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## The Inside Word

**“What if these devices have to be used on my daughter or son?”**

**Rossiny Jacques**

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## New AAMI President Named, Begins Job This Month

Mary Logan, JD, CAE, an accomplished Association executive, has been selected as AAMI's new president.

During an extensive, nationwide search, the AAMI Board of Directors sought an individual who would be poised to lead AAMI into a successful future with new and updated member services and programs, a strong position in medical technology management, and collaborative relationships with outside stakeholders throughout the world.

“Mary Logan is ideally suited to guide AAMI successfully through the transition from our respected long-term leader, Mike Miller,” says Chuck Sidebottom, chair of AAMI's Board of Directors and director of corporate standards at Medtronics. Miller is retiring at the end of June after nearly 40 years of dedicated service to AAMI.

Logan has 20 years of senior management experience, most recently serving as chief operating officer (COO) of the American Dental Association (ADA) in Chicago. As the ADA's COO, she was responsible for the operational management of the organization. Most of its divisions reported to her, including the ADA's well respected Standards Area and its large

Science Division. During her tenure, the ADA was named one of the most remarkable associations in the United States in *Seven Measures of Success*, a report issued by the American Society of Association Executives. Logan also served as the ADA's general counsel, and as general counsel for the global finance and administrative arm of The United Methodist Church.

“Mary Logan brings a unique combination of skills and talents to AAMI, with her facilitative style of leadership, a passion for healthcare and what medical technology can do to improve patients' lives, knowledge of the regulatory and standards arena, and a solid reputation for getting things done,” says Sidebottom.

Logan says she is looking forward to joining the AAMI team.

“AAMI is a gem of an organization with an inspiring mission and dedicated members.” ■



Mary Logan

## To Seek Efficiencies . . .

## FDA Outlines Proposed Changes to Standards Form

When manufacturers seek approval for new medical devices, they often submit and cite standards as evidence of the device's safety and efficacy. But current paperwork to submit standards data to regulators can be burdensome and long.

As a result, the U.S. Food and Drug Administration (FDA) is considering revisions to the submission process for standards data for medical devices. FDA officials detailed a potential update to Form 3654, a Standards Data Report, for 510(k)



Barbara Zimmerman, left, and Carol Herman, center, both of FDA, speak with a conference participant during the International Standards Conference.

# NEWS IN BRIEF

## Report: Healthcare IT Funds May Not Be Enough

New financial incentives in the recently passed economic stimulus bill will still leave many physicians in small practices facing significant up-front healthcare information technology (IT) implementation costs, according to a review from Avalere Health, an analytic research firm.

The stimulus package contains roughly \$17 billion in incentives for physicians and hospitals to adopt electronic medical record (EMR) systems. Avalere researchers found that a solo or small-group physician practice will spend an estimated \$124,000 over the five-year period of 2011–2015 to adopt EMRs, and will receive up to \$44,000 in federal incentive payments.

For more information on the report, visit [www.avalerehealth.net](http://www.avalerehealth.net).

## TMC Career Brochure in Hot Demand

AAMI has distributed more than 3,800 copies of a new version of its popular career brochure in less than a two-month period.

The new brochure—titled *Servicing Technology, Saving Lives: A Career in*



*Biomedical Equipment Technology*—was created by AAMI's Technology Management Council (TMC) to help hospitals, manufacturers, schools, and others recruit students to the biomed field.

The brochure includes information about the responsibilities of biomedical equipment technicians (BMETs), their skills and training requirements, salary and fringe benefits, and the long-term outlook for the field.

It also includes testimonials from a number of BMETs who talk about why they find the field so rewarding.

The brochure also promotes the fact that *U.S. News & World Report* has selected the field as a top career choice for 2009.

To request the brochure, contact Patrick Bernat at [pbernat@aami.org](mailto:pbernat@aami.org). Please include your complete mailing address and the number of copies you would like to receive.

## AAMI Dialysis Collection Available as PDF

For the first time, AAMI's complete dialysis standards collection is available as a single PDF.

The searchable PDF format allows quick access to all of AAMI's dialysis standards. The standards collection is also available in book and CD format. The individual standards are also available for purchase.

The standards—which address home hemodialysis, reprocessing of hemodialyzers, and recommended practices and guidance for dialysis—also continue to be available in print and on CD.

The 2008 edition includes three updated standards: RD47 (*Reprocessing of hemodialyzers*), RD5 (*Hemodialysis systems*), and RD52 (*Dialysate for hemodialysis, Amendment 1—Annex C: Special considerations for home hemodialysis and Amendment 2—Annex D: Self-assessment of compliance with recommendations for dialysate preparation*).

To order *AAMI Standards and Recommended Practices: Dialysis*, call (877) 249-8226, use the order form on page 23, or visit <http://marketplace.aami.org>. The list price is \$325 and the AAMI member price is \$195. The order code is DSBK08-PDF. The source code is PB. ■



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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 healthcare professions providing essential information on the development and use of medical instrumentation and technology.

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## NFPA Report Seeks Compromise on Wet Locations Issue, Faces June Vote

A major hurdle has been overcome in the proposed revisions to NFPA 99—the National Fire Protection Association’s safety standard for healthcare facilities.

The document, which is undergoing a major revision and modernization, establishes criteria to minimize the hazards of fire, explosion, and electricity in healthcare facilities. As a result, the document is particularly important to biomed.

Recently, the committee responsible for updating the standard reached a compromise on a thorny issue over whether all operating rooms (OR) should be considered wet locations. The committee recommended against mandating all ORs as wet locations, but reached a compromise that would affect new and renovated ORs.

The compromise helps pave the way for possible final approval of the standard. Parties can still file a Notice of Intent to File a Motion (NITMAM) by April 3 to amend the draft standard.

All certified NITMAMs will be considered by the NFPA’s membership at its annual business meeting in June, after which the NFPA’s Standards Council will make the final decision on the revised standard. The standard is due to be published in September 2009 as a 2010 edition.

Currently, NFPA 99 is a voluntary standard to be implemented in healthcare facilities. However, the newly revised standard is written as a code to be adopted into law, says Alan Lipschultz, chair of the medical equipment sub committee for NFPA 99 and AAMI’s representative on the committee. “NFPA is inviting localities and states to adopt NFPA 99 by making it a code, but they all act on their own

timetable,” Lipschultz says.

### Wet Locations

In proposing a resolution to the wet locations issue, the NFPA’s Health Care Facilities Technical Committee has potentially resolved one of the most controversial issues about the standard.

A wet location is an area where patient care is performed that is normally subject to wet conditions while patients are present. Wet locations should use ground fault circuit interrupters, which will interrupt the power, or isolated power, Lipschultz says. Since one doesn’t want to interrupt power during an operation, interrupters aren’t a valid option, and that leaves isolated power.

In the current version of NFPA 99, each healthcare institution decides whether an OR is a wet location. However, the revised version requires isolated power in ORs unless the governing body makes a conscious

CONTINUED ON PAGE 4



Alan Lipschultz

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# NFPA 99 Standard Faces Vote

CONTINUED FROM PAGE 3

decision that the ORs are not wet. Many hospitals already use normal grounded power in their operating suites. Typically, existing facilities are not subject to new requirements.

"It has never been disputed that wet conditions exist in some, if not many, ORs during medical procedures," the committee said in its report. "The real question raised . . . was whether all ORs must be designed, by code, to comply with wet location requirements as defined by the codes and standards."

The report noted that the committee didn't find a single documented instance of electrical problems in ORs caused by the use of grounded systems, nor of problems averted through the use of isolated power systems.

After weighing the issue, the committee said that mandating all ORs as wet locations would be an unnecessary hardship on the healthcare industry. However, "compared to the existing

language in NFPA 99, a greater burden of proof has been placed on the facility to do anything other than design for a wet location," the report indicates. "All new and renovated ORs will be required to be designed to wet location standards, unless the facility, through a detailed evaluation and review, including user groups, determines that some ORs may be deemed as not being wet locations, and constructed accordingly."

## Routine Safety Testing

A proposed change to eliminate a requirement for routine safety testing of medical equipment didn't receive any comments, Lipschultz says. The change eliminates the requirements for routine periodic testing.

Under the current NFPA 99, biomedics must conduct routine safety testing every six months or a year. The proposed revision says biomedics wouldn't need to do testing except when a device is being accepted or following repair, Lipschultz says. "Just because it isn't required anymore doesn't mean you shouldn't do it," he adds. "It just means it is not required."

A facet of the proposed standard that

generated numerous comments focused on requirements for manufacturers to supply technical documentation to their customers. The committee originally decided to eliminate a chapter in the standard concerning this issue because it was redundant. But many commented that in eliminating that chapter the committee deleted requirements for manufacturers to supply technical documentation such as service manuals. The committee agreed to incorporate the requirements into another chapter of the standard.

For more information about NFPA 99, visit [www.nfpa.org](http://www.nfpa.org). ■

## Want to Learn More?

**A**lan Lipschultz will be a presenter on NFPA 99 during a session at AAMI's 2009 Annual Conference & Expo, which runs from June 6-8 in Baltimore, MD. He will discuss changes in the NFPA 99 standard and address questions from the audience.

For more information about the conference, or to register, visit [www.aami.org/ac](http://www.aami.org/ac). ■

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## How to Promote Your Department's Value

*As many healthcare institutions cut back due to the poor economy, it's more important than ever for clinical engineering departments to promote their value to administrators. In this edition of Tech World, Ken Schwarz—who works in the healthcare sector for Francis Cauffman, an architecture and design firm in Philadelphia—discusses how departments can do just that.*

**B**iomedical or clinical engineering (CE) may have been born out of necessity, but today it has become an integral part of healthcare. The CE department, whether in-house or out-sourced, faces many challenges.

Most biomedical equipment technicians and managers have strong technical backgrounds, but we as a field don't sell our value very well. That needs to change in today's market. While finding the time to do this may be difficult, not promoting your department can harm not only the operation of your department but also the healthcare institution.

I have found that you must show people what you do for them, and then continue to remind them. We have all saved money on sourcing parts or finding a qualified, less expensive vendor,

or even negotiating a service contract or charges with a service engineer from an original equipment manufacturer. This type of information should not just be filed and stored. It should be compiled and brought to the healthcare institution's attention.

Think about what you accomplish during your day. How many preventive maintenance (PM) inspections have been performed and how many hours did it take? How much did you save on parts and outside services today? You need to show your "customer" what you do for them and explain it. Invite administration, department managers, and key users to quarterly or semi-annual meetings. It helps to schedule these meetings during lunch and provide lunch.

Do some preparation and make sure you know your hospital's mission, value statements, and strategic plan. Open up the presentation with



Ken Schwarz

introductions and a quick PowerPoint presentation (keep it less than 25 slides). Remind them of your department's mission and key services. You can take some of this from your medical equipment management plan. Tell your customer what accomplishments and improvements you have made in recent months. Make the presentation about them. It's good to quickly review your performance indicators and what you are doing to improve them. Show a slide on your workload, including how much equipment you take care of, number of PMs, and repairs. Show them any projects you have completed or are working on, and don't forget the slide on cost savings.

The most important part of these meetings is interaction. If your customer is involved with your service (not just using it) they will see the value. Ask them what improvements they want to see and make sure you report back to them at the next meeting.

How can you do all of this? If you get organized and collect the data as you go along, preparation time is minimized. Also, once you find the format that works best, it becomes easier to update the presentation, rather than re-creating it. Although this will take some time, it's time well spent.

Set up a process to capture the data you want to present, and find out what the staff wants to learn and understand. Frequently, staff sees us only when we are busy running from one place to the next. Meetings like this will open up their eyes. I conducted a meeting once where a department manager said he "didn't realize all we did." This process will also help you with the annual evaluation of your medical equipment management plan. You should have all the data you need.

When other staff members fully understand and appreciate what you do and how you can help them, you will develop a better relationship and form a better team.

—Ken Schwarz

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## Biomed Shops Should Leverage Economy to Their Advantage

With many hospitals facing tough economic times, some biomed departments are under the gun to cut spending and possibly services, but biomed shops should seek to do just the opposite, a longtime clinical engineering leader says.

"Biomed is a cost-saving department. The way that we save money in hospitals is to get bigger, not to shrink," says Pat Lynch, a biomedical support specialist for Global Medical Imaging, and a 34-year veteran of the industry.



Pat Lynch

Lynch—who will be among the speakers at AAMI's Annual Conference to discuss how biomed shops can cope in this economy—says biomed shops should consider expanding their department's responsibilities to maintain and repair more

equipment. "Historically, most biomed shops are only doing the general biomedical equipment in hospitals. They are not very involved in the higher-end imaging, ultrasound, and equipment that costs big dollars to maintain."

By bringing higher-end equipment such as ultrasounds in-house, biomed shops could reduce maintenance and repair costs. Lynch will illustrate the savings by showing how a hospital can save money on diagnostic imaging maintenance. He will also provide tips on how to convince administrators to make the change by using a chart to demonstrate anticipated savings.

Other session speakers include Keith D. Persinger, senior vice president and chief financial officer for the University of Maryland Medical Center, and Britton Berek, director of regulatory compliance for ARAMARK Healthcare.

While training and travel costs often face added scrutiny when the economy is poor, biomed shops should emphasize to their administrators how important

training is for them, Lynch says.

"Hospitals need to realize that training is a true investment in the future," he says. "If a nurse doesn't go to a nursing conference for two or three years, she is still a nurse and can still practice nursing. If a biomed engineer doesn't go to training on new equipment coming out, he will not be able to service that equipment." ■

### Here to Help

The Annual Conference session on the economy is one of 50 educational sessions that will be offered during the conference, which will be held in Baltimore from June 6–8. To register for the conference, visit [www.aami.org/ac](http://www.aami.org/ac).

For more tips on surviving in the poor economy, visit [www.aami.org/economy](http://www.aami.org/economy). ■

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Many Amendments Considered for ST79 . . .

## Webinar Gives Peek at Potential 2009 Changes

Potential changes to AAMI's popular steam sterilization standard, ST79, this year include a new section on risk analysis, a committee leader says.

The first webinar in a five-part series on ANSI/AAMI ST79, *A comprehensive guide to steam sterilization and sterility assurance in health care facilities*, detailed some of the 26 potential changes to ST79 and provided an overview of the standard. ST79 is a consolidated revision of several AAMI standards that, prior to being superseded by ST79,

focused on various aspects of steam sterilization and sterility assurance.

One proposed amendment under consideration this year offers a new section on risk analysis. "It is recognized that the effectiveness of certain processes cannot be verified by inspection and testing," says Cynthia Spry, webinar speaker and co-chair of AAMI's Steam Sterilization Hospital Practices Working Group, which is responsible for ST79 authoring and updating. "We can't tell if our product

is sterile by looking at it, and we obviously can't test our devices before we send them to the operating room. Therefore performance of the sterilization process is routinely monitored and equipment maintained."

Because manufacturers validate sterilization cycles based on the assumption that a device is being processed alone, which is not the usual case in a health-care facility, a facility should perform a risk analysis, Spry adds.

A risk analysis includes a risk assessment, which identifies the source of a sterilization failure, estimates the likelihood that failure will occur, and assesses the consequences of failure. A risk analysis includes risk management, which determines failures that require attention, and plans to ensure sterilization failures are controlled.

The ST79 standard has a continuous maintenance process to keep it current. There are 25 other potential amendments to the standard, including new tests for assessing the efficacy of cleaning, currently under consideration.

These amendments will not be final until AAMI and the American National Standards Institute (ANSI) complete the approval processes later this year. The amendments are expected to be published this summer. ■



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## Standards Submission Form Changes

CONTINUED FROM PAGE 1

submission of medical devices during a recent session at the AAMI/FDA International Conference on Medical Device Standards and Regulation. Most significantly, the proposed form contains changes to the conformance table for some standards, with the goal of simplifying the process.

Form 3654 has a critical role in the 510(k) submission process, session speakers noted. "It is really important to make this work," said Dave Osborn, manager for international standards for Philips Healthcare and a member of AAMI's Board of Directors.



Dave Osborn

"FDA needs appropriate information, and manufacturers have to provide it if they want the process to work quickly and efficiently."

Osborn said manufacturers are permitted to use standards in submissions, particularly 510(k), as a risk control method. "For a device like an intensive care unit (ICU) monitor, a manufacturer will cite anywhere from eight to 20 standards," he said.

Many industry professionals find Form 3654 hard to use, particularly the conformance table manufacturers must fill out to show their compliance with standard sections. "One of the interpretations of the original form is that you have to report in the summary table every clause and sub-clause, which could be thousands of entries, while in fact FDA only needs to know about those few clauses that are not applicable or have been modified," Osborn said.

In the proposed Form 3654, manufacturers only have to list certain clauses and sub-clauses. One example of a clause that must be listed is a clause

where some parts of the standard aren't applicable.

Some of the language in the footnotes of the existing form also implies that all testing has to be completed before a manufacturer could send in a submission, Osborn said. That is in conflict with other FDA guidance. The proposed form explicitly states that manufacturers are permitted to submit a promissory note detailing that the testing will be completed, Osborn said.

Osborn was part of a team of device manufacturers that proposed the new form to replace the existing Form 3654. FDA distributed the proposed form to conference participants, and plans to distribute it to various trade groups for comments. After comments have been received, FDA will consider whether to make the changes, said Carol L. Herman, director of the standards program for FDA's Center for Devices and Radiological Health (CDRH). The U.S. Office of Management and Budget will make the final decision, she added. FDA expects a decision by this fall. ■

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## Speakers Provide Insight on Regulating Software as a Medical Device

The software expert for the U.S. Food and Drug Administration (FDA) shared how to determine when your software product would become a medical device. The session, presented during the AAMI/FDA International Conference on Medical Device Standards and Regulation, also included insight on security for information technology (IT) networks incorporating medical devices.

John Murray, software compliance expert for FDA, explained how he makes recommendations for software device decisions. "The intended use is what drives device decisions," he said. "When we start this process, the first thing we need to have is a good intended use definition. If you have a product where the intended use is to store, transfer, or display data, then that is an IT product. The product can become a medical device if the storage, transfer, or display of that data has some specific 'intended' clinical application that



Brian Fitzgerald speaks about IT network security during the International Standards Conference.

meets the legal definition of a device."

Some examples of device clinical application or use include calculating doses and calculating and controlling treatment timing.

When FDA determines that a software product is a medical device, it must also decide which device class it is. Devices are divided into three classes based on their risk to patients, with Classes I being the lowest and Class III the highest risk. "For software medical

devices, the idea here is to classify medical device infrastructure IT systems such as data acquisition systems in a Class I arena," Murray said. "Anything that has automatic control of the delivery, treatment, or diagnosis of care typically would be in the Class III arena. The majority of other products would fall between these two risk levels, and fall into Class II."

### IT Network Security

The session also included a segment on IT security. Traditional IT security is based on a static approach where aspects stay in place, said Brian Fitzgerald, deputy division director for FDA's Division of Software and Electronic Engineering. But this approach doesn't work in the medical field. Devices and patients move around.

Fitzgerald offered tips for IT security. For example, users may need separate device-level and network central account administrations, he said. ■

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## Expert Details 2010 Changes to European Device Regulations

Manufacturers who sell their products overseas must get ready for some changes to medical device regulations in Europe.

In March 2010, a revised version of the Medical Device Directive (MDD), which provides the basis for the European Union's medical device regulatory requirements, will go into effect. A session at the AAMI/FDA International Conference on Medical Device Standards and Regulation detailed some of the changes.

One of the major changes in the MDD focuses on the labeling of carcinogenic, mutagenic, or toxic to reproduction (CMR) substances. There was a debate within Europe about whether such substances should be banned, said Roger Gray, vice president of regulatory affairs for Rome-based Donawa Consulting and the session speaker. If CMRs were banned, it could have had a profound effect on medical device manufacturing, Gray said. Di(2-ethylhexyl)phthalate (DEHP), a widely used

plasticizer in medical devices, is classified as a CMR in Europe.

Recognizing this concern, the European Parliament, which approved the MDD revisions, reached a compromise. Rather than banning CMRs outright, all devices that contain DEHP will have to be labeled as such when the new rules take effect in 2010, Gray said.

The MDD revisions also opened the way for the use of electronic labeling—providing instructions to customers by a CD, DVD, or the Internet rather than paper copies. Like the current MDD, the revisions don't allow electronic labeling. But the European Commission has included in its 2009 work program meetings with stakeholders to address the issue, which may lead to a process for manufacturers to supply information by non-paper means. "It does give us hope that we could see guidance to tell us that we can use something other than paper," Gray said.

But there may be certain restrictions for using alternative means. Gray cited



Roger Gray speaks during a session at the AAMI/FDA International Standards Conference.

conditions from a European guidance document approved in January 2007 for in vitro diagnostic products. Some conditions specify that when making Instructions for Use (IFU) downloadable from a website, the manufacturer must provide clear direction to a dedicated area of the site and ensure the downloadable IFU is identical to the paper IFU, Gray said.

For more information on the MDD revisions, visit the European Commission's website at <http://ec.europa.eu>. ■

### Pop Quiz

Are you doing all you can to promote patient safety in your organization?  Yes  No

Are you actively working to raise the standard of your profession?  Yes  No

Do you stand out among your peers in your dedication to the field?  Yes  No

If you answered "no" to any of these questions, you should consider becoming certified.

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# AAMI's Annual Business Meeting to Feature Nominee Elections

AAMI members are invited to attend the association's annual business meeting on Saturday, June 6, during AAMI's 2009 Annual Conference & Expo. The meeting will include a report on 2008 and 2009 activities, and plans for the future.

The annual business meeting will be held from 4:30 p.m. to 5 p.m. at the Sheraton Inner Harbor Hotel in Baltimore, MD, the site of this year's annual conference.

During the meeting, AAMI members can review past, present, and future policies and programs, and pose questions to the AAMI leadership and staff.

AAMI members will also vote to elect two new Nominating Committee members and re-elect two members of AAMI's Board of Directors. David W. Braeutigam, CBET, and Larry Fennigkoh, PhD, have been chosen to serve on AAMI's Nominating Committee, which is responsible for recommending individuals to serve on the Board of Directors. Charles Philip Cogdill, vice chair, industry, and David G. Osborn, director, have been re-nominated to AAMI's Board of Directors. Both were elected to the board in 2006.

Braeutigam is director of biomedical engineering at Baylor Health Care System in Dallas, TX, and Fennigkoh is a professor of biomedical engineering at Milwaukee School of Engineering in Milwaukee, WI. Osborn is manager of international standardization at Philips Healthcare, and Cogdill is director of corporate sterilization and microbiology for Boston Scientific.

Members who do not plan to attend this meeting should complete and return the proxy card enclosed in this issue of *AAMI News*. The proxy card can also be completed online at [www.aami.org/private/ProxyCard/proxyform.htm](http://www.aami.org/private/ProxyCard/proxyform.htm). Under association bylaws, a minimum number of AAMI members must either be present at the meeting or submit a proxy card to ensure a quorum and to conduct necessary association business.

The agenda for the meeting is as follows:

- I. Call to Order—Chuck Sidebottom, PE, Chair, AAMI Board of Directors
- II. Approval of Minutes of the 2008 Annual Business Meeting—Sidebottom



The Baltimore Convention Center is the site of this year's AAMI Annual Conference & Expo.

- III. Report from the Chair of the Board—Sidebottom
- IV. Report on AAMI Strategic and Business Plans and Goals—Michael J. Miller, JD, AAMI President
- V. Report of the Treasurer and Finance Committee—Michael H. Scholla, PhD, AAMI Treasurer
- VI. Nominating Committee Report—Sidebottom
- VII. Election of Officers and Directors—Sidebottom
- VIII. Old and New Business
- IX. Expression of Appreciation to Officers
- X. Adjournment ■

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## Featured Speakers

[www.aami.org/ac](http://www.aami.org/ac)

### These distinguished speakers will share their insights at AAMI 2009!



**Ben Carson, MD**, will share the philosophies that have enabled him to rise from a life of poverty in America's inner cities to become a world-renowned pediatric neurosurgeon (as portrayed in the TV movie, "Gifted Hands: The Ben Carson Story"). He will discuss how the keys to a life of satisfaction, accomplishment, and peace lie in one's ability to discover his or her potential for excellence. (Sponsored by GE Healthcare)



**W. Randolph Chitwood, Jr., MD**, will explore the fascinating evolution of robotics being used in surgery today. He will outline the tremendous advancements in the technology, as well as the patient outcomes that have been achieved with surgical robots. He also will provide his unique perspective on what the future holds for this technology. (Sponsored by PSICOR)



**Marc Ringel, MD**, will discuss the intelligent use of information technology, focusing on which tasks are best accomplished by technology and which tasks are best accomplished by humans. He will describe how clinical information systems can enhance the patient-provider relationship by freeing clinicians to do what they, as humans, do best — understand social contexts, values, and ethics.

For details about these and other AAMI 2009 events, visit [www.aami.org/ac](http://www.aami.org/ac)

## Paying Tribute to the Behind-the-Scenes Stars of Technology Management

Most patients who walk into a hospital will never meet or even know about a biomedical equipment technician or clinical engineer. Yet, the biomedes who help purchase, service, and repair medical technology play a vital role in helping to improve patient safety and controlling healthcare costs.

Next month, AAMI's Technology Management Council (TMC), hospitals, biomedical associations, and schools around the country will honor these healthcare technology professionals during the 3rd annual National Biomedical/Clinical Engineering Appreciation Week from May 10–16.

In celebration, AAMI has collected a sample of tributes to individual biomedes who make a difference through their numerous contributions. These stories, submitted by colleagues and supervisors, illustrate the unique contributions that these managers of medical technology make every day.

### The Big Picture

Richard Swim will celebrate his 30th anniversary with Baylor in July. He is our clinical engineering coordinator, managing our clinical engineers and providing many other services.

During his time working for Baylor, Richard has seen many changes within Baylor and in healthcare in general. Not only has Richard survived those changes, he has thrived. He has all of the attributes you would want from someone who works in biomedical engineering.

The biggest example of how Richard has adapted is with computers and networking. Richard understood early on that computer technology was going to be a big part of medical equipment, and that understanding this technology

was going to be required for effective medical equipment support. Richard not only learned about personal computers and how to support them, he also learned about networking.

He was self-educated to a large extent, but supplemented that with formal training. He is the most knowledgeable in our department with respect to computers and networking.

Richard realizes that he may not always have enough information to understand the big picture, but he knows that there is a big picture and



Richard Swim

that computer technology is part of it. I am truly honored to be able to work with Richard.

Kenneth E. Maddock  
Corporate Director, Biomedical  
Technology Services  
Baylor Health Care System, Texas

### A Strong Commitment

We were about to open a new surgery center, and some people from our department offered to help. Senior Technician Rossiny Jacques was one of them.



Rossiny Jacques

We had less than four days to prepare four operating rooms for surgeries, as well as a 16-bed post anesthesia care unit/pre-operation area equipped with a patient monitoring network.

Without Rossiny's hard work and dedication, this might not have been possible. He showed up early in the morning and left late at night. Every day he built new anesthesia machines, electrosurgical units, patient monitors, and a multitude of devices. Not only did he work hard to put them together, but he worked harder to test them properly. His reason for the extensive testing was, "What if these devices have to be used on my daughter or son?"

The center opened in February, and ever since it has housed multiple surgeries. There hasn't been one issue with the equipment we set up, and a big reason for that is Rossiny's excellent work.

Ibir Kullolli  
Clinical Engineer  
Brigham and Women's Hospital, Boston

### Being a Mentor

Horace Hunter has been the assistant director of engineering at our hospital for roughly 30 years. He started our program here, and actually has the responsibility for four other hospitals in addition to the doctors' offices, clinics, seven dialysis facilities, and four nursing homes we maintain.

He and a few others actually started

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the Georgia Biomedical Instrumentation Society. He continues to mentor the employees and holds educational workshops, including one for middle school kids to prepare them for the biomed field.



**Horace Hunter**

Horace also helped Southwest Georgia Technical College start its electronics program, and helped recruit and keep individuals interested in the field of biomed. He is an individual who deserves to be recognized in every possible way.

Christa Shiver  
Clinical Engineer Technician  
John D. Archbold Memorial  
Hospital, Georgia

### Forging Partnerships

John Loua, CBET, a senior clinical engineering technician at The Mount Sinai Medical Center, New York, effectively managed a patient monitoring

hardware upgrade of eight bedside monitors and one central station in the pediatric intensive care unit (PICU).

The PICU had patient monitoring technology that was intended for replacement toward the end of the year. However, at the beginning of this year, the central station needed to be upgraded and the department looked to clinical engineering to suggest an interim solution. John resurrected a patient information center that the clinical engineering department kept from past de-installations.

John worked with the medical company's technical support to configure the new central station and ensured it was compatible with the eight bedside monitors.

Izabella Gieras  
ARAMARK Healthcare  
Director, Clinical Engineering Department  
Mount Sinai Medical Center, New York



**John Loua, CBET**

### How to Celebrate Your Week

National Biomedical/Clinical Engineering Appreciation Week is on the horizon, and there are many ways to celebrate.

AAMI's Technology Management Council (TMC) has launched a new web section—[www.aami.org/tmc-connect/promoting.html](http://www.aami.org/tmc-connect/promoting.html)—featuring helpful tools for biomed to celebrate the week, which runs from May 10-16.

The tools include a sample letter that biomed can send to state or local elected officials asking them to formally recognize the week.

The web page includes a poster that biomed can print or distribute at their facilities. AAMI members can request large-size posters by e-mailing Patrick Bernat, AAMI director of healthcare technology management, at [pbernat@aami.org](mailto:pbernat@aami.org). ■



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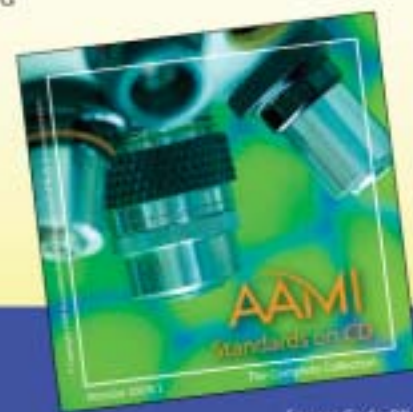
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## Report Clarifies Requirements in Electrical Equipment Standard

A new AAMI Technical Information Report (TIR) provides a bridge between the second and third editions of IEC 60601-1.



ANSI/AAMI/IEC TIR62296, *Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements*, includes clarifications on clauses and

requirements within ANSI/AAMI ES60601-1, *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*, which is the U.S. adopted version (with national deviations) of IEC 60601-1, 3ed.

"The standard 60601-1 is written to apply across the board to all medical electrical equipment. You have a situation where what makes sense in general may not make that much sense when you look at a specific piece of equipment," says Mike Schmidt, a medical device safety and standards consultant who is co-chair of AAMI's Electrical Safety Committee, which adopted the

report in the United States. Originally the report was developed by IEC Subcommittee 62A, Working Group 14.

Experts from test houses or "testing laboratories" that offer certification services to the medical industry are members of Working Group 14.

"Obviously, they are familiar with ways of interpreting how a given requirement in 60601-1 needs to be applied," Schmidt says.

"The TIR explains how to apply those requirements where there is flexibility within certain clauses and requirements," Schmidt says. "Where a straight read of the requirement would suggest a more or less stringent interpretation, the technical report gives insight into how you might apply the requirement for a specific device or for a specific application. Essentially, the 60601 series allows you to take a different approach with any requirement as long as you provide an equivalent level of safety to that you would achieve by straightforward compliance with the requirement."

"Some of the recommendations raised within the TIR are device-specific, but in many cases it talks

about certain types of configurations of equipment," Schmidt says. "If the equipment has no connection to the main power source because it is battery powered, does the requirement apply and, if so, how?" he says as an example. ■

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## State Biomed Society Leaders to Share Ideas, Network

State and local biomedical associations will have an opportunity this summer to get together to share ideas and best practices.

AAMI's Technology Management Council (TMC) will host the 2nd annual Biomed Society Roundtable on Sunday, June 7, during AAMI's Annual Conference & Expo in Baltimore.

"It's a great opportunity for individuals representing biomedical societies to have a national forum to share ideas, concepts, and relationships regarding information that will be enriching and



Dave Francoeur

thought-provoking," says Dave Francoeur, the TMC's vice chair. "Society leaders can learn what others from around the country are doing and share what's working for them. By putting faces to names, they can also learn who to reach out to for guidance when situations arise that others may have already worked through."

During the roundtable, society leaders are expected to discuss how societies can form certification study groups, modeled after the successful experiences of the Colorado Association of Biomedical Equipment Technicians (CABMET). The Colorado society is credited with helping to increase pass rates of the exam.

Society leaders are also expected to share ideas on how to attract speakers and attendees to meetings, and discuss what topics are most interesting and useful to members. "Certified biomedical equipment technician (CBET) training is the number one requested topic at California Medical Instrumentation Association (CMIA) meetings," says James Knight, a board member of CMIA's Central Valley Chapter.

Finding ways to increase society membership and meeting attendance is critically important, adds Anthony Campos, vice president of CMIA's Central Valley Chapter. "The more biomedical techs who become members

increase our treasury with membership dues and add credibility to the society by their experience," he notes.

Also, during the roundtable, Francoeur hopes that society leaders will share their ideas on how AAMI and the TMC can continue to strengthen membership benefits and outreach efforts to local biomedical associations.

If you have questions or are interested in attending the roundtable, contact Patrick Bernat at [pbernat@aami.org](mailto:pbernat@aami.org). ■

### Are You an Early Bird?

You can save \$55 by registering for AAMI's Annual Conference by Friday, April 24. To register or learn more about the conference, visit [www.aami.org/ac](http://www.aami.org/ac).

## Document Control and Records Management

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This program is designed for professionals that have responsibility for making decisions related to the use of documents and records in the areas of change control, quality assurance, design, manufacturing, purchasing, regulatory affairs, FDA inspections, and ISO audits. AAMI recommends this course for those who have medical device experience and a working knowledge of the Quality System regulation and the ANSI/AAMI/ISO 13485:2003 standard.

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# MEMBER NEWS

## IN PROFILE

### CE-IT Community Braces for New Challenges

*Rick Schrenker is a member of the CE-IT Community, a collaboration among members of AAMI, the Healthcare Information and Management Systems Society (HIMSS), and the American College of Clinical Engineering (ACCE). The coalition aims to create a unified voice to address clinical engineering (CE) and information technology (IT) concerns. In this issue of AAMI News, Schrenker discusses important issues facing CE-IT convergence, including recent funding in the economic stimulus package for healthcare IT.*

**AAMI News:** You are vice-chair of the CE-IT Community's working group on integration. What are some challenges with integrating systems in this multi-vendor environment?

**Rick Schrenker:** From where I sit, what challenges me most are not the technical and cultural issues that we are addressing but rather the implications that derive from moving toward a

substantially and fundamentally different world. Integration is more than getting data from devices into medical records. It's about decision support and control.

No one can argue that the information we are being provided by manufacturers for complex systems today is sufficient to fully characterize its operation. And in fairness to manufacturers, in many cases they cannot provide similar information because today's systems are too complex. But that doesn't remove the requirements to come up with other documentation that is as effective.



**Rich Schrenker**

**AN:** How do you hope the CE-IT Community will help address those challenges?

**RS:** The community offers a number of opportunities. It's a safe place for CE and IT to talk with each other. Success will be marked by the presence of conflict as well as cooperation. Not only does the ability to argue indicate the presence of trust, but it is in the resolution of conflict that stronger relationships often emerge.

**AN:** You currently work as systems engineering manager for Massachusetts General Hospital. How did you get involved with systems engineering?

**RS:** What a long, strange trip it's been. It'd be great to say I planned it out, but it would be more truthful to say it evolved out of chasing down interesting problems. Early in my career I always liked design and development



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engineering, hardware, and software. When the ability to do that diminished in clinical engineering, I moved into software development management for our departmental systems. Along the way, I picked up an interest in medical device interoperability, but there was no way to act on it until I had a clinical champion to work with. And then one day Julian Goldman, MD, an anesthesiologist at Massachusetts General involved in the interoperability among medical devices, walked up to me and said, "I hear you've been involved in IEEE 1073, the standard for medical device communications . . ."

A little bit of research took me to software engineering, which in turn reminded me how medical device companies working on interoperability had stressed the importance of requirements engineering. I realized clinical engineering needed to learn about software engineering.

**AN:** How has the introduction of systems affected a biomed's duties regarding repair and maintenance of medical devices?

**RS:** It remains to be seen. A very real question is the fact that the creation of a system results in properties of the system that are not present in its constituent components (if that were not so, then why create a system in the first place?). So do devices need to be inspected as well as a system? Can system inspection remove the need for individual device inspection?

We are entering a different world where what was done in the past may not be appropriate for the future.

**AN:** The recent economic stimulus package included roughly \$19 billion in spending for healthcare IT. Will this have an impact on the CE-IT integration and, if so, how?

**RS:** Given the Obama administration's intent on realizing the electronic medical record system, I have to believe that stimulus money will flow to this work. Hopefully it will initially do so in the form of funding proof-of-concept and other prototype efforts. ■

## MEMBERS ON THE MOVE

• **John Coraluzzi** has joined IV Technologies as vice president of critical sales in the company's new critical care division. The company specializes in infusion pumps and replacement parts. Coraluzzi previously worked for Mediq/Hill Rom.

• **Rick Hampton** has joined the Editorial Board of AAMI's peer-reviewed journal, *Biomedical Instrumentation & Technology (BI&T)*. As a member of the Editorial Board,



**Rick Hampton**

Hampton will help write and review articles, critique the bi-monthly journal, and develop the content for future editions. Hampton is the wireless commu-

nications manager for Partners Healthcare, a group of hospitals in Boston, MA.

• **Mohammed M. Kaleem** has joined Health Hero Network Inc., a Robert Bosch GmbH company, as its director of quality and regulatory affairs for North America. The company offers



**Mohammed M. Kaleem**

products and solutions for remote health monitoring. Kaleem will be responsible for ensuring that the company is in compliance with domestic and international quality systems and regulations, among other duties. He was previously manager of quality systems for Philips Healthcare's Nuclear Medicine Business Unit. ■

## NEW MEMBERS

### New Member Organizations

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E-MAIL: jdecosta@ajh.org

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E-MAIL: john\_defoggi@bptm.com

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E-MAIL: jrr@clinicaldynamics.com

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For a complete list of new members, see [www.aami.org/publications/AAMINews/members.html](http://www.aami.org/publications/AAMINews/members.html).

## National Standards

### New Publications

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**ANSI/AAMI/IEC TIR62296, Considerations of unaddressed safety aspects in the second edition of IEC 60601-1, 1ed.** (TIR62296 or TIR62296-PDF; \$50/\$95)

### Reaffirmations

**ANSI/AAMI/ISO 10993-04:2002/(R)2009, Biological evaluation of medical devices, Part 4: Selection of tests for interactions with blood, 2ed.** Reaffirmed 10 March 2009 as an American National Standard. (1099304 or 1099304-PDF; \$45/\$90) Identical to ISO 10993-04:2002.

**ANSI/AAMI/ISO 10993-16:1997/(R)2009, Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables from medical devices, 1ed.** Reaffirmed 5 March 2009 as an American National Standard. (1099316 or 1099316-PDF; \$35/\$70) Identical to ISO 10993-16:1997.

### Call for Comments

*Proposed standards and recommend-*

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*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/about.forms.html](http://www.aami.org/standards/about.forms.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 8 May 2009

**AAMI/CDV-1 8637 (ISO/DIS 8637), Cardiovascular implants and artificial organs—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, 3ed.** (proposed AAMI/American National Standard). This International Standard specifies requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, hereinafter collectively referred to as "the device," for use in humans. (8637-D, \$20/\$25; 8637-D-PDF, \$0/\$25)

**AAMI/CDV-1 8638 (ISO/DIS 8638), Cardiovascular implants and artificial organs—Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters, 3ed.** (proposed AAMI/American National Standard). Specifies requirements for the single-use extracorporeal blood circuit (hereafter referred to as "the device") and (integral and non-integral) transducer protectors which are intended for use in haemodialysis, haemodiafiltration and haemofiltration. (8638-D, \$20/\$25; 8638-D-PDF, \$0/\$25)

### Comments due by 11 May 2009

**AAMI/CDV-1 60601-2-25 (IEC 62D/758/CDV), Medical electrical equipment—Part 2-25: Particular requirements for the basic safety**

**and essential performance of electrocardiographs, 3ed.** (proposed AAMI/American National Standard). Specifies particular basic safety and essential performance requirements for electrocardiographs, recording and analyzing single channel and multi-channel electrocardiographs intended for the production of detachable electrocardiograms for diagnostic purposes. This particular standard also applies to vector cardiographs and medical electrical equipment for exercise testing. Special requirements concerning use in ambulances, phono-cardiographs, cardiographic monitors, polygraphs, telemetering, special tests (for example, His bundle electrocardiographs, electrocardiographs for late potential detection), Holter electrocardiographs, invasive electrocardiography etc. are not covered by this particular standard. Medical electrical equipment with microelectrodes used directly in the fibres of the heart muscle is also excluded. (601225-D, \$20/\$25; 601225-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 are available from the Standards section of the AAMI website ([www.aami.org](http://www.aami.org)).*

### Approved/Work in Progress

**AAMI/ISO 10993-12/Ed.4, Biological evaluation of medical devices—Part 12: Sample preparation and reference materials, 4ed.** Contact: [hwoehrle@aami.org](mailto:hwoehrle@aami.org)

**AAMI/ISO 13485:2003/C1/Ed.1, ANSI/AAMI/ISO 13485:2003, Corrigendum 1, 1ed.** (being processed as an amendment). Contact: [hwoehrle@aami.org](mailto:hwoehrle@aami.org)

### Recently initiated periodic reviews

**AAMI EC53/Ed.2, Periodic review of ANSI/AAMI EC53:1995 and A1:1998, ECG cables and leadwires (as amended in 1998)—Decision: Revise document, 2ed.** Contact: [hchoe@aami.org](mailto:hchoe@aami.org)

**AAMI ID26-Reaff/Ed.3, Periodic review of ANSI/AAMI ID26:2004, Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers, 3ed.** Contact: [jmoyer@aami.org](mailto:jmoyer@aami.org)

## International Standards

### New 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](http://www.ansi.org)). If a PDF order code is provided, electronic copy also can be purchased from the Marketplace at [www.aami.org](http://www.aami.org).*

**IEC 60601-2-19:2009, Medical electrical equipment—Part 2-19: Particular requirements for basic safety and essential performance of baby incubators, 2ed.** International Standard.

**IEC 60601-2-2:2009, Medical electrical equipment—Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, 5ed.** International Standard.

**IEC 60601-2-20:2009, Medical electrical equipment—Part 2-20: Particular requirements for basic safety and essential performance of transport incubators, 2ed.** International Standard.

**IEC 60601-2-21:2009, Medical electrical equipment—Part 2-21: Particular requirements for basic safety and essential performance of infant radiant warmers, 2ed.** International Standard.

**IEC 80601-2-30:2009, Medical electrical equipment—Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers, 1ed.** International Standard.

### Errata

**ISO 11137-2:2006 (Corrected copy), Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose,**

**1ed.** International Standard. Technical Corrigendum ISO 11137-2:2006/Cor 1:2009 issued 2009-2-10.

**ISO/TS 11135-2:2008, Sterilization of health care products—Ethylene oxide—Part 2: Guidance on the application of ISO 11135-1, 2ed.** International Technical Specification. (1113502; \$50/\$95). Technical Corrigendum ISO/TS 11135-2:2008/Cor 1:2009 issued 2009-2-9. (Note: Correction already made to the AAMI adopted version.)

## 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](http://www.aami.org) to order electronic (pdf) version for immediate download.

### Parallel Adoptions (see National Standards Call for Comments for details)

- IEC/CDV-1 60601-2-25 (IEC 62D/758/CDV)
- ISO/DIS-1 8637
- ISO/DIS-1 8638

### Comments due by 8 May 2009

**ISO/DIS-1 13960 (ISO/DIS 13960), Cardiovascular implants and artificial organs—Plasmafilters, 2ed.** (proposed International Standard). Specifies requirements for sterile, single use plasmafilters, intended for use on humans. (13960-D, \$20/\$25; 13960-D-PDF, \$0/\$25)

### Comments due by 11 May 2009

**IEC/CDV-1 60601-2-23 (IEC 62D/759/CDV), Medical electrical equipment—Part 2-23: Particular requirements for basic safety and essential performance of transcutaneous partial pressure monitoring equipment, 3ed.** (proposed International Standard). This particular standard specifies the particular basic safety requirements and essential performance, for transcutaneous partial pressure monitoring equipment, whether this ME equipment is stand alone or part of a system. It applies to transcutaneous monitors used with adults, children and neonates, and it includes the use of these devices in foetal monitoring during birth. It does

not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa). (601223-D, \$20/\$25; 601223-D-PDF, \$0/\$25)

**IEC/CDV-1 60601-2-34 (IEC 62D/760/CDV), Medical electrical equipment—Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment, 3ed.** (proposed International Standard). Applies to invasive blood pressure monitoring equipment. This particular standard does not apply to catheter tubing, catheter needles, Luer locks, taps and tap tables. This particular standard also does not apply to non-invasive blood pressure monitoring equipment. (601234-D; \$20/\$25)

**IEC/CDV-1 60601-2-49 (IEC 62D/761/CDV), Medical electrical equipment—Part 2-49: Particular requirements for the basic safety and essential performance of multi-function patient monitoring equipment, 2ed.** (proposed International Standard). Applies to the safety requirements of multifunction patient monitoring equipment. This standard does not specify requirements for individual monitoring functions. (601249-D, \$20/\$25; 601249-D-PDF, \$0/\$25)

## New Work Proposals

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**ISO 13485:2003/C1/Ed.1, ISO 13485:2003, Corrigendum 1, 1ed.** (Being processed as an amendment.) Contact: [hwoehrle@aami.org](mailto:hwoehrle@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 website ([www.aami.org](http://www.aami.org)). Agendas for open meetings are usually available from AAMI Committee Central. (Go to [www.aami.org/committeecentral](http://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](mailto:standards@aami.org)) indicating the name and date of the meeting so that staff can contact you in the event of a cancellation.

**AAMI/BG, Blood/Gas Exchange Device Committee** (Open Meeting). 07-May-09, 08:00 to 17:00 h. Large Conference Room, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795, USA. Directions to AAMI, important information about building security, and a list of nearby hotels are available at [www.aami.org/about/directions.html](http://www.aami.org/about/directions.html). Develop Working Draft of ISO 11658 on coatings for blood contact equipment. Contact: [cbernier@aami.org](mailto:cbernier@aami.org)

**AAMI/HE, Human Factors Engineering Committee** (Open Meeting). 22 to 24-Jun-09, 10:00 to 14:00 h. Chicago, IL, USA. Contact: [jmoyer@aami.org](mailto:jmoyer@aami.org)

**AAMI/PC, Cardiac Rhythm Management Device Committee** (Open Meeting). 12-May-09, 13:00 to 18:00 h. Boston Marriott Copley Place, 110 Huntington Avenue, Boston, MA 02116, USA. Contact: [jmoyer@aami.org](mailto:jmoyer@aami.org)

**AAMI/RD, Renal Disease and Detoxification Committee** (Open Meeting). 25-Apr-09, 08:00 to 18:00 h (ANNA meeting). Indigo 204 Room, Hilton San Diego Bayfront, 1 Park Boulevard, San Diego, CA 92101, USA. Status of RD52 and RD62 amendments; status NWIP on testing methodologies for water and NWIP on

ultrapure dialysate; develop US positions on ISO 8637, ISO 8638, and ISO 13960 DISs; results of RD52 formatting revision ballot. Contact: [cbernier@aami.org](mailto: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). 08 to 10-Jun-09 (AAMI Annual Conference and Exposition). Baltimore Marriott Inner Harbor, Baltimore, MD, USA. Contact: [jljewelling@aami.org](mailto:jljewelling@aami.org)

**AAMI/ST, Sterilization Standards Committee (U.S. TAG for ISO/TC 198) and affiliated working groups and sub-TAGs** (Open Group Meeting). 16 to 18-Nov-09. Arlington, VA, USA. Contact: [jljewelling@aami.org](mailto:jljewelling@aami.org)

**Joint meeting of the U.S. TAGs for IEC/TC 62, IEC/SC 62A, and IEC/SC 62D** (Open Meeting). 5-May-09, 10:00 to 15:00 h. AdvaMed, 701 Pennsylvania Avenue, NW, Suite 800, Washington, DC, USA Contact: [hwoehrle@aami.org](mailto:hwoehrle@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/SC 62D/JWG 06, Joint ISO/TC 121/SC 1-IEC/SC 62D WG: Respiratory gas monitors (ISO/TC 121/SC 1/JWG 06)** (Closed Meeting). 06 to 08-May-09. Cambridge, MA, USA. Contact: [hchoe@aami.org](mailto:hchoe@aami.org)

**IEC/SC 62D/MT 17, High frequency surgical equipment** (Closed Meeting). 21 to 22-Apr-09. Vancouver, Canada. Discuss revision of IEC 61289-1 and -2. Contact: [sbalboni@aami.org](mailto:sbalboni@aami.org)

**IEC/SC 62D/MT 20, Hemodialysis equipment** (Closed Meeting). 26 to 28-May-09. Milano, Italy. Contact: [cbernier@aami.org](mailto:cbernier@aami.org)

**IEC/TC 62, Electrical equipment in medical practice, affiliated subcommittees and working groups** (Closed Group Meeting). 08 to 19-Jun-09. Brussels, Belgium. Contact: [hchoe@aami.org](mailto:hchoe@aami.org)

• **IEC/TC 62, Electrical Equipment in Medical Practice** (Closed Meeting). 18-Jun-09. Contact:

- hchoe@aami.org**
- **IEC/TC 62 CAG, Chairman's Advisory Group** (Closed Meeting). 17 to 18-Jun-09.
  - **IEC/SC 62A, Common Aspects of Electrical Equipment Used in Medical Practice** (Closed Meeting). 16-Jun-09. *Contact: hwoehrle@aami.org*
  - **IEC/SC 62A CAG, Chairman's Advisory Group** (Closed Meeting). 15-Jun-09. Meeting on second day starts at 9 am.
  - **IEC/SC 62A/JWG 07, Joint IEC/SC 62A-ISO/TC 215 WG: Application of risk management to information technology (IT) networks incorporating medical devices** (Closed Meeting). 10 to 12-Jun-09.
  - **IEC/SC 62A/MT 29, Mechanical hazards** (Closed Meeting). 12 to 15-Jun-09. MT will decide first day on exact start/end time for second day.
  - **IEC/SC 62B, Diagnostic imaging equipment** (Closed Meeting). 17-Jun-09. *Contact: hchoe@aami.org*
  - **IEC/SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry** (Closed Meeting). 16-Jun-09. *Contact: hchoe@aami.org*
  - **IEC/SC 62D, Electromedical Equipment** (Closed Meeting). 17-Jun-09. *Contact: hchoe@aami.org*
  - **IEC/SC 62D CAG, Chairman's Advisory Group** (Closed Meeting). 15-Jun-09.
  - **IEC/SC 62D/MT 18, Therapy equipment** (Closed Meeting). 11 to 15-Jun-09. MT will decide first day on exact start/end time for second day.
  - **IEC/SC 62D/MT 22, Electromedical diagnostic and patient monitoring equipment. NOTICE—MEETING CANCELLED** (originally scheduled for 08 to 11-Jun-09).
  - **CENELEC/TC 62, Electrical equipment in medical practice** (Closed Meeting). 19-Jun-09. *Contact: hchoe@aami.org*
- ISO/TC 121 and IEC/SC 62D Joint Working Groups Meeting** (Closed Group Meeting). 11 to 19-Jun-09. Orebro, Sweden. *Contact: hchoe@aami.org*
- **IEC/SC 62A/JWG 06, Joint IEC/SC 62A-ISO/TC 121/SC 3 WG: Medical electrical equipment and systems for use in home care applications (ISO/TC 121/SC 3/JWG 06)** (Closed Meeting). 15 to 19-Jun-09 (Tentative date & time). *Contact: hwoehrle@aami.org*
  - **IEC/SC 62D/JWG 01, Joint ISO/TC 121/SC 3-IEC/SC 62D WG: Critical care ventilators (ISO/TC 121/SC 3/JWG 01)** (Closed Meeting). 15 to 19-Jun-09 (Tentative date & time). *Contact: hchoe@aami.org*
  - **IEC/SC 62D/JWG 02, Joint ISO/TC 121/SC 1-IEC/SC 62D WG: Anaesthesia workstations (ISO/TC 121/SC 1/JWG 01)** (Closed Meeting). 11-Jun-09 (Tentative date & time). *Contact: hchoe@aami.org*
  - **IEC/SC 62D/JWG 05, Joint ISO/TC 121/SC 3-IEC/SC 62D WG: Pulse oximeters (ISO/TC 121/SC 3/JWG 10)** (Closed Meeting). 15 to 19-Jun-09 (Tentative date & time). *Contact: hchoe@aami.org*
  - **IEC/SC 62D/JWG 07, Joint IEC/SC 62D-ISO/TC 121/SC 3 WG: Non-invasive blood pressure monitoring equipment (ISO/TC 121/SC 3/JWG 07)** (Closed Meeting). 15 to 19-Jun-09 (Tentative date & time). *Contact: hchoe@aami.org*
  - **IEC/SC 62D/JWG 08, Joint ISO/TC 121/SC 3-IEC/SC 62D WG: Clinical thermometers (ISO/TC 121/SC 3/JWG 08)** (Closed Meeting). 15 to 19-Jun-09 (Tentative date & time). *Contact: hchoe@aami.org*
- ISO/TC 150, Implants for Surgery, affiliated subcommittees and working groups** (Closed Group Meeting). 07 to 11-Sep-09. Kyoto, Japan. *Contact: cbernier@aami.org*
- **ISO/TC 150/SC 2, Cardiovascular Implants and Extracorporeal Systems** (Closed Meeting). 07 to 11-Sep-09. Detailed schedule for SC and its WGs to be announced. *Contact: cbernier@aami.org*
  - **ISO/TC 150/SC 6, Active Implants** (Closed Meeting). 07 to 11-Sep-09. Detailed schedule for SC and its WGs to be announced. *Contact: jmoyer@aami.org*
- ISO/TC 150/SC 6/JWG 01, Joint ISO/TC 150/SC 6-IEC/SC 62D WG: Cardiac pacemakers and implantable defibrillators (IEC/SC 62D/JWG 03)** (Closed Meeting). 11 to 12-May-09. Boston, MA, USA. *Contact: jmoyer@aami.org*
- ISO/TC 150/SC 6/JWG 02, Joint ISO/TC 150/SC 6-IEC/SC 62B WG: Effects of magnetic resonance imaging on active implantable medical devices (IEC/SC 62B/JWG 01)** (Closed Meeting). 27 to 29-May-09. Washington, DC, USA. *Contact: jmoyer@aami.org*



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	ANSI/AAMI/IEC TIR62296, Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements (page 16)	Print	TIR62296	\$50/\$95	
	ANSI/AAMI ES60601-1, Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (page 16)	Print	6060101	\$75/\$150	
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## UPCOMING EVENTS

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April 20–24 • St. Pete Beach, FL

### Radiation Sterilization for Medical Devices

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### Process Validation Requirements and Industry Practice

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## ST79 Webinar Gives Peek at Potential 2009 Changes—see page 8.

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