. The most recent edition, released in 2004, includes updated statistics, the basic elements that should be contained in electrical safety programs, and discussions of changing preventive maintenance programs and philosophies.



Bob Stiefel, CCE, MS

Mission: To serve the interests of the clinical engineering field.

Leader: Robert H. Stiefel of the University of Maryland Medical System

Highlights: Members author articles and publications, speak at educational forums, and meet annually to discuss emerging clinical engineering issues.

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For more information: www.aami.org/publications/books

In addition, the authors—Marvin Shepherd, PE (Safety) and Matthew Baretich, PE, PhD—expanded the publication in 2004 to include a new chapter that addresses the medical device operators and how their actions or inactions might result in an adverse event. This book is also being offered this year on CD for the first time.

A third CEMC book, *Computerized Maintenance Management Systems for Clinical Engineering*—authored by Ted Cohen, MS, CCE—is designed to provide guidance on computerized maintenance management systems (CMMS) in use at hospitals and independent service organizations (ISOs), and an overview of new technologies that are driving future enhancements. ●

An Annual Gathering . . .

In 1985, about a dozen clinical engineering leaders gathered at Massachusetts General Hospital to discuss measuring and managing productivity and other business aspects of in-house programs.

They never imagined that the gathering would become an annual event—one that would grow in size each year—but that’s exactly what has happened.

In 2004, the group celebrated its 20th anniversary back in Boston at an affiliated site of Massachusetts General Hospital. Officially, the meeting is called the “Annual Conference on Clinical Engineering Productivity and Cost Effectiveness” and “AAMI Subcommittee on Technology Management.” But almost everyone just calls the event, “Manny’s Meeting.”

“Manny” is Manny Furst, PhD, CCE, who has organized the meeting every year for two decades, with the help of Elliot Sloane, PhD, Villanova University.

“The initial concept was to provide a forum for clinical engineering managers and of others to address the issues of productivity and cost effectiveness,” says Furst. “Having gotten to know a number of people who were gathering data and managing in business-like ways, I organized the meeting to exchange ideas and data.”

As times have changed, so too have the topics. The group has broadened its scope and interests. Each year, the group meets on the Friday before the AAMI Annual Conference for a full-day session that consists of brief presentations delivered by various members of the group.



Manny Furst, PhD, CCE

“We’ve always had an agenda set by the members who suggest ‘hot topics’ that they feel are important or may become important to clinical engineering,” he said. “Our motivation is to provide a forum for brainstorming and sharing ideas that are just conceptual, staying up-to-date on important issues, and learning about new issues from someone ‘out in front’ which may have no immediate impact on routine responsibilities. Our mission includes developing publications and presentations to share leading thoughts and solutions with the field, and helping develop ‘new leadership’ for AAMI.”

Over the years, attendance has grown to more than 50, and today includes software vendors, members who are now employed by independent service organizations, and manufacturers in the area of service management, as well as those who work at in-house programs.

CONFERENCE PROGRAM COMMITTEE

Delivering Timely, Topical Education for More Than 30 Years . . .

For the 1,500 professionals who walked through the doors of the Tampa Convention Center in May to attend AAMI's Annual Conference, it was the beginning of a three-day networking and learning experience. But for the 16 dedicated volunteers who serve on the Program Committee, it was the culmination of a year-long effort to attract the best and the brightest to discuss topics affecting patient safety and the medical technology field.

In fact, plans to develop the 2005 Conference content were launched eight months earlier—in September 2004—when the Program Committee gathered at AAMI headquarters in Virginia to begin the cumbersome task of identifying 50 cutting-edge and relevant topics and more than 100 qualified speakers. To ensure that attendees stay up to date on new developments in the field, the Program Committee provides 95% new educational content each year.

Members of the Program Committee—led in 2004-2005 by Andrew Currie of Johns Hopkins Hospital and Jay Crowley of the U.S. Food and Drug Administration—carefully reviewed feedback received from previous conference attendees and combed

through dozens of proposal submissions to seek out the most practical and timely topics for educational sessions. The committee also monitored health care and industry trends which, for example, led to a greater emphasis this year on the importance of patient safety, risk management, human factors, and quality systems.

Over the last year, committee members divided into specialty areas to find the best speakers and topics on information systems, imaging, business and management, patient safety, technical operations and support, and medical innovations and research.

The committee's success shines through with a scheduled lineup this year that included



Andrew Currie, CBET



Jay Crowley

presentations on advanced medical laser safety, ultrasound equipment maintenance, telemetry monitoring, and advances in proton beam therapy. As always, the committee's goal was to provide

Mission: To organize and plan the educational content for AAMI's Annual Conference—the Premier Conference for Healthcare Technology Management

Leaders: Andrew Currie of Johns Hopkins Hospital and Jay Crowley of the U.S. Food and Drug Administration

Highlights: More than 50 educational sessions, 100 speakers, with 95 percent new content each year

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For more information: www.aami.org/ac

professionals in the biomedical management and technology field with the latest information and the highest value for their educational dollar.

The Annual Conference also serves as home to the AAMI Expo, in which more than 120 manufacturers and service providers are brought together with conference attendees to network and learn about recent developments in technology and services. More than 10 hours are set aside exclusively to provide this valuable opportunity to attendees. In 2005, the committee helped revise the program schedule so that attendees can better plan their time at the conference and visit the Expo Hall.

Although the committee will have a little time to see their success come to fruition, committee members will soon meet again to map out plans for the 2006 conference, which will be held June 24–26 in Washington, DC.

To paraphrase the famous line from the 1989 movie, *Field of Dreams*, “if you build it, they will come; but if you build it well, they will learn.” But what’s not always evident or appreciated is the untold number of volunteer hours that go into what has become known as The Premier Conference for Healthcare Technology Management. ●

WORTH NOTING . . .

The **AAMI/FDA International Conference on Medical Device Standards and Regulation** celebrated its 15th anniversary in 2005 in grand fashion, with an informative program near Washington, D.C., that highlighted standards activity relating to medical device software, human factors, quality systems, risk management, and more. The hallmark of this annual event is that it brings together industry and government leaders to explore the latest developments in international standards key to global market access and regulatory compliance. The 2005 edition featured a special analysis of the application of standards throughout the medical device industry by Chuck Sidebottom of Medtronic, Inc., in which he discussed the gap between what regulators want and what a manufacturer’s system can deliver, if and how they can meet, and the challenges that both face when applying standards and regulatory requirements in the international arena. Other highlights included a presentation by Les Weinstein, Esq., Ombudsman for the FDA’s Center for Devices and Radiological Health, on the FDA’s efforts to help resolve disputes between the FDA and device manufacturers.

In 2004, AAMI was extremely active in the **quality systems field**, participating in standards and guidance development (with the release of ANSI/AAMI/ISO TIR14969: 2004, *Quality management systems—Medical devices—Guidance on the application of ISO 13485:2003*) and continuing its popular series of training programs for quality system requirements, design control, software validation, process validation, corrective and preventive action, and risk management. A new program on incorporating the key requirements of ANSI/AAMI/ISO 13485 was launched, and an initiative to expand the offering of specialized versions of its **training programs** on an in-house basis has put a new twist on employee education and is playing a key part in the compliance efforts at a growing number of companies.

Medical technology professionals just starting out or looking for new challenges, and companies looking for the best candidates have a great resource in **AAMI’s Career Center**. Re-launched in 2004, the Career Center—at www.aami.org/career—is an online service that offers a wealth of resources for both employers and job seekers. Employers can post jobs and choose qualified candidates from the resumes available on the site.

COMMITTEE ON STANDARDS STRATEGY

Harmonization in a Global Marketplace

In the last quarter of the 20th Century, borders between nations have kept their geo-political importance, but in many cases they no longer are the barriers to the exchange of information, ideas, and commerce that they once were. The globalization of the medical equipment field and harmonization of the standards that apply to it have been an important backdrop to AAMI's recent programs and initiatives, and the future will likely see AAMI standards reaching into new corners of the globe and touching more lives.

AAMI's Committee on Standards Strategy (CSS), previously called the International Standards Committee, 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 the 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. Moreover, the leadership positions that AAMI and its



Phil Cogdill

Mission: To provide guidance and oversight of AAMI's role and participation in the world standards community.

Leaders: Phil Cogdill of Boston Scientific Corporation and David Osborn of Philips Medical Systems

Highlights: Provides a forum where leaders from industry, the FDA, and health care institutions come together to discuss issues of mutual concern related to standards policies and strategies.

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members hold in the international standards bodies help to ensure that member interests and positions receive fair and equitable consideration.

The CSS has been a driving force in AAMI's ascendancy to global leadership in medical device standards, and is composed of representatives from AAMI member organizations, hospitals and user communities, medical societies and trade organizations, and the FDA. Phil Cogdill with Boston Scientific has chaired the committee since 2001; in 2006 Dave Osborn with Philips Medical Systems will succeed him.

2004 was a busy year for the CSS. AAMI was one of only five organizations worldwide that were invited to partner with ISO, IEC, and the International Telecommunications Union's standardization sector (ITU-T) in a February 2004 Workshop on Global Standards for Health Care and Medical Devices. Several CSS and AAMI Board members made presentations at the workshop (See also report of Board of Directors). The CSS continues to advise staff in responding to initiatives resulting from the workshop, including most recently a proposed ISO/IEC/ITU-T Task Force on Medical Technologies. AAMI supported the appointment of

Don Marlowe of FDA as chair of the task force, and Chuck Sidebottom with Medtronic will represent AAMI on the task force. CSS members will be key advisors to these leaders as issues are debated within the task force. AAMI's goal is to ensure that there is a demonstrated need for any "coordination" activities undertaken by the task force and that medical device experts retain the authority to make decisions about priorities for standards in our sector. AAMI will oppose the creation of any international coordinating mechanisms that may impede decision-making and standards development by the experts best equipped to carry out these functions.

The CSS provides a unique forum where leaders from industry, the FDA, and health care institutions come together to discuss issues of mutual concern related to standards policies and strategies. An ongoing issue is the trade-off between offering AAMI standards as the basis of international standards and the consequential loss of AAMI intellectual property rights (and income). From the start, AAMI realized that its international standards strategy would entail this trade-off. So far the benefits from influencing global standards have been judged worth



Chuck Sidebottom, CE



Don Marlowe

the loss of income from the intellectual property developed by AAMI and its members.

The CSS also serves as a valuable sounding board for the staff and leadership of AAMI on matters that concern corporate members, including the corporate dues structure. As the standards program has expanded over the past 15 years, the CSS has regularly reviewed funding mechanisms; at each of its biennial meetings the committee receives an evaluation of the corporate dues funding required and provided for the standards program. In addition, the committee offers a forum for discussing educational programs of primary interest to the industry and government segments of AAMI's membership. ●

HUMAN FACTORS ENGINEERING COMMITTEE

Safer Medical Devices by Design

Human factors engineering (HFE) for medical devices is maturing and finding an identity of its own. In a field where many current concepts can still trace their legacy to military or aeronautic documents, the AAMI HFE Committee has recognized that future advancements in device design and safety will be dependent on medical device-specific HFE research, data, principles, guidelines, and regulation. Taking the discipline's key general concepts and tailoring them to the unique demands of medical equipment and its safe application in the health care arena is a challenge that the AAMI committee has embraced in its newest standards and activities.

AAMI's leadership and support has played a key role in the acceptance of human factors engineering and has helped push the field to the forefront of medical device standards and regulation. The HFE Committee, which includes 35 members (and seven alternates), divided roughly equally between users, industry and government/general interests, is responsible for developing human factors (sometimes referred to as ergonomics or usability) guidelines in the medical device

field. The committee also acts as the unofficial U.S. Technical Advisory Group (TAG) for national positions on international documents that deal with HFE for medical devices. The development of national standards in this area dates back to 1988 when AAMI published *Human factors engineering guidelines and preferred practices for the design of medical devices*



Members of AAMI's Human Factors Engineering Committee

(AAMI HE48:1988). The revised version in 1993 included a new chapter on the HFE process. Ten years after the publication of the first standard, the committee decided to

Mission: To advance human factors engineering concepts in the development, design, and use of safe and effective medical equipment.

Leaders: Edmund W. Israelski, PhD, of Abbott Laboratories and Matthew B. Weinger, MD, of Vanderbilt University Medical Center

Highlights: International adoption of American National Standard *Human factors design process for medical devices*.

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For more information: www.aami.org/standards

AAMI@Work

divide HE48 into two parts: one part dealing with the HFE process and the other part dealing with HFE design principles (with examples of their use in the medical device field). The first part was published in 2001 as ANSI/AAMI HE74, *Human factors design process for medical devices*. The second part is planned for completion in 2006 with a designation of HE75, *Human factors engineering—Design of medical devices*.

The committee's leadership in this area was evident by the international adoption of HE74, which was incorporated in its entirety as an annex of a standard published by the International Electrotechnical Commission (IEC), IEC 60601-1-6:2004, *Medical electrical equipment—Part 1-6: General requirements for safety—Collateral Standard: Usability*. Some members of the committee are heavily involved in an international joint working group between IEC/SC 62A and the International Organization for Standardization (ISO) committee, ISO/TC

210 (both administered by AAMI) that is working to apply these HFE concepts to all medical devices, not just medical electrical equipment. This much-awaited standard will be designated IEC 62366, *Medical devices—General requirements for safety and essential performance—Usability*, and is planned for completion in early 2007. The AAMI HFE Committee is considering U.S. adoption of the IEC draft as a revision of HE74 using AAMI's parallel adoption procedures.

A more immediate challenge for the HFE Committee is the completion of HE75, which will cover design principles for medical devices. A great deal of data and an extensive body of knowledge exists for general human factors design principles, especially from aerospace and the military. Not so for the medical field, where the lack of specific information has forced the committee members to draw on their extensive network to find experts that could somehow help develop the necessary guidelines for HFE design principles specific to medical devices. The

project is gaining momentum with many topics extensively discussed from a medical device context. HE75 will include topics like biomechanics and anthropometry, human centered design, visual display, intercultural ergonomics, tools, controls, mobility, environmental considerations, alarms and warning, use errors, workstations, and documentation.

The national and international projects are challenging but the group is confident in its abilities and in each other. Respect and cooperation have forged a group dedicated to improving the usability of medical devices. With improved usability, the hope is to improve safety as well. The committee is progressing HE75 toward a standard that has weaned itself from its military past and is now able to stand on its own as a mature product for the growing HFE field in medical devices, which is also a major area of concern for the U.S. Food and Drug Administration Center for Devices and Radiological Health. ●

MEDICAL DEVICE SOFTWARE COMMITTEE

Patient Safety, Changing Technology are Driving Forces

Medical devices have become more complex and so has the software that controls their functions. Increasingly, we rely on software to track, analyze, record, control, and manage medical care. In so doing, there needs to be some assurance that the software embedded in a medical device will function as intended. The AAMI Medical Device Software (MDS) Committee is leading the way in developing standards in this field and is busy trying to stay ahead of the rapidly advancing technology.

The AAMI MDS Committee is responsible for developing software standards and guidelines in the medical device field. The committee also acts as the unofficial U.S. Technical Advisory Group (TAG) for national positions on international documents that deal with software for medical devices. The committee, which is cochaired by Sherman Eagles, Medtronic, and John F. Murray, Jr., FDA, includes 30 members (and 17 alternates), primarily from industry, although user and general interests also are represented. The development of technical documents in this area dates back to 1987 when AAMI convened various discussion groups to

identify new areas of potential work. One such discussion group agreed that there was a need for a greater awareness of the fundamental aspects of medical software development. The product of this meeting was the publication of an AAMI Monograph, *Developing safe, effective, and reliable medical devices* (AAMI MDS:1991). The monograph was subsequently replaced by a standard, ANSI/AAMI SW68:2001, *Medical device software—Software life cycle processes*.

The 1991 monograph contained chapters written by experts in the field and reflected their personal views on the subject. SW68,



Sherman Eagles



John F. Murray, MS, CSQE

on the other hand, represents a national consensus, having undergone committee ballot as well as AAMI and ANSI public

Mission: To develop medical device-specific software standards and guidelines to enhance the safety and efficacy of medical equipment.

Leaders: Sherman Eagles of Medtronic Cardiac Rhythm Management and John F. Murray of the U.S. Food and Drug Administration

Highlights: Publication of AAMI TIR32:2004, *Medical device software risk management*, which guides users in applying accepted risk management concepts to medical devices containing software.

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For more information: www.aami.org/standards

review prior to finalization. SW68 was based on an international standard that could be used by any business sector. The AAMI MDS Committee used this generic standard as a framework to develop a standard for the medical device sector that took into account the critical function of software that qualifies as a medical device under FDA regulations or that is used in medical devices. The work was originally proposed by FDA and Underwriters Laboratories, both of which considered the work urgent. Because of the urgency, it was decided to develop the document nationally, but at the same time, the committee felt there was potential for an international standard and kept appropriate international experts apprised of progress and opportunities to comment.

More recently, the committee completed a technical information report (TIR) titled *Medical device software risk management* (AAMI TIR32:2004, approved December 2004) and is currently working on another TIR on *Software validation for automated process equipment and quality system software*. Both of these projects were proposed by the committee.

AAMI and its MDS Committee have emerged as leaders in developing software standards for medical devices. For example, the IEC/SC 62A-ISO/TC 210 international joint working group (JWG) on medical device software agreed to use SW68 as the “point-of-departure” document for the future International Electrotechnical Commission (IEC) standard, IEC 62304, *Medical device*

software—Software life cycle processes (planned for completion by late 2005).

AAMI serves as the secretariat of the JWG, which includes 26 members from eight countries, and both the IEC and ISO (International Organization for Standardization) parent committees. Mr. Eagles serves as the convener of the JWG, and Mr. Murray is one of five U.S. expert members on the JWG. With its new work on software risk management and validation, combined with AAMI’s willingness to share its technical documents with ISO and IEC, members of the AAMI Medical Device Software Committee will continue to influence the direction of software standards at both the national and international levels for years to come. ●

AAMI FOUNDATION

Dedicated to Excellence in Patient and Public Safety

Dedication and commitment to public and patient health and the recognition of the many people who have achieved excellence in the biomedical technology field is what the AAMI Foundation is all about.

The AAMI Foundation's primary mission is to serve public welfare and improve patient safety by fostering support and recognition for the advancement of medical technology. It does this through certification programs, recognition awards for excellence, and through various educational activities.

Dwight E. Harken Memorial Lecture

Each year, the AAMI Foundation and PSICOR support a lecture in honor of the work of Dr. Dwight E. Harken, one of AAMI's founders and pioneer cardiovascular surgeon and device innovator. The lecture, which features the brightest and best in the medical technology field, is presented at the AAMI Annual Conference & Expo.

Foundation Recognition for Excellence

The AAMI Foundation also recognizes individuals for their extraordinary role in

improving public health care safety. The AAMI Foundation Awards recognize career achievement as well as superior work in medical instrumentation development, research, and applications, including engineering and related service.

The Foundation Awards Committee performs rigorous reviews of candidates who have demonstrated outstanding service or accomplishment with a significant impact on a specific medical device or on medical instrumentation in general, a service that results in the development of an important new medical device, a distinctive contribution toward the improvement of the use or safety of a medical device, or critical contributions to the enhancement of patient care through medical instrumentation. Others have been honored for their humanitarian efforts by applying health technology to improving global human conditions. The annual awards include the:

- **AAMI Foundation Laufman-Greatbatch Prize**, honoring an individual or group that

has made a unique and significant contribution to the advancement of medical instrumentation.

- **AAMI Clinical/Biomedical Engineering Achievement Award**, recognizing individual excellence and achievement in the fields of clinical engineering and biomedical engineering.
- **AAMI Foundation Educational Advancement Award**, recognizing 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.
- **AAMI Foundation/ACCE Robert L. Morris Humanitarian Award**, honoring individuals who have worked to improve global health conditions through the application of health technology.

Mission: To recognize excellence in the field.

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For more information: www.aami.org/awards

- **AAMI Foundation/Institute for Technology and Healthcare Clinical Application Award**, which is awarded to a clinical engineer in recognition of an innovative solution that has been developed to address a clinical patient care problem and that demonstrates clinical application and efficacy.

Certification Programs

Certification demonstrates that health care professionals have the knowledge to ensure a safe, reliable health care environment. The AAMI Foundation provides leadership in public safety through its certification programs and oversight of the International Certification Commission (ICC) and the United States Certification Commission (USCC).

The ICC Certifications for Biomedical Equipment Technicians (CBET), Laboratory Equipment Technicians (CLES), and Radiology Equipment Technicians (CRES) are formal recognitions by the ICC and USCC for individuals who have demonstrated excellence in theoretical and practical knowledge of the principles of biomedical equipment technology.

The ICC Clinical Engineering Certification (CCE) is a formal recognition by the ICC and USCC for

individuals who have demonstrated excellence in theoretical and practical knowledge of the principles of clinical engineering. Although the CCE exam process was suspended in 1999, the renewal program for CCEs is maintained and on-going.

The International and U.S. Certification Commissions and Board of Examiners

The International Certification Commission (ICC) is composed of representatives from the international health care biomedical technology community. Its role is to formulate general policies on certification; advise national commissions and examining boards in matters of certification; grant certification upon review of the Board of Examiners' and national commissions' recommendations in each discipline; assist the educational community in developing a body of knowledge relevant to continuing education and fundamental training programs; and foster and advocate the advancement of professional standards of practice.

Reporting to the ICC is the United States Certification Commission (USCC). The purpose of the USCC is to serve the public welfare and the health care community by certifying the knowledge base of clinical



Fran Koch, RN, Ed Snyder, CBET, and Gus Sakis

engineers, biomedical equipment technicians, and other related professions. Among its many responsibilities, the USCC formulates general policies on certification, recertification, and renewal; directs or advises the respective U.S. Boards of Examiners in matters of certification, recertification, and renewal; and recommends certification, recertification, and renewal to the ICC upon review of the Boards' recommendations in each discipline. It also ensures that the secretariat, with the assistance of the Boards operating under the USCC, carefully evaluates applications and prepares, administers, and validates written examinations to determine the qualifications of individuals seeking certification. ●

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AAMI Resources

EDUCATION

AAMI's Conference & Expo—This premier conference for healthcare technology management professionals annually features more than 100 exhibitors and dozens of educational sessions. For more information, visit www.aami.org/meetings.

Certification—ICC/USCC certification is available for biomedical equipment technicians (CBET), radiology equipment specialists (CRES), and clinical laboratory specialists (CLES). For exam dates and deadlines, visit www.aami.org/certification.

Quality System Training Programs—AAMI is offering 21 training programs in 2005 on topics such as quality systems, design control, process validation, risk management, industrial sterilization, software validation, and corrective and preventive action (CAPA) requirements. For a schedule of course dates and locations, visit www.aami.org/meetings. To bring the courses in-house to your organization, contact vschoenauer@aami.org.

AAMI/FDA International Conference on Medical Device Standards and Regulation—This annual event brings together government and industry leaders from around the world to explore developments in international standards that are key to global market access and regulatory compliance. For more information, visit www.aami.org/meetings/isc.

MEMBERSHIP

Benefits—AAMI members enjoy numerous benefits including a monthly newsletter; a bi-monthly journal; deep discounts on standards, publications, and educational events; career guidance; networking opportunities; awards recognition; and much more. For more information, visit www.aami.org/membership.

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Developing Standards—The AAMI standards program consists of more than 100 technical committees and working groups that produce standards, recommended practices, and technical information reports for medical devices. To get involved, visit www.aami.org/standards/. For an up-to-date list of technical committee meetings, visit www.aami.org/standards/tcmeetings.cfm.





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