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AAMI News

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

INSIDE . . .

The Inside Word

"In the end, the key measure of our growth and success in the industry is our people."

Brian Poplin
Vice President,
Clinical Technology Services
ARAMARK Healthcare
Management Services

See story page 18

Networking Standard Underway . . .

'Plug and Play' Connectivity Initiative Launched

A broad consortium of medical interests has joined forces to develop an open networking standard for communication and control of medical devices.

Led by representatives from Boston-based Partners Healthcare and Kaiser Permanente in cooperation with the FDA, other health care professionals, and the U.S. Department of Defense, the group plans to incorporate existing interoperability work where possible and to develop new tools where necessary, in order to produce and implement an integrated "plug and play" medical device open networking standard within three years.

"The concept is that individual medical devices would be networked to allow the communication of data from one device to the other and the control of one medical device by another, as well as allowing the implementation of clinical rules or guidelines," explains Julian M. Goldman, MD, of Massachusetts General Hospital, principal investigator for the project.

The "Operating Room of the Future" (ORF) at Massachusetts General Hospital

Such a standard would "help address the goal of integrating patient monitoring with clinical decision systems and electronic

CONTINUED ON PAGE 14

Industry Challenge Addressed . . .

Is Improved Medical Technology Worth the Cost?

Last fall, the nation's top economic guru told U.S. lawmakers that difficult choices lie ahead when it comes to balancing the need for budgetary restraint with the expense of new medical technology.

In economic outlook testimony, Federal Reserve Chairman Alan Greenspan cited recent-year outlays for Medicare and Medicaid that have grown faster than the national Gross Domestic Product (GDP), amounting to about 7% of GDP in 2003.

"In the context of an unprecedented increase in retirees, the need to make stark choices among budget priorities will again become pressing. Federally funding access to advances in medical technology, for example, likely will have to be weighed against other spending programs," said Greenspan.

Since that time, other economists have suggested that health spending is stifling job growth and threatening to crowd out spending on education, housing, and infrastructure. In 2004, government estimates put the American health care bill at $1.79 trillion, or $6,167 per person—leaving some to ask: Are the health benefits of new medical technology worth the cost?

David Cutler

"Rising health costs are a challenge, but not a menace—much the way that high blood pressure is a problem to be addressed, but needn't be fatal," responds Harvard economist and health care expert David Cutler. Cutler suggests that lawmakers must come up with a "sound financing system"

CONTINUED ON PAGE 2

DUES IN ACTION

- **Looking for a change?** How can you land a job that's right for you?

  This is the focus of the cover story in the Jan/Feb issue of AAMI's peer-reviewed journal, *Biomedical Instrumentation & Technology* (*BI&T*). The article highlights issues to consider when choosing a career path.

  Also in *BI&T*, Gerald Zion discusses the fundamentals of gas flow analyzers, including how to maintain and troubleshoot them. Other articles include a Q&A with JCAHO officials, tips on communication skills, and how to kick start a corrective and preventive action (CAPA) process.

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AAMI News is the official newsletter of the Association for the Advancement of Medical Instrumentation (AAMI), a unique alliance of the health care professions providing essential information on the development and use of medical instrumentation and technology.

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Advertising rates and deadlines:
Contact Steve Campbell at (703) 525-4890, ext. 241, or e-mail scampbell@aami.org

President: Michael J. Miller, JD

Vice President of Communications and Marketing: Steve Campbell

Associate Editor: Jody Lannen Brady

Communications Assistant: Marti Walker

AAMI
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795
(703) 525-4890 (Phone)
(703) 276-0793 (General fax)
(703) 525-1424 (Publication orders)
www.aami.org

Health Costs Questioned

CONTINUED FROM PAGE 1

but believes that "we are rich enough to afford to spend more on health care if we want. The real question is whether the value of what we are buying is high—and it is."


Chuck Swanson

Long-time industry executive Chuck Swanson of Medtronic agrees with Cutler's outlook: "I think this cost of technology issue is way overblown. I'm not convinced that technology is the problem; the problem is understanding the value of medical therapies."

Swanson points to implantable defibrillators as a case-in-point. The defibrillators may run upwards of $20,000, says Swanson, but they save lives, cut back on drug costs, reduce hospital stays, and allow patients to return to work. "I don't pretend to be an economic expert, but I think that we focus too much on what we see as the immediate cost of medical technology—and we fail to assess the value that these products bring to society."

A recent editorial in the *New England Journal of Medicine* (December 9, 2004) suggests that clinicians begin to look at this issue of cost assessment. "As doctors, we have been taught not to address issues of social significance at the bedside. Still, as recent history amply demonstrates, economics is at the forefront of the minds of policymakers," Sandeep Jauhar, MD, PhD, and David Slotwiner, MD, write in the editorial.

Medical device industry consultant Art Ward points to a recent example of what he sees as "expensive, but cost-effective" technology: drug-eluting stents. "Yes, the cost of a drug-eluting stent is much more than a regular stent—but I think it's significant that this technology can reduce the amount of repeat surgery and enhance the effectiveness of the procedure for the patient."


Jori Frahler

The Medical Device Manufacturers Association (MDMA) will continue to make this case to policymakers, the press, and the public. "While health care costs are on the rise, it is important to look at the overall improvement in the quality of care," argues Jori Frahler, policy director for MDMA. "Rather than simply looking at the 'price' of a device, one must also look at the cost savings realized from the improved technology. Shorter hospital stays and faster recovery times often more than make up for a more costly technology." ■

AAMI/FDA Conference in March Set . . .

International Experts Examine Challenges to Standards

"Participation" in international standards-setting represents a growing concern, according to medical device experts preparing to speak at the 15th annual AAMI/FDA International Conference on Medical Device Standards and Regulation this March in Reston, VA.

Klaus E. Stinshoff

"I see a major problem in the unbalanced participation of the three constituent parties—manufacturers, regulators, and users—in the standards development process; industry is so strongly represented that there is a permanent risk that their interests will predominate over the concerns of regulators and users," says Klaus E. Stinshoff, European director of regulatory and quality assurance for Digene Sàrl in Geneva, Switzerland.

"As a result, standards are being challenged after their implementation and alternative tools—such as the Common Technical Specifications of the EU—are being developed," adds Stinshoff, a speaker at the March event.

The AAMI/FDA conference, which will attract government and industry leaders from around the world, will explore developments in international standards key to global market access and regulatory compliance. Participants will hear directly from representatives of FDA, network with international colleagues, and participate in discussions with speakers and fellow attendees during the program.

Other featured topics include: risk management for medical devices; human factors and patient safety; an update on ANSI/AAMI/ISO 13485 and its related guidance; and a comparison of regulatory approval processes around the globe.

The timing for the conference coincides with new emphasis on international standards. "The FDA has traditionally valued and used technical and procedural standards," explains Stinshoff. "Since the New and Global Approach Directives of the European Community have introduced the tool of 'harmonized' standards, the acceptance and importance of standards have received a major boost." ■

2005 AAMI/FDA International Conference on Medical Device Standards and Regulation

DATE: March 23–24, 2005

LOCATION: Reston, VA (10 minutes from Dulles International Airport)

INFORMATION: Visit **www.aami.org/meetings/isc/index.html**, or call Chris Dinegar at (703) 525-4890, ext. 210.

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

Changing Times: One Technician Looks Back Over 30 Years

The last three decades have witnessed a revolution in medical technology. Here, one biomedical technician looks back on the evolving role of his profession. John Armstrong retired in 2002.

From vacuum tubes and relays to surface-mounted integrated circuits and IP addresses, my career has been an exciting journey. I began as a service engineer for Picker Medical and retired as the chief of the biomedical engineering section at the Veterans Administration Medical Center in Des Moines, IA.

During the 28 years that I spent with the Veterans Administration, medical equipment changed dramatically requiring the technician to develop new skills and abilities.

In the beginning, replacing a vacuum tube or burnishing the contacts of an open-frame relay would repair many of the medical equipment malfunctions, and it was common for the equipment to be repaired by hospital maintenance personnel without any formal education in electronics or medical instrumentation. Being a hospital electrician or a self-taught radio/TV repairman prepared you to repair medical equipment.

During the 1970s, medical equipment began appearing with the components soldered directly into printed circuit boards. It was no longer feasible to substitute vacuum tubes until the problem was resolved. Skill in using multimeters and oscilloscopes became an important attribute for the repair technician.

Repair of medical equipment became a specialty and was frequently moved out of the hospital maintenance department. Increasingly, technicians with training in solid state electronics were recruited to staff these new departments. The signs on the doors to these new departments began to say "Biomedical Engineering" or "Biomedical Electronics" and the technicians began to be called BMETs.

John Armstrong

Biomedical departments were no longer just "fix-it shops." The role of the technicians began to expand as the medical staff discovered that the BMETs had the skills necessary to provide

training in the use of medical equipment and could help resolve problems with the patient/instrumentation interface.

Hospital management frequently became aware of biomedical engineering only when a facility began preparing for an accreditation survey and discovered the requirement for preventive maintenance (PM) of medical equipment. Granted, while the PM program was frequently implemented as only electrical safety testing, the BMET was able to provide this service and gain visibility and responsibility in the organization.

During the 1980s, the personal computer came into widespread use both for stand-alone applications and controlling medical devices. BMETs were called on to support both the hardware and software of this new technology.

Computer technology also expanded into the medical equipment itself with microprocessors and embedded software replacing hardwired logic in printed circuit boards. Component-level troubleshooting was replaced by board replacement.

Another group of technicians appeared in hospitals at this time. With the number of non-medical computers and systems mushrooming, information technology departments were being formed. The technicians to staff these new departments were frequently siphoned away from the biomedical departments. Some turf wars erupted as the responsibilities for these new departments were being defined.

The 1990s introduced computer networking into medical equipment systems. The wonderful flexibility of the hospital IT backbone was being tapped for medical systems.

Now the requirements for BMETs included knowledge of computer networks and how to set IP addresses. Since the distinction between hospital information systems and medical systems was becoming less clear, alliances were being forged between the IT technicians and the BMETs to provide seamless support to the medical staff.

VA Medical Center, Des Moines, IA

Although the health care field has advanced significantly in the last three decades, the chief role of BMETs has remained the same: to ensure the safe and effective use of medical technology. Patient safety will always be our ultimate goal.

—John Armstrong

Beyond asset tracking . . .

Health Care Providers Hopeful about New RFID Applications

When the FDA approved an external surgical marker tag for market in November, the health care industry took note. The device, the SurgiChip™ Tag Surgical Marker, relies on radio frequency identification (RFID) technology to minimize the likelihood of wrong-site, wrong-procedure, and wrong-patient surgeries.

While some experts have debated whether this high-tech approach will offer enough improvement over simpler, traditional systems—like patient wristbands and skin markers—to justify its cost, most health care providers appear to have embraced what they see as the promise of the technology itself.

"RFID has proven itself in many industries in supply chain, logistics, and decision support applications. It's a natural progression from barcodes, but it enables much more functionality. Readers can be further away and do not require line of sight, and tags can carry more than just ID information," explains Harald Fritz, director of business development for eXI Wireless Inc. of British Columbia, Canada.

Rick Hampton

The basic technology has existed since World War II, but until recently few commercial applications were developed. Today's "active" RFID technology pairs a microchip with a radio antenna in an electronic tag, which can transmit beacon signals for real-time tracking and other uses. Active tags can cost between $25 and $65, according to Rick Hampton, wireless communications manager for Partners HealthCare System in Boston.

"Passive" tags do not contain batteries and obtain their power from a signal provided by a tag reader in close proximity. Currently, passive tags cost around $2 at most, with some as low as five cents each, says Hampton.

The small size of passive tags allows them to be embedded in packaging, ID badges, or even under the skin—as is the case with Applied Digital Solution's VeriChip™, the first FDA-approved, implantable RFID microchip for human use.

Applied Digital Solution's VeriChip™

Unlike barcodes, active RFID tags do not require line-of-sight scanning, because readers automatically pick up data stored in a tag. In addition, the read/write tags offer the advantage of being updatable and reusable. In recent years, enhanced capacity of the tags has meant that high-volume data, including image files, can be stored.

With interest in the health care sector increasing, companies have experienced heightened demand. Fritz's company has put RFID systems for asset, patient, and staff tracking; wandering patient protection; and safety systems in some 2,500 long-term and intermediate care facilities as well as over 600 hospitals in the U.S., Canada, Mexico, Chile, Japan, Malaysia, Korea, Australia, United Kingdom, and Germany.

RFID tags produced by eXI Wireless

Three varieties of RFID technology dominate the market, according to Hampton. "The first uses active RFID tags operating on frequencies set aside for them. The second uses active RFID tags operating as 802.11b devices. The third uses active RFID tags operating as ultra-wideband," explains Hampton. Depending on a hospital's existing wireless infrastructure, each can offer advantages.

Beth Israel Deaconess Medical Center in Boston uses the 802.11 system developed by PanGo Networks of Framingham, MA.

John D. Hamalka

"Using PanGo and our in-hospital WiFi network, we can track the location of patient beds in the Emergency Department and thus know patient locations, which enhances workflow," says John D. Hamalka, MD, an emergency physician at Beth Israel, as well as chief information officer for CareGroup Health System, Harvard Medical School, and Harvard Clinical Research Institute.

"Similarly we can track nurses and doctors, displaying their location on a dashboard display, which makes it easier to find the people you need. This information can also be used for time-in-motion studies, to help us improve the layout of the emergency department," Hamalka explains. In addition, Beth Israel uses RFID to track EKG devices and IV pumps, which ensures equipment is available when needed.

Kenneth Maddock

When discussing RFID, "the most common thing that everyone talks about is people and asset tracking," according to Kenneth Maddock, director of clinical technology services for Baylor Health Care System in Dallas, TX. "But where I think there is value is in what you do

with the data you have. In other words, now that I know where people and assets are, what do I do with that information?" asks Maddock, who hopes to see data from RFID systems used to automate processes that currently require manual input.


Jeffrey B. Cooper

Patient safety expert Jeffrey B. Cooper, PhD, director of biomedical engineering for Partners Healthcare System and associate professor of anesthesia at Harvard Medical School, agrees: "My feeling is that RFID technology holds great promise to contribute to patient safety and productivity by tracking people and things and using the information to get the right things to the right patients at the right time."

Building on years of experience in the entertainment and game industries in Japan, Hitachi Maxell Ltd. (HML) is one of several companies exploring new RFID applications. "RFID in health care, especially in the error prevention market, is an exciting new focus for both HML in Japan and in the U.S.," says Rumi Kitatate, Maxell USA's product and marketing manager for new product development.

HML has recently developed a test tube system utilizing its passive Coil-on-Chip™ tags at the base of plastic test tubes, as well as an RFID reader that will read and write to a trayful of tagged vials. The technology replaces current 2-D barcode systems, which are "problematic in terms of data storage and data tracking and tracing, particularly in refrigerated environments," according to Kitatate.

The company's RFID technology is designed to enhance labeling accuracy; lower error rates and processing costs in laboratory automation; reduce data entry errors; ensure sample integrity; and support chain of custody, archiving, and electronic record keeping requirements of clinical trials.

Is the technology worth investing in at this point? Opinions vary. Maddock offers this advice to any facility considering RFID adoption: "With any immature technology, it is more important to evaluate the company than the product. You need to be comfortable with their financial position, with the strength of their team, with their vision, and their ability to get there. The bottom line is that none of the products are all the way there yet, so you better be comfortable that you are picking a partner who can take you where you want to go." ■


Test tube tag by Hitachi Maxell

ICC/USCC 2005 Exam Schedule

CBET • CRES • CLES Certification

Application Deadlines:	Exam Dates:
April 9, 2005	May 21, 2005
Sept. 24, 2005	Nov. 5, 2005

If you have any questions regarding any aspect of the ICC/USCC Certification, contact Iman Hannon, certification coordinator for the ICC, at ihannon@aami.org.

CBET Numbers on the Rise . . .

Certification Program Thrives as More Employers Reward Education

When Tim Hooks of Nevada passed his exam to become a certified biomedical equipment technician (CBET), he was given a $1,500-a-year pay increase and his employer paid for his test. Then, when he became certified as a radiology equipment specialist (CRES), Hooks received a $500 bonus plus a 5% pay increase.

Although not everyone receives a pay increase for achieving certification status, the career growth opportunities and other incentives have inspired a record number of biomedical technicians to apply for certification last year as CBET, CRES, and clinical laboratory equipment specialists (CLES).

Tim Hooks

In addition, more technicians are electing to maintain their certification than ever with a streamlined online-renewal process. To maintain certification, every three years those certified must submit a renewal fee and a Continuing Practice Journal in which professional activities are reported and assigned equivalency points. Some 70% of CBETs renewing certification in December 2004 chose to renew online.

Michael E. Carver

"ARAMARK CTS rewards certification by funding the expenses of those who test, recognizing those who pass, and by covering the ongoing cost of their renewals," says Michael E. Carver, vice president of program development for ARAMARK's Clinical Technology Services.

Certification is a formal recognition that individuals have demonstrated excellence in theoretical as well as practical knowledge of the principles of biomedical equipment technology. In addition to rounding out a BMET's body of knowledge, certification can pay off in terms of differentiating job applicants, enhancing professional recognition, and influencing pay and promotion decisions.

For Bryan Labbe, CBET, CRES, each certification has meant an increase in hourly pay. "I would encourage anyone to study for and take the exams. It's been great for me professionally and financially," says Labbe of Opelousas, LA.

Chris Dissinger

At Moses Cone Health System in Greensboro, NC, the biomedical department rewards CBETs by reducing the years of experience (by two years) required to be promoted to the next level. "So, being certified will help you get promoted faster than a technician who isn't certified," says Chris Dissinger, CBET, business and operations

manager for biomedical technology services at Moses Cone.

In other settings, such as the military, the rewards of certification may not be as formalized, but they still make a difference in career progression. "Airmen are expected to endeavor in self-improvement efforts. The pursuit of certification can be a significant milestone in a member's career and a noteworthy entry on their annual performance evaluation," according to Dennis B. Cox, CBET, CRES, CLES, who recently retired from the Air Force.


Richard W. Eliason

"Typically, there is no direct financial reward—but as a goal in an individual's overall career management plan, obtaining certification can be instrumental in career advancement and/or pay increase," says Richard W. Eliason, CBET, senior manager of operations support for ARAMARK Healthcare Management Services.


Kyle Gunsul

Certification can also offer a competitive advantage to the technician seeking new employment. "I'm pretty sure I've been offered jobs first because of my certification," explains Kyle Gunsul, biomedical equipment technician for Oregon Health & Science University Clinical Engineering. "Lots of places are looking for people that are 'plug-and-play,' which certification somewhat substantiates."

Eliason and Cox agree that certification can boost job prospects. "There are job opportunities that call for a certified biomedical equipment technician and many others that prefer certification," says Cox. According to Eliason, "I have seen companies that require certification as a 'pre-hire' requisite. Even when not required, in a competitive job market, certification might just be the 'edge' that makes the difference in advancing one's career."

Some measure the value of certification simply in the work it takes to pass the exam, such as Christiana Care Health System in Newark, DE, which pays for training classes, as well as exam fees—multiple times, if necessary.


Alan Lipschultz

"I have employees who have taken the exam three or more times, and I've paid each time—under the assumption that they're studying on their own time for the exam and learning something each time," says Alan Lipschultz, Christiana Care's director of clinical engineering.

Dissinger agrees that the true value of certification may lie in the process itself. "I would have to say in my own experience since I was military trained, I was missing some key aspects," he says. "In the military we never covered anatomy and physiology or medical terminology. Studying for the certification exam, made me become a more rounded technician and it filled in the gaps that were left in my education." ■

CBET Test Dates Set

The International Certification Commission (ICC) and the U.S. Certification Commission (USCC) have announced this year's test dates for biomedical certification candidates. Exams will be administered May 21 and November 5, 2005.

Of the 73 technicians who earned certification status based on November 2004 testing, 65 were certified as biomedical equipment technicians (CBET), seven were certified as radiological equipment specialists (CRES) and one was certified as a laboratory equipment specialist (CLES). Each certification requires a separate, complete examination. Applicants may test in only one discipline per examination cycle.

Exams will be given at 30 sites around the country; site locations and applications are available online. For more information, visit the AAMI Web site at **www.aami.org/certification/exam.html**.

Certified Biomedical Equipment Technician (CBET) certification demonstrates to employers that successful applicants have the knowledge to ensure a safe, reliable health care environment, and have made a significant commitment to career and competence.

To become certified, an applicant must meet work experience and educational requirements in biomedical equipment or electronic technology, and must accurately answer at least 105 of the 150 multiple choice questions on the test. The exam is divided into five sections: anatomy and physiology; safety in the health care facility; fundamentals of electricity, electronics, and solid-state devices; medical equipment function and operation; and medical equipment problem solving.

The certification renewal program ensures that those who are actively certified maintain a level of professional knowledge and skill consistent with the standard that existed when their certification was initially conferred. For information about the online renewal process, visit **www.aami.org/certification/journal.html**. ■

2005 Certification Schedule

APPLICATION DEADLINES	EXAM DATES
April 9	May 21
Sept. 24	Nov. 5

Conference Scheduled for June . . .

Human Factors Issues Come to the Forefront

With the FDA taking a closer look at human factors issues in premarket reviews, "it may be fair to say that a human factors engineering revolution is underway," says expert Michael Wiklund.

"The FDA regulations that came out in the late 1990s are really starting 'to set,' using the metaphor of concrete," explains Wiklund, an independent consultant in Concord, MA, who works with manufacturers to ensure product safety, usability, and appeal. "To form concrete, you combine an aggregate of material with a binder and then it starts to firm up. I think that's an apt metaphor of what we're seeing."

When the FDA first introduced its new human factors-related requirements, agency officials spent considerable time explaining them to the industry, according to Wiklund. Officials also supported the development of an AAMI standard on human factors that provided detail on how to shape an effective program in response to the new requirements. Now, the FDA has begun enforcing the requirements as part of their reviews and inspections.

Other developments behind the heightened focus on human factors include increased product liability concerns, studies identifying the volume and consequence of medical errors, marketplace demand for safe and usable devices, and the increasing complexity of medical devices.

To address these concerns, AAMI has planned a Human Factors, Ergonomics, and Patient Safety for Medical Devices conference, scheduled for June 28–30 in Washington, DC.

The event will highlight important developments in U.S. and international human factors standards, regulatory expectations, practical steps in planning and maintaining a human factors program, and liability risks. Speakers include FDA officials, device manufacturer representatives, and leading human factors experts.

One conference session, to be moderated by Wiklund, will focus on methods for evaluating the design of medical devices—including speakers on FDA reviews and postmarket surveillance efforts, usability testing, ethnographic observation, computer simulations, and hospital inspections.

Michael Wiklund

At another session, experts from IDEO, Abbott Laboratories, Guidant Corporation, and SonoSite will illustrate examples of human factors-driven product development such as a handheld device for sinus cavity surgery (IDEO) and a remotely controlled implantable defibrillator (Guidant).

According to Wiklund, conference planners hope that attendees will pick up on techniques that other people are using successfully, make contacts with individuals with whom they can collaborate, and "come away with information that will help them campaign more effectively within their organizations for an investment in human factors."

For more information about the conference, visit **www.aami.org**, or call (800) 332-2264, ext. 217. ■

Two Years Later . . .

Industry, Government Evaluate User Fee Law Strengths, Weaknesses

For the second time since Congress approved the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), key stakeholders from government and industry have met to assess the progress made toward implementing the act's provisions.

At a recent summit in Maryland, regulatory officials and industry representatives discussed their perspectives on the user fee law, which established fees for premarket reviews, set performance goals for FDA, authorized third-party inspections, and determined new regulatory requirements for reprocessed single-use devices.

Mark Leahey

Donna-Bea Tillman

"One major benefit of MDUFMA is that it has raised the profile of device review. It has focused more attention within the agency and within the whole government on the device program," says Linda Kahan, deputy director for the FDA's Center for Devices and Radiological Health (CDRH), who spoke at the meeting.

Industry representatives focused on fee increases, revenue shortfalls, and performance goals. Despite a 55% increase in user fees over the last two years, a $4.8 million industry shortfall in projected fees will require an additional 15% increase, reported Mark Leahey, executive director of the Medical Device Manufacturers Association. Leahey called for forgiveness of the industry's shortfall, fee increases for inflation only (eliminating current workload and compensating adjustments), and revisiting the program's performance goals.

Other speakers at the meeting included representatives from Advanced Medical Technology (AdvaMed), the National Electrical Manufacturers Association, the Association of Medical Device Reprocessors, and the American Hospital Association.

While industry representatives remain skeptical of the financial burdens imposed by increased user fees, CDRH officials contend that the user fee law has moved the review process in the right direction. The law "has given the review process a new level of seamlessness. It has forced us to always consider the total product life cycle and to be more disciplined about internal timelines," says Kahan.

CDRH officials—including Donna-Bea Tillman, director of the Office of Device Evaluation—said hiring and training efforts are planned to help improve review performance in 2005.

"There are people who ask, 'If you're meeting the goals already, why do you need any additional resources?' The answer that I have for them is that we've done a lot, but the cost to our staff is something that we can't sustain," says Tillman.

"You may be able to stay up all night the night before the final exam and study hard, but that's not something that you can do every night. We can't continue indefinitely to push our staff at the level we've been pushing them."

Tillman cites hiring and training efforts and improvements to CDRH's IT infrastructure as ongoing initiatives designed to enhance review performance in 2005. ■

Noted Safety Expert to Keynote Conference

A renowned physician, educator, and researcher in the human factors field has been selected to deliver a keynote address at AAMI's Annual Conference & Expo in Tampa, FL, from May 14–17.

Richard I. Cook, MD, assistant professor in the Department of Anesthesia and Critical Care, and director of the Cognitive Technologies Laboratory at the University of Chicago, will discuss the role of human factors in patient safety.

Cook has been involved with the National Patient Safety Foundation since its inception and sits on the Foundation's Board. He is internationally recognized as a leading expert on medical accidents, complex system failures, and human performance. He has investigated a variety of problems in such diverse areas as urban mass transportation, semiconductor manufacturing, and military software systems.

Cook's speech is one of the many highlights planned for the Annual Conference, which is expected to attract over 1,500 attendees and more than 100 exhibitors, and feature more than 50 practical educational sessions on topics ranging from telemedicine and human factors to benchmarking and plug-and-play networking standards.

Other sessions will explore the challenges and solutions to interfacing PACS-Vendor Networks and how CE/IT departments can control cost overruns. For a complete list of sessions, visit **www.aami.org/ac**.

Four contributing organizations—the American College of Clinical Engineering (ACCE), Florida Biomedical Society, Healthcare Information and Management Systems Society (HIMSS), and Japanese Society of Medical Instrumentation (JSMI)—will contribute to the 2005 Educational Program.

To register for the conference, visit **www.aami.org/ac**. Those registering by April 1 can take advantage of the early bird discount. ■

When AAMI hosts its Annual Conference in Tampa this May, it will get help from a local organization—the Florida Biomedical Society (FBS). Recently, AAMI News *spoke with incoming FBS President Victor Wong-Chong, senior biomedical technologist at Mercy Hospital in Miami.*

AN: *Please tell us a little about your current position at Mercy?*

VW-C: I provide technology support for the operating room suite and critical care areas of the hospital. I am also the facility's laser safety officer, and I'm currently working toward training and certifying laser operators for the five lasers assigned to my institution.

AN: *How will FBS be involved at the AAMI Conference?*

VW-C: We plan to provide personnel to help man booths, monitor rooms, or anywhere that our services can be utilized.

AN: *What value do you think that FBS provides to biomedical professionals?*

VW-C: We provide members with the tools to help them toward certification, and proficiency in their jobs, thus helping them advance in their careers. FBS works diligently year round to bring quality educational programs to members, and programs are open to all biomedical professionals in the state. ■

Networking Developed

CONTINUED FROM PAGE 1

medical records," according to Jennifer Jackson of Brigham & Women's Hospital. "Once the medical devices know how to talk to each other, then the devices will also be able to communicate with networked information systems."

Jennifer Jackson

Some clinicians have long understood the need for connectivity of medical devices. Goldman offers an example from the operating room: During a laparoscopic procedure, the surgeon and the anesthesiologist must carefully orchestrate monitoring with insufflation of the abdomen. "Here's a teamwork issue that requires clear communication with complex activities that are interdependent—and if there's a lapse anywhere along the way, it could cause a very serious patient problem."

The high-reliability information systems, advisory alarms, and safety interlocks of commercial aircraft are examples of what is needed in health care settings, according to Goldman. "In medicine, we have not had the opportunity to have creative, intelligent problem solvers try to apply some of the same ideas and solutions [used in aviation] to medicine because we don't have the infrastructure for them to create those things," he says.

Richard Schrenker, systems engineering manager for the Massachusetts General Hospital (MGH) Department of Biomedical Engineering, also believes that plug-and-play interoperability is long overdue. In the past, plug-and-play standardization has "suffered from a Catch-22," says Schrenker: Manufacturers didn't develop standardized medical device communications because there was no demand for them; health care providers didn't demand them because they couldn't envision the problems the technology would address.

Richard Schrenker

Schrenker hopes that projects like the "Operating Room of the Future" (ORF) at Massachusetts General will help to remedy this situation. In this "living laboratory," clinicians explore new technology platforms and systems of care for performing minimally invasive surgical procedures. The plug-and-play group convened two summits in 2004 to begin the process of developing technical and clinical requirements for a bus-independent standard for devices in the ORF.

Plug-and-play leaders are currently working through the Center for the Integration of Medicine and Innovative Technology (CIMIT), a Massachusetts-based non-profit consortium of institutions including Massachusetts General Hospital, Brigham and Women's Hospital, Massachusetts Institute of Technology, Draper Laboratory, Beth Israel Deaconess Medical Center, and Children's Hospital Boston. The consortium brings together clinicians, scientists, engineers, and industry to focus on solutions to perplexing health care problems.

Industry partners, such as LiveData, Inc. of Cambridge, MA, see the potential of plug-and-play integration to "deliver functionality and efficiency" in a cost-effective format. "In the end, it's about providing solutions so that clinicians can do their jobs better—improving patient safety and patient care," says Phil Brzezinski, vice president of Health Care Systems for LiveData, maker of an electronic whiteboard being used to display patient data in the ORF.

According to Goldman, those who have previously tried to develop a standard failed to bring in several critically important stakeholders, such as the FDA, early on—making it difficult to achieve forward progress. This time around, representatives from the FDA's Center for Devices and Radiological Health (CDRH) have joined the discussion from the beginning.

"The FDA supports the development of a medical device control and communication open networking standard. This represents a new challenge with a need to assure patient safety while incorporating new technologies," explains Sandy Weininger, PhD, a senior biomedical engineer at CDRH.

Sandy Weininger

According to Weininger, FDA has "partnered with the project team" to bring the concern for patient safety up front in the design process, to offer assistance in using a systematic development process, and to offer engineering expertise in relevant technologies—such as human factors, risk management, and systems engineering.

Organizers hope that demonstrating the potential of a plug-and-play standard in the ORF will be the breakthrough the technology has needed to gain acceptance. "The OR is just a starting point. There's a need for this in the intensive care unit, the emergency department, and home health care," says Goldman.

Once the plug-and-play concept is further developed and demonstrated, Schrenker believes its advantages will be obvious to the medical device industry. "When design engineers no longer

The Operating Room of the Future

In August 2002, Massachusetts General Hospital opened a unique operating room suite designed to assess the effect of new technologies and new systems on the safety and efficiency of patient care.

The Operating Room of the Future (ORF) integrates the best ideas in patient flow management and state-of-the-art technology identified during a visioning and technology scavenging phase. Subsequently, teams of clinicians, engineers, technicians, architects, and administrators assured that the vision of the ORF was safely realized when opened for patient care.

Patients undergoing a variety of surgical procedures are cared for in the ORF. The majority of these procedures rely upon minimally invasive endoscopic techniques ("keyhole surgery"), for which the ORF has been optimized. The ORF is used on a daily basis and serves as an example of the effectiveness of multidisciplinary collaboration.

—Julian M. Goldman, MD

need to spend their time designing proprietary machine communications interfaces, more time can be devoted to extending functionality—which in our business translates into caring for patients," explains Schrenker. "Similarly, the cost of regulation should decrease, as reviewers will no longer need to evaluate each proprietary interface for safety and efficacy."

Jackson offers a hypothetical scenario: A physiological monitoring system installed at every ICU bedside in a hospital has integrated capnography licensed by the vendor from one manufacturer. Then, a nationwide change in practice calls for an updated capnography algorithm that is adopted by three other vendors—but not the hospital's vendor.

"Do I have to tell my physicians that they cannot comply with the new trend?" asks Jackson. "Or do I have to convince my administration to find the funding to re-standardize our bedside monitoring vendor because *one* parameter of our systems doesn't meet the specification anymore? It's a no-win situation for everyone in this group."

Instead, with a standard in place, "the users would get to choose the 'best of breed' algorithms that provide the best patient monitoring possible for a given procedure," says Jackson. "We could add or change parameters as needed without too much delay, and we could avoid introducing unneeded complexity to the system."

Jackson will moderate a plug-and-play session at the 2005 AAMI Annual Conference & Expo in Tampa (for more about the conference, see page 13).

"The project will be introduced in a short presentation, but then we want the audience members to break up into groups and come up with specifications," says Jackson. "This is a great opportunity for the AAMI audience because this community can fully appreciate the value that plug-and-play can bring to health care, *and* they also know what technical issues need to be addressed to create a stable system in a typically unstable environment. The new standard will not be prototyped by the end of the meeting, but we hope to walk away with a sound list of requirements from the medical devices technical community."

Julian M. Goldman

Goldman's group hopes to "show significant, tangible results within three years." Launched in May 2004, the plug-and-play project's first-year goals include identifying and convening key stakeholders, determining clinical requirements, refining the project plan, securing long-term funding, and establishing a plug-and-play lab that will explore different schemes for device connectivity.

The key here is to create an infrastructure," says Goldman, "and then let the creativity of clinicians and biomedical engineers take over to do the things that have needed to be done for a long time but were technically impossible to implement."

For more information on plug-and-play connectivity, visit the project's Web site at **www.orfpnp.org**, or contact Sue Whitehead at **swhitehead@partners.org**. ■

NEWS CLIPS

CMS Cites Potential Benefits of Cost-Effectiveness Analysis

Though staff at the Centers for Medicare & Medicaid Services (CMS) do not currently employ cost-effectiveness analysis when evaluating coverage for medical technology, a top agency official has suggested that the practice could provide better control utilization in the future.

At the recent Global Medical Forum Summit in Washington, DC, CMS Chief Medical Officer Sean Tunis, MD, told his audience that the "formulary concept of where you have to link the cost share to some metric of cost-effectiveness really makes a whole lot of sense, because then you are giving people appropriate financial incentives based on objective metrics of value."

Under such a system, procedures with established effectiveness data—such as positron emission tomography (PET) scans for diagnosing solitary pulmonary nodules, would require minimal co-pay. New technologies lacking this sort of evidence could be subject to higher co-pays and partial coverage.

Despite Tunis's stated support for implementation of cost-effectiveness analysis, CMS has no current plans to formally adopt the procedure as a coverage requirement.

"You're not saying 'yes' or 'no' . . . ," stated Tunis. "You're saying you can have access to this, but you're going to have to pay 50% of the cost. I think [this policy] has some real potential, but it's not ready for primetime."

One-Third of U.S. Hospitals Losing Money, Says New Report

Increasing costs of providing care to patients, rising demand for care, workforce shortages, caring for those without health insurance, emergency readiness preparedness, and soaring medical liability insurance premiums challenge the financial stability of many U.S. hospitals, according to the results of the latest American Hospital Association (AHA) Annual Survey.

Among continuing trends, the survey reports that one-third of America's hospitals currently operate in the red. Overall, payments failed to keep pace with the cost of caring for patients, causing operating margins to decline.

In particular, Medicare reimbursed 95 cents of every dollar hospitals spent caring for Medicare patients, continuing a pattern of declining reimbursements over the past five years. Medicaid reimbursement dropped to 92 cents on the dollar. While hospitals saw improvements in their investments that caused overall margins to increase slightly, continued volatility in the markets means this is not a stable and reliable source of income.

Results of the survey were released in *AHA Hospital Statistics 2005*, a reference source on hospitals published by the AHA subsidiary Health Forum. AHA Hospital Statistics contains data gathered from more than 5,000 hospitals and health systems across

the country and includes data arranged by state, region, and Metropolitan Statistical Area.

To order a copy of the report, call 1-800-AHA-2626, or visit the online store at **www.ahaonlinestore.com**.

Leavitt Nominated as HHS Secretary

President Bush has nominated Mike Leavitt, Environmental Protection Agency administrator and former governor of Utah, to become secretary of the Department of Health and Human Services.

"I look forward . . . to the implementation of the Medicare prescription drug program in 2006, medical liability reform, and finding ways to reduce the cost of health care," Leavitt said at the December 13 White House announcement.

If confirmed by the Senate, Leavitt will assume leadership of HHS from current secretary Tommy G. Thompson, who announced in December that he will resign February 4 or as soon as his replacement can be confirmed.

"As a former governor, Mike knows how to make government work for the benefit of our citizens in a way that is responsible to taxpayers. He knows the value of bringing people together to solve the tough challenges facing America. And he knows the importance of continuing to strengthen the health care system and the well-being of the American people," said Thompson in response to the announcement.

Carbon Nanotubes Prompt Bone Growth

A new study demonstrates that carbon nanotubes—stronger than steel and more durable than diamond—can be aligned to stimulate bone growth in a way that might make better and longer lasting artificial joints.

Artificial joints depend upon a tight bond between bone and a man-made surface. Carbon nanotubes have a surface texture in the realm of 100 nanometers, or billionths of a meter. Conventional artificial joint materials such as titanium have much larger surface textures. As a result, titanium attracts fewer bone cells.

Research led by biomedical engineer Thomas Webster, PhD, of Purdue University demonstrates two ways of aligning the tiny carbon tubes to mimic the surfaces of collagen fibers and ceramic crystals found in natural bone. The engineered surface attracts and holds a higher percentage of developing bone cells (osteoblasts) than conventional surfaces do.

Webster's group experimented with two approaches for making nanotubes align in parallel. Cultures were allowed to grow for seven days, at which time the bone cells were still holding strong.

"In a very short period of time, we're already seeing a big improvement in how well the cells stick to the nanotubes," Webster said.

The current research suggests that carbon nanotubes might form a seal between natural bone and artificial joints, creating implants that are stronger and longer-lasting than those currently available.

For more information, visit the Purdue University Web site at **www.purdue.edu**. ■

IN PROFILE

Brian Poplin: Advancing Technology Management

Brian Poplin, CHE, CBET, vice president for clinical technology services at ARAMARK Healthcare Management Services, serves on AAMI's Technology Management Council. Since joining ARAMARK in 1994, Poplin has held various positions including radiology engineer, business manager, director of clinical engineering, and senior director for clinical equipment. Poplin earned his bachelor's degree in business administration and his master's in management from Indiana Wesleyan University.

Brian Poplin

AAMI News: Can you tell us about your role at ARAMARK?

Brian Poplin: I support the overall mission of ARAMARK Healthcare Management Services by providing technical and management insight to our clients. My areas of responsibility are focused on support for our technology management offering including our capital asset protection programs.

Having started with ARAMARK as a BMET in 1994, I consider a major portion of my responsibility to connect with and advocate for our technical staff and managers as we explore new opportunities within the clinical equipment marketplace.

AN: In recent years, ARAMARK has evolved into a major force in health care technology management. Why do you think that's the case?

BP: The strategic acquisitions by ARAMARK of the ServiceMaster Clinical Equipment Management business in 2001 and the 2002 acquisition of Premier Clinical Technology Services has laid the foundation for our growth in health care technology management. These acquisitions brought the depth and breadth of two well-respected, long-standing organizations together with the common vision of providing value for our health care clients.

In the end, the key measure of our growth and success in the industry is our people. Their interactions with our clients on a daily basis shapes our reputation in the marketplace and results in the collective achievement of our goals.

AN: Recently, you took part in the second meeting of AAMI's Technology Management Council (TMC). What do you hope the Council will accomplish in 2005 and beyond?

BP: The TMC is taking on a great leadership responsibility for the technology management industry. ARAMARK recognizes the importance of this commitment and has contributed significant resources to the committee as it works to advance technology management within the health care industry.

As the committee begins to push forward on the goals laid out during the first meeting, I expect 2005 will bring

significant progress. The areas most likely to progress rapidly are in Web resource availability, support for local biomedical associations, and further discussion around useable benchmarking criteria.

AN: As the president of North Carolina Biomedical Association (NCBA), how have you managed to turn your association into one of the most active biomed organizations in the country?

BP: Support for local biomedical societies and associations begins at home. Health care is a mission-driven industry with a core belief that we all contribute to patient care and a healthier community. That commitment helps us seek out opportunities to improve our skills and advance our knowledge.

The members of the NCBA make a personal commitment to become better technicians, managers, and support staff. The NCBA provides an educational vehicle to help each member reach that goal.

AN: NCBA recently held its 26th annual Symposium and Vendor Exhibition. What advice can you give other biomed organizations so they, too, can arrange successful symposiums year after year?

BP: Consistency in mission is the most critical element. For 26 years, the NCBA has focused on one thing: the education of its membership. Everything we do must return educational programs and professional advancement opportunities to the group. As the years have passed, each leader of the organization has been coached and guided by others to remain focused on that key mission. If an organization's ideas and plans don't contribute to the mission of the organization, their success will be compromised.

AN: Based on your work at ARAMARK, the NCBA, and AAMI's TMC, what trends do you notice in the industry?

BP: As in previous years, our opportunities lie in our ability to promote the value we bring to health care. BMETs, CEs, and managers are slowly improving the way we communicate our contributions to patient care. We will begin to have much more interaction with key areas in health care, such as information technology and patient safety. As these opportunities present themselves, it is important for each organization—be it ARAMARK, AAMI, or the NCBA—to ensure our staff or members are ready for the challenge. ■

NEW MEMBERS

New Member Organizations

EQ2 INC.
PO Box 1483
Burlington, VT 05402-1483
PHONE: (802) 865-0920

HARVEST DATA SYSTEMS
6006 Grand Blvd.
New Port Richey, FL 34652
PHONE: (727) 843-9832

New Individual Members

Ray Baltis, Barrington, IL
Linda M. Beaver, Bridgeton, MO
Tammy Blackburn, RN, CNOR, Rochelle, IL
Mark J. Borer, San Rafael, CA
Stephen Clugston Coon, Madison, WI
Robert M. Dondelinger, CBET-E, Pleasant Prairie, WI
Andy J. Dorner, Green Bay, WI
Terrence J. Doyle, Bedford, TX
Raymond Duhamel, Goleta, CA
Andrew Hamel, San Jose, CA
Rachel A. Hartman, Hartford, CT
Yoshiko Hata, Santa Clara, CA
Sofia Hernandez, Emeryville, CA
David J. Holliday, Saranac Lake, NY
Harry Janiski, Argyle, NY
Deborah J. Kent, Panama City, FL
Jean Emiko Kihara, Redwood City, CA
Eric Koehler, Des Moines, IA
Gretchen Kunas, Walnut Creek, CA
Joshua Lasker, Pharr, TX
Frank Loncar, Six Sigma Black Belt, Mentor, OH
Ryan Lee Ludwig, Spencer, IN
James R Milostan, Lee, IL
Dennis R Minsent, Portland, OR
Juanita L. Pierson, Gallipolis, OH
Elizabeth S. Pons, Miami, FL
Todd R. Powell, Spencer, IN
Lisa L. Pritchard, Minneapolis, MN

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

MEMBERS ON THE MOVE


Matt Baretich

• **Matt Baretich, PE, PhD,** president of Baretich Engineering Inc., has been appointed to the *Biomedical Instrumentation & Technology* (*BI&T*) Editorial Board. Baretich consults in the areas of clinical engineering, health care facilities engineering, and safety management. He is editor and publisher of the *Medical Device Incident Investigation and Reporting* manual; and co-author of AAMI's *Electrical Safety Manual*. In addition to reviewing the overall content of *BI&T*, Baretich will serve as lead reviewer for a new column, JCAHO News & Views.

• **David S. Bell** has been promoted from assistant director to director of biomedical instrumentation at Thomas Jefferson University Hospital in Philadelphia, PA. The Biomedical Instrumentation department has a staff of 75, servicing 14 hospitals and more than 40 clinics and private practices.

• **Gary Borkes** has been accorded senior member status by the American Society for Quality. For the past four years, Borkes has worked for Ethicon (a Johnson & Johnson company) as a Corporate Design Quality Engineer in Somerville, NJ.

• **Dr. Betsy Hunt** has been appointed the first director of the Johns Hopkins Simulation Center in the Johns Hopkins Outpatient Center scheduled to open in 2006. The Center will work with educational programs involving students, residents, nurses, and practicing physicians to employ simulation as a way of enhancing the educational experience for trainees, promoting patient safety, and fostering medical education research. Hunt is internationally recognized for her work in CPR simulation. ■

Are you moving or changing jobs?
AAMI News would like to know!
Contact: **mwalker@aami.org**

National Standards

New and Reaffirmed Publications

Articles about some of these documents will be published in upcoming issues of AAMI News*. See order form on page 23 to order print copies, or go to the Marketplace at* **www.aami.org** *to order an electronic (PDF) version for immediate download.*

ANSI/AAMI ID26:2004, Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers, 3ed. AAMI/American National Standard. (ID26 or ID26-PDF; $50/$95). Adoption, with national deviation, of IEC 60601-2-24/Ed.1.

ANSI/AAMI II36:2004, Medical electrical equipment, Part 2: Particular requirements for safety of baby incubators, 3ed. AAMI/American National Standard. (II36 or II36-PDF; $50/$95). Adoption, with national deviation, of IEC 60601-2-19/Ed.1 and amendment.

ANSI/AAMI II51:2004, Medical electrical equipment, Part 2: Particular requirements for safety of transport incubators, 2ed. AAMI/American National Standard. (II51 or II51-PDF; $50/$95). Adoption, with national deviation, of IEC 60601-2-20/Ed.1 and amendment.

ANSI/AAMI ST81:2004, Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices, 1ed. AAMI/American National Standard. (ST81 or ST81-PDF; $40/$80). Adoption, with national deviation, of ISO 17664/Ed.1.

ANSI/AAMI/IEC 60601-1-2:2001/A1:2004, Amendment 1 to ANSI/AAMI/IEC 60601-1-2:2001, Medical electrical equipment, Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility—Requirements and tests, 1ed. AAMI/American National Standard. (601102-A or 601102-A-PDF; $35/$70). Identical to IEC 62A/60601-1-02:2001/A1/Ed.1.

ANSI/AAMI/ISO 15882:2004, Chemical indicators—Guidance on the selection, use, and interpretation of results, 3ed. AAMI/American National Standard. (15882 or 15882-PDF; $40/$80). Identical to ISO 15882/Ed.1.

ANSI/AAMI/ISO 5840:2005, Cardiovascular implants—Cardiac valve prostheses, 4ed. AAMI/American National Standard (CV5840 or CV5840-PDF; $45/$90). Identical to ISO 5840/Ed.4.

ANSI/AAMI/ISO 7198:1998/2001/(R)2004, Cardiovascular implants—Tubular vascular prostheses, 3ed. AAMI/American National Standard. Reaffirmed as an American National Standard on 13 December 2004 (7198 or 7198-PDF; $50/$95). Identical to ISO 7198/Ed.1.

Call for Comments

Proposed standards and recommended practices available for public review and comment are listed here and on the AAMI Web site at **www.aami.org***. Drafts can be obtained from AAMI. See order form on page 23 to order print copies, or go to the Marketplace at* **www.aami.org** *to order an electronic (PDF) version for immediate download.*

Comments must be received by the deadline in order to ensure their consideration. Proposed drafts may remain publicly available after the comment period closes, but late comments generally are deferred to the next review/revision cycle, usually four to five 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 1 February 2005

AAMI/CDV-1 60601-2-02, Medical electrical equipment, Part 2-2: Particular requirements for the safety of high frequency surgical equipment, 4ed. (proposed AAMI/American National Standard). Specifies requirements for the safety of high frequency surgical equipment and HF surgical accessories used in medical practice. High frequency surgical equipment having a rated output power not exceeding 50 W (for example for micro-coagulation, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this particular standard. (601202-D, $20/$25; 601202-D-PDF, $0/$25)

Comments due by 15 February 2005

AAMI/CDV-2 62304, Medical device software—Software life cycle processes, 1ed. (proposed AAMI/American National Standard). Specifies requirements for medical device software life cycle processes including primary life cycle development and maintenance processes, and supporting processes such as software hazard management, documentation, configuration management, verification and problem resolution. Applies to software that is a stand-alone medical device and to software that is an embedded or integral part of the final device and includes a compliance section based on whether or not the software can cause a hazard or controls risk. (62304-D, $20/$25; 62304-D-PDF, $0/$25)

Comments due by 1 March 2005

AAMI/CDV-3 14971, Medical devices—Application of risk management to medical devices, 3ed. Proposed AAMI/American National Standard. This standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic medical devices, to estimate and evaluate the resulting risks, to control these risks, and to monitor the effectiveness of that control. (14971-D, $20/$25; 14971-D-PDF, $0/$25)

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 Web site (***www.aami.org***).*

Revision Projects

Work on the **Revisions of ANSI/AAMI RD61:2000, Concentrates for hemodialysis and ANSI/AAMI RD62:2001, Water treatment equipment for hemodialysis** has started. *Contact:* **cbernier@aami.org** for more information on how to join the committee that is responsible for this activity or if you have comments on the 2000/2001 editions.

International Standards

New and Reaffirmed Publications

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

ISO 21647:2004, Medical electrical equipment—Particular requirements for basic safety and essential performance of respiratory gas monitors, 1ed. International Standard.

ISO 8637:2004, Cardiovascular implants and artificial organs—Haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators, 2ed. International Standard.

ISO 8638:2004, Cardiovascular implants and artificial organs—Extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters, 2ed. International Standard.

ISO 7198:1998, Cardiovascular implants—Tubular vascular prostheses, 1ed. International Standard. Reaffirmed 2004-09-16.

ISO/TS 15539:2000, Cardiovascular implants—Endovascular prostheses, 1ed. International Technical Specification. Reaffirmed 2004-12-13.

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

AAMI Call for Comments

The following international drafts can be obtained from AAMI. See order form on page 23 to order print copies, or go to the Marketplace at **www.aami.org** *to order an electronic (PDF) version for immediate download.*

Parallel adoptions (see National Standards Call for Comments)

- **IEC/CDV-1 60601-2-02 (IEC 62D/508/CDV)**
- **IEC/CDV-1 62304 (IEC 62A/474/CDV)**
- **ISO/CDV-3 14971**

Comments due by 1 February 2005

ISO/CD-V-1 23500 (N375), Fluids for haemodialysis and related therapies, 1ed. (proposed International Standard). This recommended practice covers the appropriate prescription of dialysate, handling of concentrates, operation of water treatment equipment and handling of its product water, monitoring of systems and the dialysate produced, and risks and hazards of dialysate preparation failure. It presents a systems diagram and explanation for the production, monitoring, and use of dialysate for hemodialysis in the facility. (23500-D, $20/$25; 23500-D-PDF, $0/$25)

Comments due by 1 March 2005

ISO/DIS-1 13408-03, Aseptic processing of health care products—Part 3: Lyophilization, 1ed. (proposed International Standard). (1340803-D, $20/$25; 1340803-D-PDF, $0/$25)

ISO/DIS-1 13408-05, Aseptic processing of health care products—Part 5: Sterilization in place, 1ed. (proposed International Standard). (1340805-D, $20/$25; 1340805-D-PDF, $0/$25)

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

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 Web site (***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.*

AAMI/BE, Biological Evaluation Committee (Open Meeting). 3-Feb-05, 10:00 to 17:30 h. AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795, USA. Directions to AAMI and a list of nearby hotels are available at **www.aami.org/about/directions.html**. Review results of the July 2004 meeting of ISO/TC 194 and any action items that have taken place since the meeting. *Contact:* **hwoehrle@aami.org**

AAMI/HE, Human Factors Engineering Committee (Open Meeting). 22 to 24-Jan-05, 13:00 to 13:00 h. Diamond, Hilton Grand Vacations Club at Las Vegas Hilton, 455 Karen Avenue, Las Vegas, NV 89109, USA. Review sections for HE75. *Contact:* **ntongson@aami.org**

AAMI/RD, Renal Disease and Detoxification Committee (Open Meeting). 27-Feb-05, 08:00 to 18:00 h (Annual Dialysis Meeting, 28-Feb-05 to 2-Mar-05). Riverview, Radisson Riverwalk Hotel, 200 North Ashley Drive, Tampa, FL 33602, USA. Review comments on RD61 and RD62 revisions; ballot results on

reaffirmations of RD16 and RD17; ballot results on U.S. adoptions of ISO 8637 and ISO 8638; U.S. position on ISO/CD 23500. *Contact:* **cbernier@aami.org**

AAMI/ST, Sterilization Standards Committee and Affiliated Working Groups (Open/Part Open Group Meeting). 27 to 30-Jun-05. Arlington, VA, USA. *Contact:* **jlewelling@aami.org**

AAMI/ST, Sterilization Standards Committee and Affiliated Working Groups (Open/Part Open Group Meeting). 14 to 17-Nov-05. Arlington, VA, USA. *Contact:* **jlewelling@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.

IEC/TC 62, Electrical Equipment in Medical Practices, affiliated subcommittees and working groups (Closed Group Meeting). 11 to 22-Apr-05. Williamsburg, VA, USA. *Contact:* **ntongson@aami.org**

ISO/TC 150, Implants for Surgery, and affiliated subcommittees and working groups (Closed Group Meeting). 10 to 14-Oct-05. Gyeongju, Republic of Korea. *Contact:* **ntongson@aami.org**

- **ISO/TC 150/SC 2, Cardiovascular implants.** 14-Oct-05. *Contact:* **cbernier@aami.org**
- **ISO/TC 150/SC 6, Active implants.** 13-Oct-05. *Contact:* **ntongson@aami.org**

ISO/TC 150/SC 2/WG 03, Vascular prostheses (Closed Meeting). 10 to 12-Feb-05 (International Society for Endovascular Surgery meeting). Scottsdale, AZ, USA. To develop ISO 25539-2 on vascular stents. Members of the ad hoc Task Group 2 of WG 3 helping to develop the first working draft will meet with the WG. *Contact:* **cbernier@aami.org**

ISO/TC 194, Biological Evaluation of Medical Devices and affiliated working groups (Closed Group Meeting). 27-Jun-05 to 01-Jul-05. Utrecht, The Netherlands. *Contact:* **hwoehrle@aami.org**

ISO/TC 194/SC 1, Tissue product safety and affiliated working groups (Closed Group Meeting). 08 to 11-Mar-05. Rockville, MD, USA. *Contact:* **smongini@aami.org**

- **ISO/TC 194/SC 1, Tissue Product Safety.** 11-Mar-05
- **ISO/TC 194/SC 1/WG 01, Risk assessment, terminology and global aspects.** 08-Mar-05
- **ISO/TC 194/SC 1/WG 02, Sourcing controls, collection and handling.** 09-Mar-05
- **ISO/TC 194/SC 1/WG 03, Elimination and/or inactivation of viruses and TSE agents.** 10-Mar-05

ISO/TC 198, Sterilization of health care products (Closed Group Meeting). 18 to 22-Apr-05. Sydney, Australia. *Contact:* **jlewelling@aami.org**

ISO/TC 198/WG 01, Ethylene oxide sterilization WG (Closed Meeting). 26 to 28-Jan-05. London, United Kingdom. Interim meeting to review comments submitted on ISO/DIS 11135, Sterilization of health care products—Requirements for development, validation and routine control of a sterilization process for medical devices—Ethylene oxide. *Contact:* **jlewelling@aami.org**

ISO/TC 198/WG 02, Radiation sterilization (Closed Meeting). 31-Jan-05 to 02-Feb-05. Orlando, FL, USA. To resolve international comments on ISO/DIS 11137-1 and ISO/DIS 11137-3. *Contact:* **jlewelling@aami.org**

ISO/TC 198/WG 03, Moist heat sterilization (Closed Meeting). 14 to 16-Feb-05. London, United Kingdom. *Contact:* **jlewelling@aami.org**

ISO/TC 210, Quality Systems and Corresponding General Aspects for Medical Devices and affiliated working groups (Closed Group Meeting). 16 to 20-May-05. Toronto, Canada. See specific meetings. *Contact:* **hwoehrle@aami.org**

- **ISO/TC 210, Quality Systems and Corresponding General Aspects for Medical Devices.** 20-May-05. *Contact:* **hwoehrle@aami.org**
- **IEC/SC 62A and ISO/TC 210, Joint working group on medical device software.** 16 to 18-May-05 (Tentative date). *Contact:* **ntongson@aami.org**
- **ISO/TC 210 and IEC/SC 62A, Joint working group on application of risk management to medical devices.** 16 to 18-May-05. Resolve comments on ISO/CD3 14971 (IEC/CD3 14971). *Contact:* **hwoehrle@aami.org**
- **ISO/TC 210/WG 01, Application of quality systems to medical**

devices. 17 to 18-May-05. Discuss proposed Amendment to ISO 9001:2000. *Contact:* **hwoehrle@aami.org**

- **ISO/TC 210/WG 02, General aspects stemming from the application of quality principles to medical devices.** 18-May-05. Discuss comments on ISO/DTR 16142. *Contact:* **hwoehrle@aami.org**
- **ISO/TC 210/WG 03, Symbols and nomenclature for medical devices.** 16 to 18-May-05. Resolve comments on ISO/CD 15223. *Contact:* **hwoehrle@aami.org**

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Other Standards News

ANSI Public Review

ISO drafts on ANSI public review covering anesthetic gas scavenging systems, health informatics—The following ISO drafts are on ANSI public review until the date indicated. Send comments to **hscully@ansi.org**. Drafts can be obtained from **http://global.ihs.com** (check Global for price). ISO/DIS 8835-3, Inhalational anaesthesia systems—Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (3 March 2005 comment deadline). ISO/HL7 DIS 21731, Health informatics: HL7 version 3—Reference information model, release 1 (25 February 2005 comment deadline). ISO/DIS 21549-4, Health informatics—Patient healthcard data—Part 4: Extended clinical data (10 March 2005 comment deadline).

ISO and IEC drafts on ANSI public review covering anesthetic vaporizers, lung ventilators, wheelchairs—The following ISO drafts are on ANSI public review until the date indicated. Send comments to **hscully@ansi.org**. Drafts can be obtained from **http://global.ihs.com** (check Global for price). ISO 5360/DAmd1, Anaesthetic vaporizers—Agent-specific filling systems—Amendment 1; comments due 27 January 2005 (ISO/TC 121). ISO/DIS 10651-5, Lung ventilators for medical use—Particular requirements for basic safety and essential performance—Part 5: Gas-powered emergency resuscitators; comments due 10 February 2005 (ISO/TC 121). ISO/DIS 7176-25, Wheelchairs—Part 25: Requirements and test methods for batteries and their chargers for electrically powered wheelchairs and motorized scooters; comments due 10 February 2005 (ISO/TC 173).

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UPCOMING EVENTS

Quality System Requirements & Industry Practice
Jan. 31–Feb. 3 • Washington, DC

Corrective and Preventive Action Requirements & Industry Practice
Feb. 7–9 • Coronado, CA

Software Validation Requirements & Industry Practice
Feb. 28–March 2 • Washington, DC

Industrial Sterilization for Medical Devices
March 14–17 • Dallas, TX

AAMI/FDA International Conference on Standards & Regulations
March 23–24 • Reston, VA

ANSI/AAMI/ISO 13485:2003
March 30–April 1 • Washington, DC

AAMI 2005 Conference and Expo
May 14–17 • Tampa, FL