Gearing Up for the IHE Connectathon 2007

The IHE North America Connectathon will be held at the Hyatt Regency Hotel in Chicago, IL, the week of January 15-19, 2007. Currently, there are events annually in North America, Europe and Asia. The major goal of the Connectathon is to promote the adoption in commercially available healthcare IT systems of the standards-based interoperability solutions defined by IHE. The Connectathon serves as an industry-wide testing event where participants can test their implementations with those of other vendors.

This year, for the first time, IHE will present an educational conference at the same site on January 16-17 in association with the Connectathon, and also for the first time, ACCE, through its sponsorship of the Patient Care devices domain, will participate in the event.

The Connectathon provides the most detailed validation of the participants’ integration work. Participating companies prepare for the event using testing software, the MESA test tools, which were specially developed for this purpose.

During the Connectathon, systems exchange information with complementary systems from multiple vendors, performing all of the transactions required for the roles they have selected, called IHE Actors, in support of defined clinical use cases, called IHE Integration Profiles. Thousands of vendor-to-vendor connections have been tested overall, and tens of thousands of transactions passed among the systems tested.

The Connectathon offers vendors a unique opportunity for connectivity testing—removing barriers to integration that would otherwise have to be dealt with on site, at the customer’s expense. Companies taking part have responded overwhelmingly that the IHE process addresses important issues in their product development plans.

Connectathon results are published and promoted by the sponsors to inform the healthcare community about the breadth of adoption of IHE solutions by industry and to encourage purchasers of healthcare IT systems to require support of IHE Ac-

(Continued on page 2)
Connectathon 2007

(Continued from page 1)

tors and Integration Profiles in their requests for proposals and purchasing specifications.

A second purpose of a Connectathon is to prepare for public demonstrations at meetings of the sponsoring organizations or other medical professional societies. Near the end of the testing period, systems registered for public demonstrations are organized into demonstration groups and walked through the demonstration process. This happens after the systems have completed their Connectathon tests.

The Patient Care Devices domain, cosponsored by ACCE and the Healthcare Information Management and Systems Society (HIMSS), will test interoperability for the transmission of patient information, such as vital signs, directly from the monitor to the Electronic Medical Record or other receivers in the Enterprise. This data will be transmitted using Health Level 7 (HL7) messaging protocols. This is the first step down a road that will include the communication of waveform, alarm, point of care testing, and home care information over the next few years. For further information about ACCE involvement in the IHE and how Clinical Engineers are playing a role in the process, see the June 2006 issue of 24x7 Magazine, “The IHE Initiative” or send an email to iheinfo@accenet.org.

Ray Zambuto, IHE PCD Task Force Co-Chair

CCE Certification—What You Need to Know

1) The written exam will be given in 29 cities throughout the US on November 18, 2006. Application deadline is September 28.

2) For an extra fee, the written exam can be given in almost any city in the US or in almost any major city in the world.

3) Applications are being accepted now for the November 18 exam. Please include references and transcripts with application.

4) The handbook that describes the process, and the application that needs to be completed, can be found on the certification website: www.acce-htf.org/certificaton.

5) A study guide has been recommended by several who recently passed the CCE exam and became certified. Walter Burdett of the VA Medical Center in Syracuse, NY said "The Study Guide was an excellent fit to the style, vocabulary, content and level of difficulty of the written exam. The bibliography was very useful."
Perspectives from ECRI: FDA Recall Audits

I recently conducted a medical device hazard and recall seminar at William Beaumont hospital in Royal Oaks Michigan. One of the topics that I talked about during my presentations had to do FDA recall audits at U.S. hospitals. I was curious how many of the seminar attendees had recently experienced an audit from FDA and asked for a show of hands. I was very surprised to see that about one third of the nearly thirty attendees had been visited by FDA for a recall audit. The seminar attendees included clinical engineers, BMETs, materials managers, risk managers, safety officers, and administrators from hospitals or health systems in Michigan, Ohio, and Georgia. The surprisingly high number of the ECRI seminar attendees that had received FDA recall audits is consistent with a growing number of hospitals that have informed ECRI about similar experiences. Has your hospital had an FDA recall audit? If not, are you prepared in case it does happen?

FDA recall audits are not an inspection of a hospital per se, but are a mechanism for FDA to investigate the effectiveness of manufacturers’ recall-related efforts and to verify that recalling manufacturers are complying with appropriate regulations. The audits are also intended to ensure that each owner or consignee of a recalled device has followed the instructions of a manufacturer’s recall notification. The audits typically involve unannounced visits by FDA Investigators or Consumer Safety Officers and despite the fact that they are not truly inspections of the hospitals (i.e., for punitive reasons) it can seem so and can be very tense for hospitals that are not organized or prepared.

When FDA investigators visit a facility to perform a recall audit, they typically ask hospital staff to respond to a long list of detailed questions. Questions may address when a recall notification was received, if it was understood, and if it was followed. Investigators may also ask how much recalled product was in the facility’s inventory at the time the notification was received and how the recall has been resolved. FDA’s staff will expect to see clear documentation describing any actions your hospital has taken to address the recall. FDA investigators may also check various locations within the facility to ensure that all recalled product has been identified, removed from use, and properly quarantined or returned. And even though FDA does not regulate facility response to recalls, if the audit reveals that a recall has not been performed the failure to follow recall instructions will likely be discussed with top management at the facility and the FDA investigator may return to ensure that requested recall actions have been completed.

ECRI has been in contact with several hospitals that were caught off guard by FDA’s audits and they have sought our advice on how to plan for future visits from FDA. As a result, ECRI wrote a Health Devices Alerts Special Report with our perspectives on this issue and a detailed list of recommendations for how to be better prepared.

Recommendations include organizing a core group of individuals to be involved in the recall management process at your facility, identifying a representative from your organization who can be the primary contact for FDA investigators when they arrive at your facility, and choosing at least one alternate staff member in case the primary contact is not available at the time of inspection or audit.

ECRI’s Special Report was published in Health Devices Alerts on March 17, 2006 and is available on the member Web sites for our Health Devices and SELECTPlus membership programs. Feel free to contact me at jkeller@ecri.org if you would like information on how to access this article or if you have any questions about FDA’s recall audits.

Jim Keller is ECRI’s Vice President for Health Technology Evaluation and Safety and a past Member at Large for ACCE’s Board.

Jim Keller, Vice President, ECRI jkeller@ecri.org
View from the Penalty Box: Delivering Results

This is a great time of the year as all the sports are in action, the weather is generally good, and the political ads will only be running for a few more weeks. If the people seeking office do 10% of what the claim they will do we will all have better healthcare, higher pay, better schools, lower taxes and lower gas costs. But we all know that words and actions do not always correlate, especially with politicians.

We are starting to see some old issues resurface that will take time and effort on our part to get cleared up. We have the issues surrounding the changes in AED protocols, shock, compressions and energy levels. See www.circ.ahajournals.org and go to issue 112 November 28, 2005 pages 35 to 46 for the details. JCAHO in its September 6, 2006 Sentinel Event Issue 37, is revisiting the potential problems with emergency power systems in hospitals. Unfortunately, to get the level of power that JCAHO is talking about will be expensive in many hospitals as we keep adding more and more items to the critical circuits. I recently viewed a patient monitoring system that was able to share information with any computer in the hospital system without going through a bunch of servers and “special software” that limits what can be distributed. The bedside units could also be connected to other items, such as a ventilator, and sends all the patient data to the hospital data system. Gee, this type of a patient monitoring system was described in the late 80’s and is just coming onto the market, finally a company listened to clinical engineers and is offering what is needed not what has been comfortable for years.

As Clinical Engineers we have the skills and information to move medical care forward but we need to work together better, put out more position papers and get our voices heard in hospital board rooms and in the public forums. This is not an easy task for many engineers, as they are not comfortable in voicing opinions or leading the charge to change policies and procedures. Just think about the time that is wasted in our departments by doing leakage testing, PM inspections on items that cannot be PM’ed, preparing reports that no one reads or understands but “it has always been done” so it continues. While we concentrate on old thinking and processes the present is getting away from us and the future is fading. As Clinical Engineers we need to concentrate on the real problems of safety in hospitals, such as in-service education of staff, having the right equipment where it is needed, getting rid of obsolete technology and techniques and communicating with the professional staff on what they should be looking at when it comes to equipment.

There are hospitals still testing conductive floors even though there have not been explosive anesthesia agents used there in years. That extra work because nobody wants to do the work to declare the OR as explosive agent free and write the memo. The same holds true for LIM’s in non wet areas, redundant grounds, along with other ancient items. Please let us not be like politicians and only deliver 10% of what we say to our clients.

A couple closing points. Starting later this year our colleague Arif Subhan will be writing a column in 24X7 on CCE certification. It will alternate with the one for technician certification. Also please take some time to give the ACCE board and the various committees the benefit of your thoughts on how to promote our profession, what new things we should be looking at and what old things we should move to the back burner.

Have a great fall and remember to vote in November.

Dave Harrington
dharrington@techmed.com

Little Additions to the ACCE Family

Congratulations to ACCE Member Kelley Harris on the birth of two beautiful sons on Saturday, August 19th!

Braxton Cole was born at 8:50am and weighed in at 5 lbs 1 oz and 18 in long. Carter Anthony was born at 9:02am. He weighed 5 lbs 11 oz and 18.5 in
The ACCE Healthcare Technology Foundation has been working diligently on many projects. Following is a compilation of recent press releases summarizing our progress.

New Officers

The ACCE Healthcare Technology Foundation has elected new officers. The new officers include president Wayne Morse, president of Morse Medical, Mercer Island, WA; vice president Jennifer Ott, director of clinical engineering at St. Louis University Hospital, St. Louis, MO; secretary William Hyman, professor of biomedical engineering, Texas A & M University, College Station, TX; and treasurer Henry Montenegro, director of clinical engineering, St. Mary's Medical Center, West Palm Beach, FL.

“We’re delighted that the success plan we put into place is now taking hold and that the foundation has completed its first two publications designed to increase patient safety,” said Yadin David, immediate past president and director of biomedical engineering at Texas Children’s Hospital.

Clinical Alarms White Paper

Clinical alarms that warn hospital personnel of patient problems aren’t as effective as they could be because of an unacceptable number of false and nuisance alarms, the complexity and number of alarms in the patient care environment, inadequate training of hospital staff and a lack of alarm system standardization.

These and other findings appear in the first educational white paper published by the ACCE Healthcare Technology Foundation, formed in 2002 by the American College of Clinical Engineering.

The paper, available on the foundation’s website after September 21, 2006 (www.acce-htf.org) was prepared by a task force headed by Tobey Clark, director of instrumentation and technical services at the University of Vermont, and Yadin David, director of biomedical engineering at Texas Children’s Hospital. The efforts of the task force were also supported by experts from ECRI, who shared their experiences and contributed to the written document.

“We think the effectiveness of clinical alarms could be improved if medical device manufacturers, clinical engineers, clinicians, risk managers and standards agencies worked together on alarm system design, better integration into the clinical environment, standardization and user training,” Clark said.

The white paper includes a review of clinical alarm-related literature, analysis of adverse event data, summaries of forums held at national meetings, and results of a wide reaching survey on the state of clinical alarms in healthcare.

Although improvements have been made in the design of alarm mechanisms, best practice guidelines and caregiver training, problems with clinical alarms have continued, the report says. The Food and Drug Administration (FDA) Manufacturer And User Device Experience (MAUDE) adverse event database has shown an increase in the number of death and serious injury reports with the term “alarm” in the problem description. Further analysis of valid FDA MAUDE reports points to the need for operator education and training.

The task force acknowledged that alarms are addressed in a number of voluntary medical device standards, but that there is no global harmonization of alarm enunciation criteria based on priority or parameter.

“IEC/ISO standards for alarm systems represent an improvement in design and should be considered for implementation in the U.S.,” the paper noted. “Standardization offers the opportunity to eliminate some elements of confusion over what different alarms mean, as well as how they are operated.”

The ACCE Foundation completed a survey of clinical alarm use in January 2006 with 1,327 respondents, with more than half being registered nurses. A large portion of the respondents identified false and nuisance alarms as a significant problem which occur frequently, disrupt patient care, reduce trust in alarms and cause caregivers to sometimes disregard them.

“At a minimum, false alarms are distracting and can interfere with clinicians effectively performing other critical tasks. They also contribute to nurse desensitization to alarms, such that alarms for ‘real’ events are less likely to catch the attention of staff. Some amount of false and nuisance alarming is inevitable,” the paper states. “Mitigating the problem posed by them lies in the hands of both device manufacturers and clinicians.”

Furthermore, healthcare organizations and clinicians should recognize the limitations of alarm systems and utilize them only as a tool in the overall assessment of patient condition, the task force said. Hospitals must recognize the complexities of clinical alarm management and devote the necessary resources to develop effective management schemes. Clinicians should also take an active role in learning how to use equipment safely over its full range of capabilities.

“Effective education and training must take place to better understand proper

(Continued on page 6)
ACCE 2006 Membership Survey Summary

The American College of Clinical Engineering initiated this survey to assess membership satisfaction with the current offering of programs and services. The survey also measured membership interest and support for current programs while collecting suggestions for future development.

The results of the survey will be used to make recommendations to help ACCE increase or maintain membership awareness of and satisfaction with our current and future programs.

The survey was built using questions from previous surveys to cover the specific areas of membership status, activities and issues, the Healthcare Technology Foundation, collaboration with other professional organizations, and communications to membership. This year, a survey on Clinical Engineering Certification was submitted separately and those results are not included in this report.

Using the service SurveyMonkey (www.surveymonkey.com), the 2006 ACCE Membership Survey was distributed to members in May of 2006. Users were provided the link to the online survey through email correspondence and by using a link on the organization’s website. Data was collected until June 15, 2006.

The survey contained rich information that will help the organization to meet needs of the membership. Overall, 22% of our membership responded. Factors such as too little time for the survey and not enough advertising of the survey contributed to the small response sample.

There seems to be continued interest in fostering the relationship with IT organizations. This is evident in the free text responses, attendance at HIMSS, and suggestions for the teleconference series. Other IT-related interests are with networking medical devices and interoperability.

There seems to be an interest to get more involved. Members are most interested in getting involved with ACCE’s international activities, whether through the committee or through the Advanced Clinical Engineering Workshops. Medical Equipment Donation Guidelines as a teleconference topic suggestion also supports the focus on ACCE’s international leadership role.

Medical Errors and Patient Safety initiatives are also important to our members. This is evident in the support for the Foundation’s mission, the request for more safety-related materials on our website, and a teleconference topic on the subject, “CE Role in Patient Safety Goals, JCAHO; Human Factors applications in CE/Healthcare” as well as risk management which has a direct connection with many safety programs.

One underlying theme is the desire for more cross-fertilization with other healthcare-related communities. While IT, International Activities, and Medical Errors continue to dominate our members’ interests, it is noteworthy to mention that our members are attending several clinical conferences. AARC – American Association for Respiratory Care, ASA- American Society of Anesthesiologists, and AACN – American Association of Critical-Care Nurses are just three examples of such conferences. They are also looking to our website for more white papers and published information. This suggests that ACCE should continue to focus on our goal of providing educational resources for our members so that they can continue to provide clinical engineering services to their community.

Detailed results of the membership survey are available online on the ACCE website (http://www.accenet.org).

Jennifer Jackson, ACCE President Elect

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Healthcare Technology Foundation Update Continued

(Continued from page 5)

operation, the implications of misconfiguration or defeating alarms, and the limitations of current alarm systems,” the task force said.

The task force’s future actions will be to distribute the white paper via print and website publications, authoring related articles in nursing and clinical engineering journals. It will also call for a forum of all constituents involved in clinical alarms

**Home Medical Devices**

Can I bring my own medical device with me to the hospital?

That question and others commonly asked by anyone with an apnea monitor, infusion pump or other medical device are answered in a new brochure from the ACCE Healthcare Technology Foundation.

Published as part of a public education outreach by the nonprofit foundation, the brochure available as of September 21, 2006 to prospective hospital patients at www.acce-htf.org.

The brochure notes that most hospitals have rules about bringing medical devices to the hospital from home, but that they will work with patients to determine whether an individual’s device can be safely used in the hospital.

The brochure also addresses such questions as: What is the process for accepting my device, will I need my doctor’s permission, will the hospital maintain my device, what about non-medical devices?

The brochure is one of two new publications by the foundation, formed in 2002 by the American College of Clinical Engineering. It is available in English and Spanish.

Jennifer Ott, AHTF Secretary

Jennifer.ott@tenetstl.com
Board Highlights—September/October 2006

August and September were transitional months for the ACCE Board. The August meeting kicked off with a vote to accept the Board election results. Shortly after the election results were approved, we were sad to receive Kelley Harris’ letter of resignation from the position of secretary for personal reasons. We congratulate Kelley on the birth of her twins and look forward to her future contributions to ACCE! During the September meeting, Barbara Maguire was appointed to the position of Secretary to fill the vacancy for the remainder of the term. Welcome, Barbara!

The Board also reviewed the criteria for the new ACCE/HIMSS ‘Excellence in Clinical Engineering and Information Technology Synergies Award.’ The Board discussed how the potential increase in membership applications (nominees must be members of both HIMSS and ACCE) will impact the membership committee. The Board voted to move forward with this award and will support the membership committee and its new chair, Jennifer McGill, as needed.

The Board also discussed revisiting the memorandum of understanding with the World Health Organization to make sure that Advanced Clinical Engineering Workshops are prepared with enough advanced notice and administrative support to ensure a safe and effective trip for the ACCE faculty.

Dave Smith, our new Advertising Manager submitted a draft of a letter and application inviting companies to join our community as supporters by buying advertising space. The Board reviewed these materials and the advertising rates and decided to move forward with this exciting campaign.

ACCE received the proposed contract to participate in AAMI 2007 in much the same way that we participated last year. The Board discussed the contract and reviewed our expenses from this past summer’s events. Steve Grimes, ACCE President, will follow up with AAMI to discuss potential changes to the contract and bring the results back to the Board and to the membership.

These have been an exciting two months of transition preceded by a wonderful year as ACCE Secretary. Thanks to everyone who made this a wonderful year and I hope to improve my contributions to ACCE this year as President-Elect.

Jennifer Jackson, ACCE President Elect

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Electrical Standards Updated

ANSI/AAMI ES60601-1:2005, Medical electrical equipment –Part 1: General requirements for basic safety and essential performance is the third edition of the electrical safety “bible” for medical equipment. This newly updated national standard for the safety of electrically powered medical equipment is part of the continuing effort by AAMI (Association for the Advancement of Medical Instrumentation), ANSI (American National Standards Institute), IEC (International Electrotechnical Commission) and various other US and international standards organizations to harmonize (i.e. bring as much commonality as possible to) electrical safety requirements that have historically varied dependent on which standards were referenced and where.

New information in the updated standard can be grouped into three categories:

1) a requirement that specific tasks and analyses be performed in compliance with a risk management system (ISO 14971);

2) two distinct levels of safety requirements are listed; one for patients and one for users depending on who is coming in contact with the device, and;

3) latitude in design for meeting the safety requirements. It states “Equipment or parts thereof having forms of construction different from those detailed in this Standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained…”

Although the updated standard moves toward harmonization, there is a table labeled “US Deviations” that lists where the US version and the international version still differ. For example, the IEC (International Electrotechnical Commission) concept of “touch” leakage current to indicate those leakage currents that can be contacted by users and/or patients by touching an enclosure and therefore, are potential hazards to the users and/or patients is used throughout the standard. The standard for enclosure touch currents is 100 microamps for patient equipment in normal condition, 500 microamps for a single fault condition (e.g. open ground wire) in the international version and the US “deviation” lists this requirement as 300 microamps. There are a few other US deviations in order to comply with the National Electrical Code (NEC).

There are many other editorial and technical changes to this standard in order to make it conform closer to IEC 60601-1. Also, note that there are some jurisdictions that reference other specific safety standards for electrically powered medical devices that have not yet been changed (e.g. NFPA 99). It is expected that eventually all these other standards will be harmonized with the new ANSI/AAMI standard and the “deviations” will continue to dwindle.

More information is available on the AAMI website http://www.aami.org/standards.

Ted Cohen, ACCE Member at Large, ACCE Newsletter co-editor
The 2006 ACCE Educational teleconference Series continues:

10/19/2006
Patient Safety; Incident investigation and reporting.
Glenn Scales from Duke University Medical Center will lead a presentation on incident investigations, reporting of incidents, sharing of the recommendations and their implementations.

11/16/2006
The impact of wireless implementations on patient safety in healthcare.
Rick Hampton from Massachusetts General Hospital will present on wireless implementations in healthcare and their impact on patient safety.

12/14/2006
Emergency Planning.
Yadin David of Texas Children’s Hospital and Douglas Dreps, Memorial Hermann Hospital will help clinical engineering staff better understand their role in emergency preparedness planning and will be based on experience gained from operating before, during and after an extraordinary natural disaster at two hospitals in Houston, Texas.

1/18/2007
Economical impact on clinical engineering.
Wayne Morse of Morse Medical, Inc. will discuss the needs of the present and future healthcare system.

2/15/2007
Radiology – Latest developments in PACS.
Todd Starnes from Catawba Valley Medical Center will review the latest developments in PACS. The speaker will address the interconnection of PACS with other clinical applications in healthcare.

These teleconferences are held the 3rd Thursday of each month at 12 Noon Eastern Time (9:00AM Pacific Time etc). Unless otherwise noted, the teleconferences are one hour long, typically a 45-50 minute presentation followed by 10-15 minutes of Q and A. Registrants will receive the call-in number and presentation material prior to each session.

The cost for each Teleconference is $150 per site. This allows for four (4) participants from each site, each additional participant is $10. If nine (9) teleconferences are purchased the tenth one is at no additional charge.

In addition, each registrant receives a CEU certificate from the University of Arkansas for Medical Sciences for each session they participate in.

Audio CCE Review Course
ACCE is offering the CCE Review Course on CDs. This review was taped live at a recent five-session, 8-hour CCE Review Course. The review course was presented by a faculty of clinical engineers who have broad experience working in hospitals, independent service organizations, consulting, government, and industry. Major topics of the CCE examination are reviewed by a subject specialist.

The Audio Course includes:

- 8-Hour Review on Audio CDs (including Q&A from the audience)
- Power Point Presentations
- Reference Material for the examination
- Sample Questions

The topics covered in the course are:

1. Introduction to the CCE Exam
2. Management
   - 2.1 Overall CE Program Management
   - 2.2 Financial & Service Contract Management
   - 2.3 Technical Supervision
   - 2.4 CMMS
3. Technology Assessment
   - 3.1 Product/Vendor Selection
   - 3.2 Capital Planning
   - 3.3 Clinical Trials Management
   - 3.4 Building Plan Review
   - 3.5 Building Design
   - 3.6 Human Factors
4. Regulatory/QA Issues
5. Risk Management/Safety
6. Education
7. Product Development
8. Repair/Systems Thinking
9. Miscellaneous Clinical Engineering topics

The Audio Course is available for $300 (ACCE members) and $345* (nonmembers). For more information or to purchase please contact Alan Levenson at secretariat@accenet.org

*Special ACCE Membership Offer – Purchase the audio course and receive ACCE Membership at 25% discount. You need to qualify for ACCE membership and complete the application form. See the membership section at www.accenet.org for details.

ACCE-Teleconference Series
5200 Butler Pike
Plymouth Meeting PA 19462-1298
http://www.accenet.org
Calendar of Events

- November 18, 2006
  CCE Written Exam
  Various US locations

- January 15-19, 2006
  IHE North America Connectathon
  Chicago, IL

- February 25—March 1, 2007
  HIMSS 2007
  New Orleans, LA

- June 16-18, 2007
  AAMI 2007
  Boston, MA

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ACCE Clinical Engineering Certification Study Guide

The American College of Clinical Engineering has completed a Study Guide for the Clinical Engineering Certification examination offered by the Healthcare Technology Certification Commission established under the ACCE Healthcare Technology Foundation. The Study Guide is available through ACCE for $30. To order a copy of the Guide, please make out a check payable to ACCE and send to:

Alan Levenson, ACCE Secretariat
5200 Butler Pike
Plymouth Meeting, PA 19462

Or e-mail Secretariat@ACCEnet.org and include credit card information (name on card, type of card, card number, and expiration date). Applications are now being accepted for the November 2006 exam. Applications and the applicant handbook can be found at www.ACCEnet.org/certification.

The ACCE Study Guide was written by an independent group of clinical engineers not associated with the exam process.