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AAMI News

Association for the Advancement of Medical Instrumentation WWW.AAMI.ORG

SPECIAL CONFERENCE ISSUE

INSIDE . . .

The Inside Word

"Our circumstances have helped us better understand the importance of networking . . ."

German Giles

See story page 10

Up Close with Bob Stiefel . . .

Incoming AAMI Chair Wears Many Hats . . . and Ribbons

If New York is the city that never sleeps, then Bob Stiefel is the man who never sleeps. So say colleagues who marvel at his ability to juggle his role as clinical engineering director at the University of Maryland Medical Center and a rewarding family life—all while giving of himself to seemingly every AAMI committee, council, or task force under the sun.

Bob Stiefel (left) accepts Clinical/Biomedical Engineering Achievement Award at 2000 Annual Conference from then-Chair **Stan Nolan**.

In fact, Stiefel's contributions became the target of a friendly ribbing at one recent AAMI event.

At each Annual Conference, participants who are involved with an AAMI committee receive a ribbon bearing the name of their committee to be affixed to their name badge. So AAMI Board member Michael Scholla, PhD decided to assemble a name badge for Stiefel featuring every ribbon AAMI had to offer—plus a few phony ribbons thrown in for good measure. Scholla presented the string of ribbons to a chuckling red-faced Stiefel in the middle of a meeting.

"One of the ribbons even said 'Chief Bean Counter' on it," laughs Stiefel. "The thing ended up being about three feet long."

In reality, Stiefel's AAMI activities include, among others, service on numerous standards committees, the Board of Directors, Finance Committee, the Nominating Committee, the Clinical Engineering Management Committee, the AAMI Foundation, the Technology Management Council, and the *BI&T* Editorial Board.

But at AAMI's 2006 Annual Conference

CONTINUED ON PAGE 12

Celebrating Its 2nd Anniversary . . .

TMC Advances Biomed Interests, Targets New Projects

When members of AAMI's Technology Management Council (TMC) met for the first time in June 2004, David Francoeur was somewhat skeptical. Would the group, he wondered, be able to meet the unique needs of the healthcare management community?

He wonders no more.

Over the last two years, the TMC has tackled and accomplished numerous major projects. The Council has created several new services for local biomedical societies; increased AAMI members' access to the Joint Commission (JCAHO); and developed a number of important career and IT-related resources and publications.

Dave Francoeur

"I was always hopeful, but just never really sure that it could be done," says Francoeur, vice president of service operations with TriMedx Healthcare Equipment Services and a member of the TMC's Executive Committee. "Now I feel

CONTINUED ON PAGE 18

AAMI ASKS . . .

AAMI News *poses a monthly question, which you can respond to online at* **www.aami.org**. *The question appears in the lower right hand corner of the AAMI home page. Read* AAMI News *each month to see the outcome of last month's question and to find the new question.*

JUNE'S QUESTION:

What benefit do you wish your employer offered?

- More than two weeks of vacation
- Life insurance
- 401K or other retirement plan
- Bonuses/Profit sharing
- Full paid health insurance
- Other (please describe)

MAY'S QUESTION:

How have you used your technical expertise as a medical technology professional outside of work?

MAY'S RESULTS:

- Fixing odds and ends around house 71%
- Teaching technical skills to others 86%
- Community volunteer work 29%
- Helping your children with schoolwork (science projects, etc.) 43%
- Other 14%
  (Examples included "improving and maintaining general health" and "assisting spouse with job")

ABOUT *AAMI NEWS*

AAMI News is the official newsletter 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.

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New Job Fair to Launch at AAMI 2006

For the first time ever, the Career Center at AAMI's Annual Conference will feature a job fair, where participants will have an opportunity to meet employer representatives from ARAMARK, Sodexho, Stephens International Recruiting, Universal Hospital Services, ISS Solutions, TriMedx Healthcare Equipment Services, and other healthcare technology companies.

In addition to the new job fair, AAMI's Career Center offers a variety of other complimentary benefits to conference attendees who are seeking a new job, looking to advance their career, or searching for qualified employees.

The Career Center will also feature career development speakers, including Tim Hopkins of Stephens International Recruiting, who will present "Career Development—Practical Advice and Tips;" and Chuck Hardenstein, MBA, CBET, of the U.S. BMET Board of Examiners, who will discuss ICC certification. (Visit the Career Center for times and details.)

Job hunters will be able to post their resumes for free at the Career Center and arrange for interviews with potential employers. They can also review an up-to-date list of job openings, have a resume critiqued by professional recruiters, and discuss effective interviewing techniques.

Professionals seeking career guidance can participate in roundtable discussions focused on advancing their careers and learning new skills, and obtain important career resources.

Companies looking to fill a position can find hundreds of qualified professionals from the medical device community by posting job openings on AAMI's website. All postings will be made available to Annual Conference attendees. AAMI staff will assist with scheduling interviews and notifying applicants of appointment times.

The Career Center will operate from 7 AM–5 PM on Saturday, June 24 and Sunday, June 25, and from 7 AM–4 PM on Monday, June 26. ■

To post a job opening, visit www.aami.org, click on "Resumes," then click on "Career Center."

Washington Welcomes AAMI Conference Attendees . . .

A Growing Center for Medical Technology

Imagine yourself walking outside along the National Mall in Washington, DC on a bright summer day. But instead of watching the usual flocks of tourists and school groups milling about, you find yourself surrounded by cows, goats, and other animals slogging through mud.

Welcome to Washington—19th Century style. Over the last two centuries, this sleepy backwater of a fledgling capital city has evolved into a buzzing metropolis and a thriving area in the medical technology field.

As more than 1,500 professionals gather in Washington to attend AAMI's Annual Conference & Expo in June, local experts note that this region has become a formidable player in the biotech industry.

"Even longtime [DC] residents are often surprised to learn that the biggest sector in the local economy is not government, but technology," writes Richard Florida, Hirst professor of public policy at George Mason University in an editorial in *The Washington Post*.

In fact, according to Florida, the national capital region boasts more scientists and engineers than any other metropolitan region in the country.

Just why has Washington developed into such a hub? Peter Reichertz, the DC-based leader of the Food and Drug Law Group of the law firm Sheppard, Mullin, Richter & Hampton, LLP, cites a variety of reasons.

"Certainly the proximity to FDA, NIH (National Institutes of Health), CMS (Centers for Medicare and Medicaid Services), and other healthcare-related agencies plays a big part in why the region has become an important player in medical product development," says Reichertz. "Another reason is undoubtedly the high educational level of the local population."

Reichertz also points to initiatives in suburban Maryland to recruit this type of business to the state. "I think history has shown that hubs tend to develop in medical product development—like the 128 corridor in Boston—as a synergistic result of a few of these factors," he says.

In neighboring Virginia, Inova Health System announced plans recently to establish a center focused on the future of medical sciences, education, and technology. The idea behind the center is to create a gathering place for the best minds in healthcare sciences, medical education, and patient-care technology and practices to explore and develop best practices in an integrated, collaborative setting.

"What seems to happen is a confluence of an educated workforce, regional development initiatives, a few pioneering companies that are successful, and then an explosion due to all those reasons," says Reichertz. ■

2006 Foundation Award Winners Announced . . .

AAMI Honors Achievements of Seven Medical Technology Leaders

They are the innovators and leaders—the achievers and the committed professionals. This year, the AAMI Foundation is recognizing seven individuals for their outstanding achievements in research and technology at the *Dwight E. Harkin, MD Memorial Lecture and Awards Luncheon* on Sunday, June 25 during AAMI's Annual Conference in Washington, DC.

Nathaniel Sims: Patient Safety Innovator

Nathaniel Sims

While the efforts of Nathaniel Sims, MD have resulted in numerous medical innovations, patents, and technology implementations, his development of "smart pump" technology and "flexible monitoring" systems have been lauded by colleagues as landmark breakthroughs in patient safety. In fact, these developments have earned Sims recognition as the winner of the 2006 AAMI Foundation Laufman/Greatbatch Prize.

About 15 years ago, recognizing the dosage hazards that can be associated with drug infusion technology, Sims began working from his lab at Massachusetts General Hospital (MGH) with two collaborator colleagues on a way to incorporate an "intelligent" programming capacity into drug infusion pumps. The idea was to allow institutions to configure unique, care-specific profiles with pre-defined drug dose limits and other parameters to ensure patient safety. "Smart pump" technology has since been applied to numerous models of medical devices.

Before developing smart pump technology, Sims, along with his colleague, James Welch, conceived of the idea of "flexible monitoring" for general care floors of medical centers.

Many patients remain in an intensive care unit (ICU) only because of their need for a level of monitoring not available on general care floors. Because equipping all floors with monitors was prohibitively expensive, Sims and Welch developed a system that allows a pool of portable monitors to be used at any bedside on a general care floor, with critical patient information displayed at a central nursing workstation. The concept later became the framework for the integration of information from multiple types of portable patient care devices.

According to Jeffrey Cooper, PhD, director of biomedical engineering with Partners Healthcare System, Inc., "in addition to his exceedingly successful achievements and the impact they have had on healthcare," Sims simply

embodies a "spirit of innovation, commitment, and persistence."

Sims is medical advisor/assistant professor of anesthesia in MGH's department of biomedical engineering.

Dustin Telford: Tireless BMET

For more than a year, the medical center for which he works has been understaffed as a result of hiring freezes. But that hasn't stopped Dustin Telford, CBET, CRES, CLES, from cheerfully devoting his vast knowledge and expertise to the betterment of the center, or from receiving accolades from nearly everyone he works alongside.


Dustin Telford

Telford's latest accolade is his selection as the winner of the 2006 AAMI/GE BMET of the Year Award.

"Dustin continues to amaze me with the wide variety of his talents by keeping our various [devices] functioning with an absolute minimum of downtime," says John Ziegler, MD, associate professor at the University of Utah School of Medicine and anesthesia service chief with the George E. Wahlen VA Medical Center, part of the Salt Lake City VA Health Care System. "He has been available at all hours of day or night whenever we have needed someone to come in and get the job done right. He does so with a smile and cooperative manner that has endeared him to our entire staff."

Telford is largely responsible for reorganizing the local Intermountain Clinical Instrumentation Society, and is an advisor and adjunct instructor for a BMET program at Salt Lake Community College.

Robert Pagett: Champion of International Relief

Robert Pagett, founder and president of the nonprofit humanitarian organization Assist International, has been active in humanitarian projects overseas every year since 1968. He founded Assist International in 1990, and the organization has since completed more than 60 medical installations in 37 countries.


Robert Pagett

"One of the great pleasures I've had was working with [Robert] on the installation of a cardiac catheter lab in Calcutta in honor of Mother Teresa," says David Harrington of Massachusetts-based Technology in Medicine, Inc. "Over the past 15 years, he has introduced many clinical engineers and BMETs to the wonderful feeling of doing for others."

In recognition of his outstanding work, Pagett has been named the winner of this year's AAMI Foundation/ACCE Robert L. Morris Humanitarian Award.

He has worked on projects in India, China, Mongolia, Ethiopia, Turkey,

CONTINUED ON PAGE 6

2006 Award Winners

CONTINUED FROM PAGE 5

Tibet, and other countries on medical equipment implementations, ICU design/installation, and diverse educational activities.

According to Izabella Gieras, president of the American College of Clinical Engineering (ACCE), Pagett's "passion and dynamic personality touch the hearts of all who work with him. He continues to be a true inspiration to all in pursuit of humanitarian endeavors."

A. Ray Dalton: Medical Support Entrepreneur

A. Ray Dalton

According to colleagues, A. Ray Dalton defines the word "entrepreneur." The company of which he is founder, president, and CEO—PartsSource—has achieved numerous awards and accolades, including being recognized by *Entrepreneur* magazine in May 2005 as one of the fastest growing companies in America.

Among his many accomplishments in the medical field are the creation of two companies—National Medical Diagnostics (NMD) and OneSource—both of which he later sold to GE. Dalton has also served as CEO of GE's clinical services division and vice president/general manager of TRW's medical electronics division.

Dalton's autobiography, *Proceed with Confidence*, illustrates how he overcame a life of poverty in East Los Angeles to not only climb to the top of the corporate ladder, but to create and sell seven companies along the way, culminating in a 2004 Ernst & Young Entrepreneur of the Year Award.

Dalton's most recent accomplishment is being named winner of the 2006 AAMI Becton Dickinson Career Achievement Award.

Alan Lipschultz: Respected Leader in Clinical Engineering

Alan Lipschultz

When Alan Lipschultz broke into the field of clinical engineering in 1973, he essentially started Waterbury Hospital's (Waterbury, CT) clinical engineering program from scratch. More than 30 years later, he is recognized as one of the most knowledgeable and respected professionals in the field.

Lipschultz, who now serves as director of clinical engineering for Christiana Care Health Services in Newark, DE, has consistently put his expertise to work over the years for the enhancement of AAMI and the field of clinical engineering. He has served on AAMI's board of directors; as co-chair of AAMI's standards board; and as a member of the editorial board of AAMI's journal, *Biomedical Instrumentation & Technology*.

According to Robert Stiefel, director of clinical engineering with the University of Maryland Medical System, what is most notable about Lipschultz is "his commitment to improving the performance of his department and his hospital," and the "quality of his service to the field of clinical engineering."

In recognition of his innumerable contributions, Lipschultz has been recognized as this year's winner of the AAMI Clinical/Biomedical Engineering Achievement Award.

Thomas Judd: Providing Health Technology Management to Developing Countries

For years, Tom Judd has dedicated himself to assisting countries with limited healthcare resources and high health technology management needs. His

most recent project is Global Assistance for Medical Equipment (GAME)—an initiative designed to mentor, support, and encourage biomedical engineering technicians and clinical engineers in war-torn Kosovo.

The project has been endorsed by the World Health Organization (WHO) and the Pan American Health Organization (PAHO). Judd "has had a very positive impact on the status of healthcare technology in the international community," says Antonio Hernandez, a regional advisor for health services engineering and maintenance with PAHO.

His years of service have not gone unnoticed, as he is now recognized as the 2006 winner of the AAMI/Institute for Technology in Health Care Clinical Application Award.

Judd's "personal devotion to the teaching and sharing of medical technology planning methodology has impacted remote communities and facilitated access to better care," says Yadin David, PhD, director of Texas Children's Hospital's biomedical engineering department. "Tom's compassion and ability to build programs and to network practitioners is contagious."

He has been involved in similar activities as director of quality for Kaiser Permanente in Atlanta—optimizing technology to solve clinical problems.

Dennis B. Cox: Achieving Excellence through Education


Dennis B. Cox

Dennis Cox, CBET, CRES, CLES has been aggressively advancing his education since 1986. He has even managed to juggle his commitments to the biomedical field and his educational aspirations with a distinguished 20-year career in the U.S. Air Force.

Most recently, Cox achieved a Master of Science degree in Management from Troy University. In addition to this degree, Cox has earned a Bachelor of Science in Management Studies, two Associate degrees, and extensive military-based education, and has toiled through years of intense technical/biomedical training.

For his commitment to achieving excellence through education, Cox is recognized as this year's winner of the AAMI Foundation Educational Advancement Award.

Employed by Modern Biomedical and Imaging, Inc., he is currently based at North Okaloosa Medical Center in Crestview, FL.

Air Force Senior Master Sergeant Conrad J. O'Rourke, CBET, recalls working with Cox at one particular assignment in which Cox "managed the training progress of over 100 personnel and provided guidance and support to supervisors and commanders. While performing this fulltime position, he also led his biomedical maintenance department and achieved astonishing results in efficiency and productivity." ■

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imagination at work

Streamlining Standards . . .

New Master Document for Steam Sterilization to be Released

AAMI has finalized a groundbreaking new recommended practice for steam sterilization that combines five existing AAMI standards into a single resource comprising all AAMI steam sterilization recommendations. The nearly 200-page document, expected to be released in mid-June, encompasses steam sterilization in all healthcare facilities, including hospitals and ambulatory care and office-based facilities.

Steam sterilization is the most common method of sterilization of heat-resistant and moisture-resistant medical devices—such as surgical instruments—in healthcare facilities.

The new document—ANSI/AAMI ST79:2006, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*—covers steam sterilization by both the wrapped and unwrapped (flash) methods and provides detailed guidance on decontamination and packaging, with special reference to rigid sterilization container systems. It also provides additional information on the integration of chemical indicators and clarifies AAMI's biological monitoring recommendations. Considerable information has also been added concerning steam quality and utility monitoring.

Anne Cofiell

"If I had the power, I would make it mandatory for every healthcare facility using steam sterilization to have a copy of ST79 available in its central service/sterile processing department," says Anne Cofiell of AAMI/ST/WG 40—AAMI's steam sterilization hospital practices working group. "Too often, staff attempts to resolve problems with less than the best recommended practices. Having this resource readily available could significantly raise the level of work performed."

The five recommended practices that have been updated and combined into ANSI/AAMI ST79:2006, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, include:

- ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*
- ANSI/AAMI ST42, *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities*
- ANSI/AAMI ST37, *Flash sterilization: Steam sterilization of patient care items for immediate use*
- ANSI/AAMI ST35, *Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings*
- ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid sterilization container systems for ethylene oxide sterilization and steam sterilization in health care facilities*

Provisions of these five source documents have been consolidated to simplify user access to all AAMI consensus recommendations for steam sterilization in healthcare facilities, and to allow for a more frequent periodic review and revision of those recommendations. The new document will be the first AAMI recommended practice to be annually reviewed and updated, with AAMI's Steam Sterilization Hospital Practices Working Group reviewing the document and considering proposed revisions each year.

"If I had the power, I would make it mandatory for every healthcare facility using steam sterilization to have a copy of ST79 available in its central service/sterile processing department."

To order ANSI/AAMI ST79:2006, see the order form on page 31 of this newsletter or visit **http://marketplace.aami.org**. The order code for the print edition is ST79 and ST79-PDF for a PDF download version. The price is $100 for AAMI members and $200 for nonmembers. ■

Loose-Leaf Format Designed for Ease, Organization

Some of the challenges AAMI faced in compiling a document with so much information included making it durable and organizing it in such a manner that users could quickly and easily find what they were looking for. Thus, ST79 is the first AAMI standard to be available in loose-leaf binder format. (It is also available individually in PDF format and as part of AAMI's electronic CD and subscription products, and is included in the book-format collection *Sterilization, Part 1: Sterilization in Health Care Facilities*). The sturdy, attractive binder features metal rings, ledger-weight pages to prevent tearing, and a laminated tab for each section for easy navigation.

Another important aspect of ST79 is that it is the first AAMI standard to be part of the American National Standards Institute's "continuous maintenance" classification. Normally, AAMI standards undergo "periodic maintenance," which calls for review (and subsequent revision, reaffirmation, or withdrawal) of a standard every five years. With continuous maintenance, the committee will consider changes annually, and if ST79 is changed as a result, AAMI will make available on its website at no charge the revised pages, which can be downloaded and substituted into the binder. ■

Tech World features local biomedical societies, personalities, and issues facing BMETs and clinical engineers.

Finding Flexible Solutions to Uncommon Challenges

German Giles is a clinical engineering coordinator with Hospital Privado de Comunidad in Mar del Plata, Argentina. Having spent 18 years in the field, he recently started a biomedical consulting company called Global HTM—Healthcare Technologies Management. In this edition of Tech World*, he discusses some unique challenges facing Argentine biomedical engineering professionals.*

Manpower shortages. Hiring freezes. Cost-cutting measures. High-stress, fast-paced work environments. Do these hurdles sound familiar?

If you work in clinical engineering like I do, then I'm sure they do. But I'd like to share with you some challenges you may not be as familiar with—but ones we nonetheless face here in my homeland of Argentina.

In terms of human resources, we have tremendous potential here for growth in biomedical engineering. Universities and health ministries are churning out greater numbers of clinical engineers, bioengineers, and biomeds, providing a stronger base for medical technology management within our hospitals.

But difficult economic and business realities have hit us particularly hard, forcing us to develop new strategies for maintaining and buying medical equipment. For example, our last government significantly devalued the Argentine peso. For 10 years, one peso was equal to one U.S. dollar. Now, it takes three pesos to equal a U.S. dollar.

Considering the critical nature of the work we do, salaries for biomeds here are not good—typically between (U.S.) $400 and $900 a month. Due to local customs and Ministry of Health restrictions, it takes a very long time for spare parts ordered from other countries to arrive. And it is a complicated process to simply renew orders for equipment produced in other countries, because the prices are typically based on the dollar or the euro, while our medical practice costs are based on the peso.

This unnerving situation has raised some difficult questions. Will we be able to afford to purchase new medical equipment? Will we be able to assure quality care and safety for patients? Will we have the capacity to conduct routine, planned maintenance on equipment, or will we only be able to repair broken equipment?

Fortunately, by combining a bit of ingenuity, input from overseas, and some positive moves by our government, we have begun to develop flexible solutions to our problems.

One practical way we found to reduce costs is to repair equipment by finding less expensive replacement parts, such as original equipment manufacturer (OEM) lamps, batteries, patient cables, etc. As a result, we've gotten quality performance from the equipment with reduced maintenance costs.

But perhaps more than anything,

German Giles (left); Argentina (above)

our circumstances have helped us better understand the importance of networking with others in the industry—not just locally, but internationally. The Internet is an incredible resource for that. To be able to chat with clinical engineering professionals around the world who can share their experiences can only help you to overcome challenges.

We've shared ideas and have asked for help through American, Spanish, and Argentine biomedical e-mail lists.

We've also participated in industry conferences here and abroad, including some AAMI events. These experiences have helped us learn from others and find innovative ideas to improve our situation at home.

To continue making progress, we hope to work together with manufacturers, universities, local societies, and our government—which thankfully has reduced the taxes on incoming medical equipment—to develop a serious long-term healthcare technology management plan. We want to maintain solid relationships with such entities as AAMI, Pan American Health Organization (PAHO), the American College of Clinical Engineering (ACCE), and the Institute of Electrical and Electronics Engineers (IEEE), while staying abreast of important updates through educational conferences. And we hope to build joint ventures with universities and hospitals from other countries to begin international internships.

Things are changing for us here in Argentina—in a good way. But we'll have to work extremely hard to maintain that momentum.

The great news is that we can all help each other. I encourage clinical/biomedical engineering professionals everywhere to become lively participants in our field. When you take advantage of online discussion groups or when you attend conferences, you are sharing your own experiences and learning from others. We are all in this together, so let's give each other a hand.

And please, pay a visit to our beautiful country of Argentina some day, where you can take in a tango show and sample some of the finest wines the world has to offer.

—German Giles

Stiefel To Take Helm as AAMI Chair

CONTINUED FROM PAGE 1

to be held this month in Washington, DC, Bob Stiefel, CCE will attach one more ribbon to his name badge: AAMI Chair. During the conference, Stiefel will begin a two-year term as chair of the AAMI Board of Directors, succeeding Alfred M. Dolan, CCE.

Stiefel's longtime colleagues and friends view his recent selection as AAMI chair as well-deserved validation of his years of service to the association and the field of clinical engineering.

"You simply won't find a guy with more energy or who's more productive than Bob," says Manny Furst, PhD, CCE, president of Improvement Technologies, LLC and a past member of AAMI's Board of Directors. "Nor will you find someone with such a keen interest in and dedication to his profession."

Stiefel has never been shy about sharing his clinical engineering knowledge—or about learning from the experiences of others—even with professionals located halfway around the world.

"When Bob was the clinical engineering director at Johns Hopkins Hospital, he organized a collaborative program with a group in Taiwan, in which he brought technical people over to his hospital to work directly in his department for several months," recounts Dolan, Samuel Lunenfeld Professor in clinical engineering at the University of Toronto. According to Dolan, the program was tremendously successful because it "provided the benefit of international experience to both the staff visiting from Taiwan and the Hopkins CE staff."

In addition to hosting clinical engineering professionals from overseas, Stiefel has had opportunities to take his show on the road as well. In fact, he enjoys traveling so much that he admits that he'll "travel anywhere and everywhere."

Few know this as well as William Betts, CCE, a past AAMI chair and a senior director with ARAMARK Clinical Technology Services. "About 10 years ago, Bob, several of our CE colleagues, and I took a trip to Saudi Arabia to learn from our colleagues in the Middle East," recalls Betts. "The meeting itself was fantastic, and on the way home we decided to make a side trip to Cairo, Egypt. I still recall dining in a darkened café along the Nile, sharing a room with several CEs, saving money by sleeping on cots, and of course taking a camel ride to see the Sphinx. We were all very sore the next day, but with Bob, it is always an adventure."

Bob Stiefel

For those interested in warming up AAMI's incoming chair, Betts offers a few lighthearted words of wisdom.

"Bob loves to eat a good meal. Particularly some fine Italian food and a nice glass of wine—or else his wife Sheila's outstanding crabcakes. Serve him some good coffee and top it off with a slice of cheesecake, and he'll be your friend forever." ■

Incoming Chair Aims to Keep Members Involved

Bob Stiefel, CCE, believes his substantial involvement in AAMI over the years has been a major factor in the successful career he has enjoyed. So it's no surprise that he sees keeping AAMI's membership involved in the association's activities as a key priority during his term as chair.

"Early in my career, I saw the organization as a worthwhile way to advance my education and training in the field," recalls Stiefel. "I was not wrong. Involvement in a professional organization is simply one of the best ways of getting the support you need to advance your career."

Stiefel sees parallels between his job as director of clinical engineering at the University of Maryland Medical Center and his new role as AAMI chair.

"At work, I have to effectively juggle priorities," he says. "In clinical engineering, we have to satisfy our administration, the nurses, the physicians, etc. AAMI has a similarly broad focus, providing support to manufacturers, regulators, users, and researchers."

According to Stiefel, both the University of Maryland Medical Center and his previous employer—Johns Hopkins Hospital—have always been supportive of his commitment to AAMI.

"My employers have recognized that my involvement with AAMI has enhanced my value as an employee. So it's done nothing but help me."

Stiefel is also committed to making sure AAMI's members get value from their membership dues. "I want to improve what we do, to ensure that our members always get the education, training, networking opportunities, and experiences they need to grow. I'd like to give our members a chance to enjoy their careers as much as I have." ■

Directory of Medical Technology Consultants

If you are searching for a medical device consultant, the AAMI Director of Medical Technology Consultants is your best resource. Visit **www.aami.org** for details about the following consultants. You can post your own listing online or call (800) 332-2264, ext. 227.

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CERTIFICATION

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WEBSITE: www.baretich.com

Medical Technology Management, Inc.
WEBSITE: www.mtminc.org

ENGINEERING

BioElectric Solutions, Inc.
WEBSITE: www.bioelectricsolutions.com

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WEBSITE: www.HuntDabney.com

Orchid Technologies Engineering & Consulting, Inc.
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Reports Emphasize Greater FDA Focus on Data

The FDA is being urged to take steps to better identify devices already on the market that could pose the risk of patient injury, in the wake of safety problems associated with some cardiac defibrillators.

Back-to-back reports issued by the Institute of Medicine and the Heart Rhythm Society recommend that FDA focus its data collection efforts to identify adverse events due to critical device malfunctions.

The Institute has recommended that the FDA better manage and review data already gathered to track adverse events reports regarding devices on the market. It's not a question of whether FDA has enough data but rather if the data can trigger an FDA investigation into a potential safety problem, says Mark Bruley, ECRI Vice President, Accident and Forensic Investigation, who was a member of the IOM expert panel.

FDA's MAUDE data reporting program fails to adequately show FDA where to pursue all needed investigations, Bruley notes. "Currently MAUDE produces over 165,000 reports a year. Where is FDA going to get the staff to determine all of those reports that are significant and warrant further inquiries," Bruley asks rhetorically.

FDA's Center for Devices and Radiological Health (CDRH) welcomes the increased scrutiny of its data systems. "The number of recalls ordered by the CDRH in the past two years has markedly increased," notes Susan Gardner, PhD, Director, CDRH Office of Surveillance and Biometrics. But "we regulate a universe of over 8,000 products. Our ability to monitor that universe presents complex problems," she says. ■

Group Urges FDA Changes

FDA should inject greater transparency into the post-market surveillance, analysis and reporting of critical medical devices, recommends the Heart Rhythm Society. Specifically, the society has urged FDA to:

- Establish a new system to identify malfunctioning devices more quickly.
- Improve standard notification of and communications to physicians and patients from the manufacturer when a device malfunction is identified.
- Enhance existing databases to more readily identify devices that may pose a danger to patients.
- Work with outside organizations to establish independent standing committees of outside experts to analyze device performance reports and to recommend appropriate action.
- Use simple language to communicate important information about device malfunctions and eliminate the term "recall" in public communications.

In addition, the Society recommended that physicians disclose more fully the benefits and risk of devices as well as the expected performance of devices including potential malfunction risks.

Comments on the guidelines may be made on line at **www.hrsonline.org/members**. Final recommendations will be published in the October issue of *Heart Rhythm Journal*. ■

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TMC: Backing Up Promises With Action

CONTINUED FROM PAGE 1

that it was not only done, but done very well, and that we've delivered more than was promised."

This month, on its 2nd anniversary, members of the TMC will gather in Washington, DC at AAMI's Annual Conference to discuss new benefits and services being developed to better serve the interests of clinical engineers, biomedical equipment technicians, and other technology managers who are members of AAMI.

The TMC, which was created by the AAMI Board in 2004, is composed of 21 biomedical equipment technicians, clinical engineers, and other medical technology managers who volunteer their time on the TMC to represent the interests of their colleagues in the field.

Ray Laxton

Vickie Snyder

Steve Yelton

"Our commitment is to represent the interests of all medical technology professionals," says Ray Laxton, TMC chair, vice president of operations at ARAMARK Healthcare Management Services. "We've come along way, but still have a lot to do."

Like Francoeur and others, Vickie Snyder wasn't sure what to make of the TMC when she became a member in 2004.

"With so many different opportunities to make a difference, I wasn't certain what the group would focus on. But it has been really fun seeing what has become of the efforts and how far it has come," says Snyder, BMET, manager of biomedical engineering at Fairview Southdale Hospital in Minnesota.

Views vary on what projects accomplished by the TMC have been most meaningful to the profession. For example, Steve Yelton—program chair of the engineering technologies and

What has the TMC Done?

Below is a brief summary of some of the major accomplishments of the TMC during its first two years.

Outreach to Biomedical Societies

- Created an online speaker's bureau to help societies identify speakers.
- Launched a booth lending program that provides complimentary use of AAMI's tabletop exhibit and educational material to local societies.
- Revised and released a publication titled, *How to Establish and Maintain a Local Biomedical Association*.
- Promoted a new form of AAMI membership to local societies.

Nursing Outreach

- Developed and released 20,000 copies of a special magazine focused on issues of mutual interest to biomeds and nurses.

JCAHO Outreach

- Created a new regular JCAHO column in AAMI's journal.
- Created a new Q/A column, whereby AAMI members pose questions directly to JCAHO officials and obtain official responses.
- Organized a new Q&A session at the AAMI Conference featuring a top JCAHO official.

Career Resources

- Conducted and published the results of a new survey to help BMETs/CEs benchmark salaries and fringe benefits.
- Created a new career resource CD—a collection of 55 career-related articles from AAMI publications and other resources.

IT Resources

- Created and distributed the 3rd edition of *IT Horizons*, featuring IT-related guidance and articles of interest to biomeds.

Advocacy/Recognition

- Created a brochure to encourage more students to consider the biomedical field as a career option.
- Launched a new *BI&T* column written by healthcare executives to promote a greater understanding of clinical engineering issues and to improve relations between the two groups.

Other Educational Initiatives

- Created an area of AAMI's website where medical technology professionals can share best practices, policies, job descriptions, forms, and other resources with colleagues.
- Helped develop a new online searchable edition of AAMI's journal.
- Provided guidance to AAMI staff on the revision of AAMI's BMET Study Guide, which is now called *Assessing Your Knowledge: A Preparation Resource for BMET Certification*.

Ongoing Initiatives

- To develop benchmarking resources to enable hospitals and clinical engineering departments to evaluate their performance, procedures, and policies. Currently seeking a consultant to perform the work.
- To consider the development of a new technology management award for an AAMI hospital institutional member as a way of recognizing members.
- To develop additional IT and career-related guidance resources.
- To define and promote the value of the field to healthcare executives and providers.
- To evaluate a new category of membership for technology managers in the early phases of their careers. ■

information technologies divisions at Cincinnati State Technical & Community College—sees great value in the TMC's release this year of a brochure that promotes the biomed field as a career option. More than 5,000 copies of the brochure have already been distributed to schools, recruiters, hospitals, biomedical societies, and others.

In addition, Yelton sees great value in the TMC's outreach programs to biomedical societies, nursing organizations, and the Joint Commission (JCAHO). See sidebar for other projects.

According to Francoeur, one of the most critical steps taken has simply been "opening the door and inviting non-management level clinical engineering professionals to be a part of AAMI and to feel that they are contributing and getting value back."

The TMC has provided "a wonderful opportunity for healthcare technology professionals to voice their needs to AAMI to assure that relevant services are being offered to the healthcare technology community," adds Richard Eliason, CBET, senior manager for operations support with ARAMARK Healthcare Management Services and Clinical Technology Services.

As for the future, TMC members seem to unanimously agree that one project in particular offers great potential to the profession: benchmarking, which they say is both critically important and full of challenges.

The project involves the development of benchmarking resources that would enable hospitals and clinical engineering departments to evaluate their performance, procedures, and policies. In the first phase of the work, a consultant would evaluate the feasibility of the benchmarking project, outline the project parameters, identify practices that could or should be benchmarked, and determine measurable indicators for these practices. If the benchmarking project is determined feasible, the consultant would then develop and conduct a benchmarking survey in the second phase.

"If we can pull it off, the benchmarking project will be great," says Francoeur.

While the project was one of the earliest goals identified by the Council, it has been far from the easiest to accomplish. As Snyder notes, "Since nothing like it has ever been done before, it is taking a little bit longer." All agree, however, that a benchmarking survey would be a groundbreaking tool.

"To be able to standardize what we do," says Francoeur, "and to be able to hold the field up to a national standard, would just be huge." In addition to benchmarking, the TMC will discuss several other potential projects to tackle in the next year during its meeting in Washington in June.

To learn more about the TMC and its initiatives, visit **www.aami.org/tmc/index.html**. ■

Want to Get Involved?

Do you want to become involved in a TMC project? Or do you have a project idea that the TMC should pursue? The TMC represents you. So please send your comments and ideas to Steve Campbell at **scampbell@aami.org**.

Also, if you are attending AAMI's Annual Conference, stop by the Technology Managers Public Forum on Sunday, June 25 from 2:30–3:30 PM to share your ideas and input. ■

AAMI Webinar Achieves Record High . . .

Human Factors Engineering: A Manufacturer's Responsibility

It's a line that Ron Kaye has heard device manufacturers say more times than he cares to remember: "We design, test, and build high-quality medical products. It is the responsibility of users to avoid making dangerous errors when using them."

"This line of thinking is still fairly prevalent, but fortunately it is fading away," said Kaye, human factors specialist at the FDA's Center for Devices and Radiological Health (CDRH).

Kaye, along with Peter Carstensen, senior systems & human factors engineer with CDRH; and Ed Israelski, PhD, program manager, Human Factors with Abbott Laboratories, discussed the importance of considering human factors during AAMI's recent webinar, *Linking Human Factors with FDA's Quality System Regulation*.

More than 900 people took part in the program—a record high for an AAMI webinar.

Ed Israelski discusses human factors engineering at recent AAMI webinar.

"Pre-design is the best time to consider how human factors can affect the safety of your product," Kaye told participants. "If you wait until after a device is in general use, you could be responding to problems such as injuries and death."

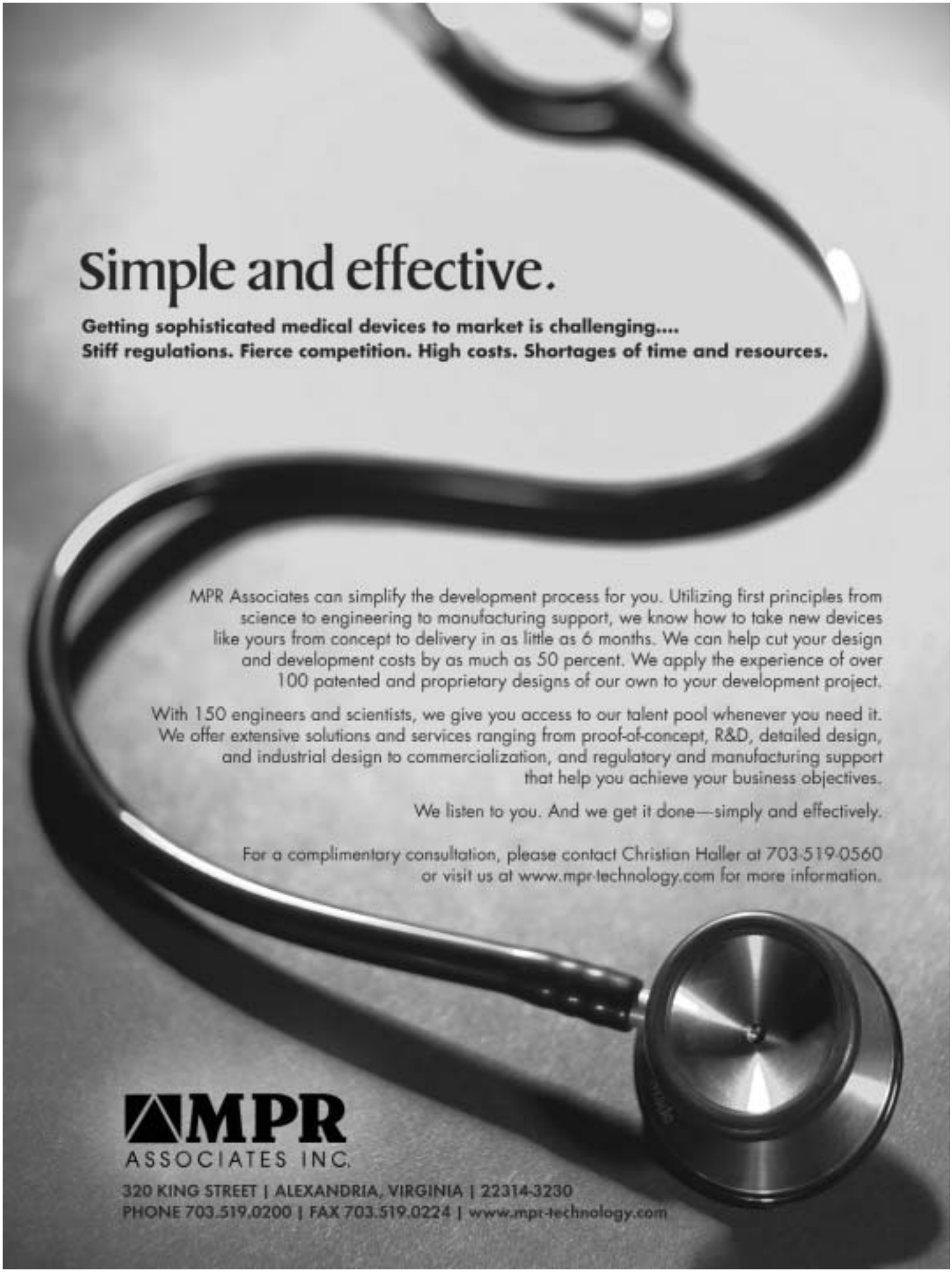
Kaye indicated that some of the common pitfalls that manufacturers run into include not considering use-error a form of risk; failing to document human factors work; and sometimes even failing to consider human factors at all.

"I've seen submissions where human factors work is simply not done," said Kaye. "It is very difficult to deal with that type of submission."

"The advantage of human factors engineering is not just that it ensures compliance with quality system regulations and related standards, but that it makes good business sense."

According to Israelski, "the advantage of human factors engineering is not just that it ensures compliance with quality system regulations and related standards, but that it makes good business sense. Your development costs are reduced because your product is designed right the first time, you have better sales . . . and you have less exposure to liability."

To order a CD of the human factors webinar, including all handouts, please see the order form on page 31 of this newsletter. ■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NEWS CLIPS

FDA and NIOSH Release Safety Notification Regarding Oxygen Regulators

The FDA and the National Institute for Occupational Safety and Health (NIOSH) have notified healthcare professionals of 12 recent incidents in which regulators used with oxygen cylinders have burned or exploded, in some cases injuring personnel.

Some of the incidents occurred during emergency medical use or during routine equipment checks. The FDA and NIOSH indicate that they believe improper use of gaskets/washers in these regulators was a major factor in both the ignition and severity of the fires, but that there may be other contributing factors.

According to their public health notification, the FDA and NIOSH recommend that plastic crush gaskets never be reused, as they may require additional torque to obtain the necessary seal with each subsequent use. This can deform the gasket, increasing the likelihood that oxygen will leak around the seal and ignite.

For more information about this safety hazard, including safety precautions to be taken to avoid explosions, tank ruptures, and fires from oxygen regulators, visit **www.fda.gov/cdrh**.

Virginia System to Establish Center for Future of Medical Sciences, Education, Technology

Inova Health System of Falls Church, VA has announced its intent to establish a center focused on the future of medical sciences, education, and technology in Loudon County, VA.

The idea behind the center is to create a gathering place for the best minds in healthcare sciences, medical education, and patient-care technology and practices to explore and develop best practices in an integrated, collaborative setting.

"Our vision is to imagine a center sharply focused on the future of high quality patient care," says Knox Singleton, president and CEO of Inova Health System. "Whether we are talking about innovative research in genomics, or development of patient-individualized treatment technologies, or patient-centered medical automation, Inova intends to be in the forefront in the future of healthcare. The Inova L.I.F.E. Center is the seed for successfully growing that future."

According to Rod Huebbers, executive vice president of Inova Health System, the designation "L.I.F.E." is meant to underscore Inova's commitment to Leadership and Innovation in the Future of Excellence in healthcare, and to suggest a partnership between Loudoun County and Inova in creating that future.

Device Could Transform Blood Pressure Technology

The Minneapolis Star reports that Massachusetts-based Medwave, Inc. has developed a wristlet that monitors blood pressure non-invasively and serves as an alternative to the traditional blood pressue cuff.

CONTINUED ON PAGE 24

The device, called "Primo," provides digital blood pressure readouts in about 12 seconds—compared with up to two minutes using a traditional cuff. Further, readings from standard cuff-based systems can vary by as much as 10 percent, Medwave CEO Tim O'Malley tells the newspaper. Also, the traditional cuff does not work as well for obese patients because it may not fit their arms, or for the elderly, who can bruise easily.

Primo was granted FDA clearance in February 2006.

Carrie Mortrud, a registered nurse with the Minnesota Nurses Association, tells the *Star* that there is a need for an alternative to the blood-pressure cuff.

"Everyone's arms are different, and there never seemed to be the appropriate size cuff in the room when you needed it, or there were missing pieces and you had to go hunting for them."

But Mortrud wonders about the accuracy of blood-pressure readings taken at the wrist. "I would have to be sold on it, but I would definitely listen," she says.

Reducing Hospital Noise by Design

Hospital patients are demanding more peace and quiet and complaining more than ever about noise, according to a recent article by *HealthLeaders News*.

The news service cites an assertion by Press Ganey Associates—a research firm that measures patient satisfaction scores—that noise is the most common patient complaint written in satisfaction surveys.

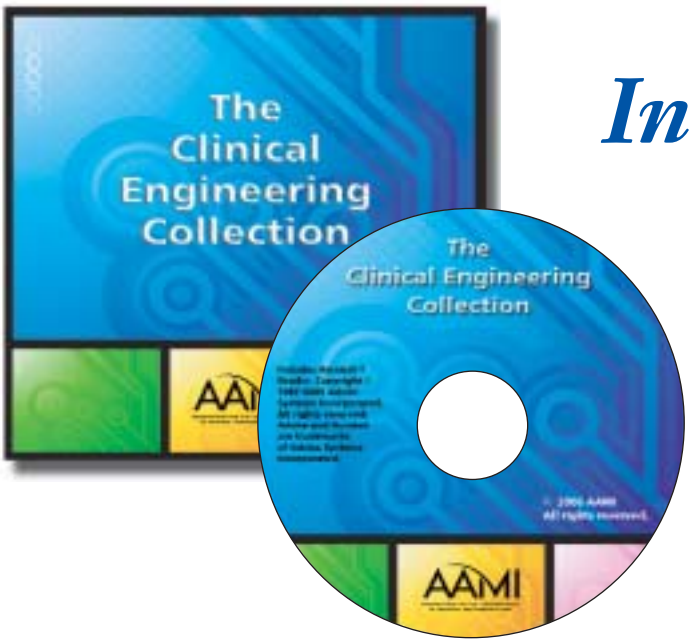
Additionally, a recent study found that patients who got plenty of rest healed more quickly than those whose sleep was interrupted by constant noise.

In response, healthcare facility designers are taking a closer look at the effects noise has on healing and how design can improve noise levels.

According to the article, "improving" noise means finding the right balance of the right noise, as total silence can be just as unnerving as clatter.

In addition to avoiding the placement of mechanical systems adjacent to or above patient rooms, the article lists the following as some of the ways to improve sound through design:

- Placing mechanical rooms at least one room away from patient rooms, or including thick wall buffers.
- Selecting interior finishes for flooring and ceilings that absorb sound.
- Placing foam rubber padding in chart holders and in pneumatic tubes to reduce clanging.
- Using folded towel dispensers, which generate no noise, instead of noisy paper rolls.
- Creating enclosed space for nurses to do reports at shift change instead of having staff congregate at a centralized station, which has shown to be one of the loudest sources of noise in patient rooms.
- Placing elevators at the end of hallways farthest away from patient rooms or locating elevators in the central core of nursing units.
- Designing private patient rooms, which have better sound quality than multi-bed rooms. ■



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IN PROFILE

Larry Hertzler: Reflecting on Career Transitions and Challenges

Last year, Larry Hertzler made a major career change—moving from TriMedx Healthcare Equipment Services to vice president of program management at ARAMARK Healthcare Technology Services/Clinical Technology Services. In this issue of AAMI News, *Hertzler discusses career transitions, new challenges, and his work within AAMI.*

AAMI News: What does your current job at ARAMARK entail?

Larry Hertzler: I'm responsible for the program management group within ARAMARK Healthcare's Clinical Technology Services business. I lead a team of technology experts responsible for the development, quality, consistency, and execution of clinical technology programs across the country. That includes ensuring that our staff are highly skilled and supported to best address the complex technical needs of our industry. This means following through on diverse requirements in a standardized way, which of course can be very demanding.

Larry Hertzler

AN: Was it a culture shock to move to a larger company?

LH: Shifting from a smaller company to one as large as ARAMARK wasn't as challenging as I expected. The strength of the company is that it can move really fast and its teams of professionals are organized in such a way that they can be small and nimble, yet act with the size of a larger organization behind them. As a large company and one organized in a matrix structure, it can be difficult to know who is specifically responsible for certain functions. But because it's such an open environment, I felt pretty comfortable asking anyone anything, which has helped me bring value and focus to the company's clinical technology expertise.

AN: What challenges did you face relocating from Indianapolis to Charlotte?

LH: It was tough to move two of my kids because they were entering their sophomore and junior years in high school. I had intended to commute until they graduated, but they decided they would rather move. The schools in Charlotte are good, and a bit smaller than they were used to, so that has helped them transition. A major move at the beginning of a school year was taxing on us, but I was lucky to have support from my family and from ARAMARK.

AN: What are the biggest challenges you face now?

LH: Adapting to the speed and depth of the organization as it serves the complex needs of the healthcare industry is a big opportunity for me. I have found that this company moves very quickly, and that we have a range of experts in almost every conceivable arena. The company is organized in a matrix fashion, which can be daunting for some, but it truly supports optimal performance. The company encourages candor—frank discussions with my healthcare professionals have really enabled us to be more effective as a team.

AN: You've served on AAMI's Board of Directors and have been very involved with AAMI for many years. What do you enjoy most about the association?

LH: AAMI represents this industry very well. It brings together the equipment manufacturers, equipment service organizations, educators, regulators, etc., from around the world. I have really enjoyed getting to know this diverse group and trying to learn more about this industry and its impact on healthcare.

AN: Having served on AAMI's Technology Management Council (TMC) for two years, what do you see as the TMC's biggest achievements? Its greatest future challenges?

LH: The TMC has taken on some significant issues and made real progress. There is a joke that any time you have two engineers in a room you will have at least three different opinions. While this may ring true at times, the TMC has stayed focused and worked to achieve results. For future success, we need to maintain the same level of energy and commitment to continue tackling tough issues effectively, while attracting new members with the same drive to make a difference. ■

Are you moving or changing jobs?
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Contact: **pbernat@aami.org**

MEMBERS ON THE MOVE


Daniel J. Vukelich, Esq.


David Stiles, CBET


Paula Graling

• **Daniel J. Vukelich, Esq.,** has been named executive director of the Association of Medical Device Reprocessors (AMDR). Vukelich has been with AMDR since 2000, previously serving as deputy executive director. In his new role, Vukelich plans to continue working to counter efforts to curb device reprocessing at both the state and federal levels. "As executive director, I plan to promote the benefits of reprocessing . . . a practice that should be embraced by the entire healthcare community in light of mounting cost-containment pressures," says Vukelich.

• **David Stiles, CBET,** biomedical engineering manager at Long Beach Memorial Medical Center & Miller Children's Hospital in Long Beach, CA, has been appointed to serve on the editorial board of AAMI's bimonthly journal, *Biomedical Instrumentation & Technology (BI&T)*. Stiles brings more than 25 years of experience working up the ranks in the biomedical field—including volunteer work as an industry liaison—to the *BI&T* board. As an editorial board member, Stiles hopes to introduce more voices and perspectives from the patient care wings and basement labs where the biomedical community exists and thrives; and assist in recruiting the next generation of biomedical professionals to contributing to AAMI's journal.

• **Paula Graling** has been named president of the Association of periOperative Registered Nurses (AORN). A graduate of George Mason University's nursing program, Graling has worked for Inova Health Systems (Fairfax, VA) for 24 years. She currently serves as Inova's clinical nurse specialist for perioperative services. As president of AORN, Graling hopes to promote AORN as the global expert for perioperative practice. After concluding her AORN presidency, Graling plans to return to school to pursue her doctorate degree and to one day teach future nurses. ■

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For a complete list of new members, see **www.aami.org/publications/AAMINews/members.html.**

National Standards

New Publications

See order form on page 31 to order print copies, or go to the Marketplace at **www.aami.org** *to order electronic (pdf) version for immediate download.*

ANSI/AAMI ST79:2006, Comprehensive guide to steam sterilization and sterility assurance in health care facilities. See article, page 9.

ANSI/AAMI BE83:2006, Biological evaluation of medical devices—Part 18: Chemical characterization of materials, 1ed. AAMI/American National Standard. An article about this document will be published in an upcoming issue of *AAMI News*.

ANSI/AAMI/ISO 11138-3:2006, Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes, 3ed. AAMI/American National Standard. (1113803 or 1113803-PDF; $35/$70). Revision of ANSI/AAMI ST19. An article about this document will be published in an upcoming issue of *AAMI News*. Identical to ISO 11138-03/Ed.2.

Call for Comments

Proposed standards and recommended practices available for public review and comment are listed here and on the AAMI website at **www.aami.org**. *Drafts can be obtained from AAMI. See order form on page 31 to order print copies, or go to the Marketplace at* **www.aami.org** *to order electronic (pdf) version for immediate download.*

Comments must be received by the deadline in order to ensure their consideration. A form for submitting comments is available (in PDF and WORD) at **www.aami.org/standards/drafts.html**. *Proposed drafts may remain publicly available after the comment period closes, but late comments generally are deferred to the next review/revision cycle, usually 4 to 5 years from approval of the currently proposed draft. Proposals that are substantially revised as a result of public comment are made available for additional public review. Note that the final text of a document may differ from the proposed version.*

Comments due by 30 June 2006

AAMI/CD-1 60601-2-21 (62D/547/CD), Medical electrical equipment—Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers, 2ed. (proposed AAMI/American National Standard). (601221-D, $20/$25; 601221-D-PDF, $0/$25)

Comments due by 31 July 2006

AAMI/DS-1 BP22-Reaff, Proposed reaffirmation of ANSI/AAMI BP22: 1994, (Reaffirmed 2001) Blood pressure transducers (proposed reaffirmation of AAMI/American National Standard). Specifies safety and performance requirements for transducers, including cables, designed for blood pressure measurements through an indwelling catheter or direct puncture and disclosure requirements to permit the user to determine compatibility between the transducer and blood pressure monitor. (BP22 or BP22-PDF; $40/$80)

Comments due by 15 August 2006

AAMI/DS-1 13488-Reaff, Proposed withdrawal of ANSI/AAMI/ISO 13488:1996, Quality systems—Medical devices—Particular requirements for the application of ISO 9002, 1ed. (proposed withdrawal of AAMI/American National Standard). The transition period set by ISO/TC 210 is ended, therefore the responsible AAMI committee is proposing withdrawal of the U.S. adoption of this standard, which is superseded by ANSI/AAMI/ISO 13485:2003. (13488 or 13488-PDF; $38/$55). Submit comments on the proposed withdrawal to **hwoehrle@aami.org**.

New Work Proposals

*To obtain more information, comment on proposed new work, or obtain a committee membership application form, contact the indicated staff person by e-mail or phone (ext. 250). An online committee membership application form as well as downloadable versions of the form is available from the Standards section of the AAMI website (***www.aami.org***).*

Approved

AAMI EC53/Ed.2, Combined revision of ANSI/AAMI EC53:1995 and A1:1998, ECG cables and leadwires (as amended in 1998). *Contact:* **hchoe@aami.org**

AAMI ST8/Ed.5, Revision of ANSI/AAMI ST8:2001, Hospital steam sterilizers. *Contact:* **jlewelling@aol.com**

AAMI ST15883-01/Ed.1, Washer-disinfectors, Part 1: General requirements, terms and definitions and tests, 1ed. *Contact:* **jlewelling@aami.org**

AAMI ST15883-02/Ed.1, Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc., 1ed. *Contact:* **jlewelling@aami.org**

AAMI ST15883-03/Ed.1, Washer-disinfectors, Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers, 1ed. *Contact:* **jlewelling@aami.org**

AAMI ST15883-04/Ed.1, Washer-disinfectors, Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for themolabile endoscopes, 1ed. *Contact:* **jlewelling@aami.org**

AAMI TIR17/Ed. 2, Revision of AAMI TIR17:1997, Medical devices—Guidance on the selection and compatibility of materials subjected to sterilization. *Contact:* **sbalboni@aami.org**

AAMI TIR(ST08)1/Ed.1, Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of health care products, 1ed. *Contact:* **jlewelling@aami.org**

AAMI TIR(ST09)1/Ed.1, Sterilization of health care products—Guidance for ultra-low bioburden products processed using an adjunct sterilization process—Products labeled "STERILE", 1ed. *Contact:* **jlewelling@aami.org**

AAMI/ISO 13408-02/Ed.1, Aseptic processing of health care products—Part 2: Filtration, 1ed. *Contact:* **jlewelling@aami.org**

AAMI/ISO 13408-03/Ed.1, Aseptic processing of health care products—Part 3: Lyophilization, 1ed. *Contact:* **jlewelling@aami.org**

AAMI/ISO 13408-04/Ed.1, Aseptic processing of health care products—Part 4: Clean-in-place technologies, 1ed. *Contact:* **jlewelling@aami.org**

AAMI/ISO 13408-05/Ed.1, Aseptic processing of health care products—Part 5: Sterilization in place, 1ed. *Contact:* **jlewelling@aami.org**

AAMI/ISO 13408-06/Ed.1, Aseptic processing of health care products—Part 6: Isolator systems, 1ed. *Contact:* **jlewelling@aami.org**

International Standards

New Publications

*The following international standards can be obtained in the US from ANSI, 25 West 43rd Street, New York, NY 10036 (***www.ansi.org***).*

ISO 15883-1:2006, Washer-disinfectors—Part 1: General requirements, terms and definitions and tests, 1ed. International Standard.

ISO 15883-2:2006, Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc., 1ed. International Standard.

ISO 15883-3:2006, Washer-disinfectors, Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers, 1ed. International Standard.

AAMI Call for Comments

The following international drafts can be obtained from AAMI. See order

form on page 31 to order print copies, or go to the Marketplace at **www.aami.org** *to order electronic (pdf) version for immediate download.*

Parallel adoptions (see National Standards Call for Comments for details)

- **IEC 60601-2-21 (62D/547/CD)**—Note: As announced last month, the deadline for commenting on national adoption and on the IEC vote are different. Comments must be submitted by 9 June 2006 to be taken into consideration in developing the U.S. vote to IEC.

Comments due by 30 June 2006

ISO/CD-V-1 14708-05 (ISO/TC 150/SC 6 N111), Implants for surgery—Active implantable medical devices—Part 5: Circulatory support devices, 1ed. (proposed International Standard). Specifies requirements for safety and performance of active implantable circulatory support devices. Excluded from this scope are intra-aortic balloon pumps, external corporeal perfusion devices and cardiomyplasty. This standard specifies type tests, animal studies and clinical evaluation requirements that are to be carried out to show compliance with this standard. (1470805-D, $20/$25; 1470805-D-PDF, $0/$25)

IEC/CDV-1 60601-1-06 (IEC 62A/518/CDV), Medical electrical equipment—Part 1-6: General requirements for basic safety and essential performance—Collateral standard: Usability, 2ed. (proposed International Standard). This standard specifies requirements for a process to analyze, design, verify, and validate the usability to ensure the safety of medical electrical equipment. This standard addresses normal use and use errors but excludes abnormal use. (601106-D, $20/$25; 601106-D-PDF, $0/$25)

IEC/CDV-1 60601-1-08 (IEC 62A/519/CDV), Medical electrical equipment—Part 1-8: General requirements for safety—Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, 2ed. (proposed International Standard). Specifies general requirements and guidelines for the application of alarm systems in medical electrical equipment and medical electrical systems in order to reduce variability between various particular pieces of medical electrical equipment and to improve patient safety and patient care via structured alarms. (601108-D, $20/$25; 601108-D-PDF, $0/$25)

IEC/CD-1 60601-2-35 (IEC 62D/552/CD), Medical electrical equipment—Part 2-35: Particular requirements for basic safety and essential performance of blankets, pads and mattresses, intended for heating in medical use, 2ed. (proposed International Standard). This standard specifies requirements for blankets, pads, and mattresses, including air-flotation mattresses and forced-air system. (601235-D, $20/$25; 601235-D-PDF, $0/$25)

Comments due by 31 July 2006

IEC/CD-1 60601-2-31 (IEC 62D/554/CD), Medical electrical equipment—Part 2-31: Particular requirements for basic safety and essential performance of external cardiac pacemakers with internal power source, 2ed. (proposed International Standard). The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of external cardiac pacemakers with an internal power source. This particular standard does not take into consideration the specific safety aspects of external pacemakers that are connected to a supply mains while simultaneously connected to the patient. (601231-D, $20/$25; 601231-D-PDF, $0/$25)

IEC/CDV-1 60601-2-16 (IEC 62D/556/CDV), Medical electrical equipment—Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment, 3ed. (proposed International Standard). Specifies minimum safety requirements for single-patient haemodialysis, haemodiafiltration and haemofiltration equipment. These devices are intended for use either by medical staff or under the supervision of medical expertise, including haemodialysis, haemodiafiltration and haemofiltration equipment operated by the patient. These requirements do not apply to: extracorporeal circuits; dialysers; dialysing fluid concentrates; water purification equipment; and equipment used to perform peritoneal dialysis (see IEC 60601-2-39). (601216-D, $20/$25; 601216-D-PDF, $0/$25)

IEC/CDV-1 60601-2-39 (IEC 62D/555/CDV), Medical electrical equipment—Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment, 2ed. (proposed International Standard). Specifies minimum safety requirements for peritoneal dialysis equipment. Applies to equipment intended for use either by medical staff or under the supervision of medical experts, including equipment operated by the patient, regardless of whether the equipment is used in a hospital or domestic environment. These particular requirements do not apply to the dialysing solution, the dialysing solution circuit, or to equipment solely intended for use as continuous ambulatory peritoneal dialysis equipment. (601239-D, $20/$25; 601239-D-PDF, $0/$25)

Upcoming Meetings

AAMI Committees and U.S. TAGs

*Open meetings of AAMI committees and U.S. Technical Advisory Groups (TAGs) are listed here and at the AAMI website (***www.aami.org***). Agendas for open meetings are usually available from AAMI Committee Central. (Go to* **www.aami.org/committeecentral***, find the committee or working group using "Browse Committees," and select the link to the committee's "Working Documents.") Note: If you plan to attend a meeting, please send a brief note to the AAMI Standards Department (***standards@aami.org***) indicating the name and date of the meeting so that staff can contact you in the event of a last-minute cancellation.*

Ad Hoc Meeting to Discuss New Work Item Proposal on Medical Device Particulates (Open Meeting). 20-Jun-06, 09:00–12:00 h. Westin Arlington Gateway Hotel, 801 North Glebe Road, Arlington, VA 22203, USA. Proposal for Technical Information Report (TIR) that applies to all products used in the vasculature. Two areas of particulate testing would be covered: (1) product integrity testing which takes place in design verification. This testing shall detect particles resulting from the use of the product in a clinial application or from product aging; (2) subvisible particles on the product, resulting from the manufacturing processes and environment. The test method must be clinically relevant for the use of the product. Visible foreign material is excluded from the scope of the TIR. *Contact:* **cbernier@aami.org**

AAMI/ST, Sterilization Standards Committee, U.S. TAG for ISO/TC 198, and affiliated working groups and sub-TAGs (Open Group Meeting). 19 to 21-Jun-06. Westin Arlington Gateway Hotel, 801 North Glebe Road, Arlington, VA 22203, USA. *Contact:* **jlewelling@aami.org**

- **AAMI/ST, Sterilization Standards Committee.** 21-Jun-06, 16:30 to 18:30 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 01, Industrial EO sterilization WG.** 21-Jun-06, 09:00 to 15:30 h. Discuss status of revision of ANSI/AAMI/ISO 11135:1994. Consider the future of AAMI ethylene oxide TIRs after ANSI/AAMI/ISO 11135-1:200x is finalized. *Contact:* **sbalboni@aami.org**
- **AAMI/ST/WG 02, Radiation sterilization WG.** 20-Jun-06, 09:00 to 15:00 h. Consider ballot results on draft AAMI TIRs for Sterilization of healthcare products—Radiation sterilization—Alternative sampling plans for verification dose experiments and sterilization dose audits and Guidance on radiation sterilization of human tissue-based products. *Contact:* **sbalboni@aami.org**
- **AAMI/ST/WG 03, Industrial moist heat sterilization WG.** 20-Jun-06, 13:00 to 17:30 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 04, Biological indicators WG.** 21-Jun-06, 09:00 to 12:00 h. *Contact:* **cbernier@aami.org**
- **AAMI/ST/WG 06, Chemical indicators WG.** 20-Jun-06, 13:00 to 17:00 h. *Contact:* **cbernier@aami.org**

- **AAMI/ST/WG 07, Packaging WG.** 19-Jun-06, 09:00 to 15:00 h. Discuss working draft of the proposed revision to TIR on packaging. This proposed TIR would include information specific to U.S. regarding both of the recently adopted and published ANSI/AAMI/ISO 11607-1:2006 and ANSI/AAMI/ISO 11607-2:2006. *Contact:* **hchoe@aami.org**
- **AAMI/ST/WG 08, Microbiological methods WG.** 20-Jun-06, 15:00 to 17:30 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 09, Aseptic processing WG.** 19-Jun-06, 09:00 to 15:00 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 10, Liquid chemical sterilization WG.** 21-Jun-06, 13:00 to 16:00 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 11, General criteria for sterilization processes WG.** 21-Jun-06, 09:00 to 12:00 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 13, Washer-disinfectors WG.** 19-Jun-06, 09:00 to 12:00 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 40, Steam sterilization hospital practices WG.** 21-Jun-06, 13:00 to 16:00 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 42, Dry heat sterilization WG.** 19-Jun-06, 09:00 to 12:00 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 43, Hospital steam sterilizer WG.** 19-Jun-06, 15:00 to 17:30 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 60, EO sterilization hospital practices WG.** 20-Jun-06, 09:00 to 12:30 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 63, Sterilization residuals WG.** 19-Jun-06, 13:00 to 17:00 h. *Contact:* **sbalboni@aami.org**
- **AAMI/ST/WG 90, Microbiological quality (SALs) of processed medical devices WG.** 21-Jun-06, 12:00 to 16:00 h. *Contact:* **jlewelling@aami.org**
- **AAMI/ST/WG 92, Process challenge devices WG.** 20-Jun-06, 09:00 to 12:00 h. Discuss revision of AAMI TIR 31:2003 and assign task assignments for areas of the document that need to be revised. Contact: **hchoe@aami.org**
- **AAMI/ST/WG 95, Water quality for reprocessing medical devices WG.** 20-Jun-06, 13:30 to 17:30 h. *Contact:* **jlewelling@aami.org**
- **Ad hoc meeting on sterilization materials qualification.** 19-Jun-06, 13:00 to 17:00 h. To begin work on new TIR, "Guidance on the selection and compatibility of materials subjected to sterilization." A copy of the proposal is available at **www.aami.org/Applications/CommitteeCentralapp/Documents/STWG02NWIP.pdf**, or contact **sbalboni@aami.org** for more information. *Contact:* **jlewelling@aami.org**

AAMI/ST, Sterilization Standards Committee, U.S. TAG for ISO/TC 198, and affiliated working groups and sub-TAGs (Open Group Meeting). 13 to 15-Nov-06. Gateway Westin, Arlington, VA, USA. *Contact:* **jlewelling@aami.org**

AAMI/VP, Vascular Prostheses Committee (Open Meeting). 24 to 26-Jun-06, 13:00 to 18:00 h (AAMI 2006 Conference and Expo). Marriott Wardman Park Hotel, 2660 Woodley Road, NW, Washington, DC 20008, USA. Develop US position on ISO/CD 25539-2, Cardiovascular implants—Endovascular devices—Part 2: Vascular stents. *Contact:* **cbernier@aami.org**

International Committees and Working Groups

Call or write the indicated staff person at AAMI (Attention: Standards Department) for more information about upcoming international standards meetings.

ISO/TC 121/SC 3 and IEC/SC 62D, Joint working group on lung ventilators (Closed Meeting). 05 to 08-Jun-06. Helsinki, Finland. Discuss progress on the revision of IEC/ISO 80601-2-12 (formerly IEC 60601-2-12) on critical care ventilators. *Contact:* **hchoe@aami.org**

ISO/TC 150, Implants for Surgery, affiliated subcommittees and working groups (Closed Group Meeting). 11 to 15-Sep-06. Vienna, Austria. *Contact:* **ntongson@aami.org**

- **ISO/TC 150/SC 2, Cardiovascular Implants.** 14-Sep-06. Review and discuss reports of working group meetings. *Contact:* **cbernier@aami.org**
  - **ISO/TC 150/SC 2/WG 03, Vascular prostheses.** 11 to 14-Sep-06. Review ballot results for ISO/CD 25539-2 (stents).
  - **ISO/TC 150/SC 2/WG 04, Blood-gas exchanges.** 12 to 14-Sep-06. Review ballot results for Systematic Reviews of ISO 7199 (oxygenators), ISO 15674 (hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags), and ISO 15675 (arterial line blood filters); discuss possible work item on connectors.
  - **ISO/TC 150/SC 2/WG 05, Renal replacement, detoxification and apheresis.** 11 to 14-Sep-06. Review ballot results for ISO/DIS 23500 (fluids); ISO/CDV 13958 (concentrates); ISO/CDV 13959 (water); and ISO/CDV 26722 (water treatment equipment).
- **ISO/TC 150/SC 6, Active Implants.** 14-Sep-06. Review and discuss reports of working group meetings.
  - **ISO/TC 150/SC 6 and IEC/SC 62D, Joint working group on cardiac pacemakers and implantable defibrillators.** 11 to 12-Sep-06. Discuss progress on projects dealing with quadripolar connectors, pacemaker magnet mode response, and symbols for cardiovascular implantable devices, and a report on the progress of the revision of IEC 60601-2-31 (external cardiac pacemakers). Contact: ntongson@aami.org
  - **ISO/TC 150/SC 6/WG 04, Implantable infusion pumps.** 11 to 12-Sep-06. Discuss progress on ISO 14708-4 (implantable infusion pumps).
  - **ISO/TC 150/SC 6/WG 05, Implantable neurostimulators.** 13 to 14-Sep-06. Discuss progress on ISO 14708-3 (implantable neurostimulators).
  - **ISO/TC 150/SC 6/WG 06, Circulatory support devices.** 11 to 12-Sep-06. Resolve comments on ISO/CDV 14708-5 (circulatory suppor devices).

ISO/TC 198/WG 04, Biological indicators WG (Closed Meeting). 15 to 16-Jun-06. Arlington, VA, USA. Begin revision of ISO 14161, Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results. *Contact:* **cbernier@aami.org**

ISO/TC 194, Biological Evaluation of Medical Devices and affiliated working groups (Closed Group Meeting). 10 to 14-Jul-06. Chicago, IL, USA. *Contact:* **hwoehrle@aami.org**

- **ISO/TC 194/WG 1, Systemic approach to biological evaluation** and terminology WG. 10 to 11-Jul-06. Resolve comments on ISO/CD 10993-1 (evaluation and testing).
- **ISO/TC 194/WG 2, Degradation aspects related to biological testing WG.** 12 to 13-Jul-06. Discuss results of voting on new work item proposals for revisions of 10993-9 (Framework for identification and quantification of potential degradation products) and 10993-13 (Identification and quantification of degradation products from polymeric medical devices). Discuss systematic reviews of 10993-14 (Identification and quantification of degradation products from ceramics) and 10993-15:2000 (Identification and quantification of degradation products from metals and alloys).
- **ISO/TC 194/WG 3, Animal protection aspects WG.** 10-Jul-06. Finalize the NWIP for the revision of 10993-2:2006 (Animal welfare requirements).
- **ISO/TC 194/WG 4, Clinical investigations in humans WG.** 10 to 11-Jul-06. Finalize the NWIP for the revisions of ISO 14155-1:2003 (General requirements) and ISO 14155-2 (Clinical investigation plans).
- **ISO/TC 194/WG 5, Cytotoxicity WG.** 11-Jul-06. continue development of ISO/CD 10993-5 (Tests for in vitro cytotoxicity).
- **ISO/TC 194/WG 6, Mutagenicity, cancerogenicity, reproductive toxicity WG.** 13-Jul-06. Finalize the NWIP for the revision of 10993-3:2003 (Tests for genotoxicity, carcinogenicity and reproductive toxicity).
- **ISO/TC 194/WG 7, Systemic toxicity WG.** 10-July-06. Update on the results of voting on ISO/FDIS 10993-11 (Tests for systemic toxicity) and update on the publication of ISO/TS 10993-20 (Principles and methods for immunotoxicology testing of medical devices).
- **ISO/TC 194/WG 8, Irritation, sensitization WG.** 11 to 12-Jul-06. Development of a new work item proposal for the revision of 10993-10:2002 and Amendment 1 (Tests for irritation and delayed-type hypersensitivity).
- **ISO/TC 194/WG 9, Effects on blood WG.** 12-Jul-06. Development of a new work item proposal for the revision of 10993-4:2002 and Amendment 1 (Selection of tests for interaction with blood).
- **ISO/TC 194/WG 10, Implantation**

WG. 13-Jul-06. Finish resloving comments on DIS 10993-6 (Tests for local effects after implantation).

- **ISO/TC 194/WG 11, Allowable limits for leachable substances WG.** 12 to 13-Jul-06. Resolve comments on DIS 10993-7 (Ethylene oxide sterilization residuals).
- **ISO/TC 194/WG 12, Sample preparation and reference materials WG.** 11-Jul-06. Resolve comments on DIS 10993-12 (Sample preparation and reference materials).
- **ISO/TC 194/WG 13, Toxicokinetic study WG.** 13-Jul-06. Development of new work item proposal for the revision of 10993-16:1997/R:2002 (Toxicokinetic study design for degradation products and leachables).
- **ISO/TC 194/WG 15, Strategic approach to biological testing of medical devices WG.** 10-Jul-06. Update on possible new work on tissue engineered medical products and status of internal guidance document on the preparation of 10993 standards.

Other Standards News

Committee News

New cochair appointed to the AAMI Autologous Transfusion committee. Mr. Kenneth Merte (Medtronic) has been appointed to serve a two-year term as cochair of AAMI/AT, Autologous Transfusion.

New cochair appointed to the AAMI Medical Devices for Injections Committee (AAMI/DI). Ms. Kelli Rosenthal (ResourceNurse.Com) has been appointed to serve a two-year term as cochair of AAMI/DI.

New cochair appointed to the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee (AAMI/QM). Ms. Carol, Herman (FDA/CDRH) has been appointed to serve a two-year term as cochair of AAMI/QM.

New cochair appointed to the AAMI Blood/Gas Exchange Device Committee (AAMI/BG). Mr. Walt Lee Carpenter (Medtronic) has been appointed to serve a two-year term as cochair of AAMI/BG.

New cochair appointed to the AAMI Blood Filter Committee (AAMI/BF). Mr. Bryan Blickhan (Baxter) has been appointed to serve a two-year term as cochair of AAMI/BF.

Nominations received for convenorships of IEC 62D working groups. The German National Committee (DKE) has nominated Dr. Hans-J_rgen Flaig (Fresenius) to succeed Mr. Lee Fischbach, who is recently deceased, as convenor of IEC/SC 62D/MT 20: Haemodialysis Equipment. DKE also has nominated Mr. Matthias Marzinko (Karl Storz) to succeed Mr. Hans-Werner Zeller as convenor of IEC/SC 62D/MT 16: Electro-optical Equipment. *Contact:* **ntongson@aami.org**

For more standards news, visit Standards Monitor Online at www.aami.org

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UPCOMING EVENTS

AAMI 2006 Annual Conference & Expo
June 24–26 • Washington, DC

Design Control Requirements and Industry Practice
September 11–13 • Washington, DC

Quality System Requirements and Industry Practice
September 18–21 • Denver, CO

Process Validation Requirements and Industry Practice
September 25–27 • Washington, DC

Industrial Sterilization for Medical Devices
October 3–6 • San Diego, CA

Integrating Risk Management into the Quality System
October 9–11 • Orlando, FL