GUIDELINE FOR CONVERGENCE OF CLINICAL ENGINEERING AND INFORMATION TECHNOLOGY

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PREAMBLE

- Clinical Engineering was developed in the healthcare environment by applying engineering principles for the safe use of medical devices. Clinical Engineers pioneered medical maintenance and safety programs, evaluated new technologies and their appropriate use, and ensured that the medical technology lifecycle was managed at a competitive cost.
- Medical equipment technology has shifted from stand-alone systems built on discrete components, to systems centered on microprocessor-based components and industry standard operating systems. This new generation of medical devices continues to integrate with enterprise level information systems, and in many cases becomes enterprise systems as in the case of PACS (Picture Archiving and Communication Systems). These developments present new challenges for both clinical engineers and information technologists regarding system reliability, performance, and patient safety.
- As they have over the years, clinical engineers must continue to use their unique skill sets for shaping the application of new technologies to the healthcare environment. Clinical engineers must learn skill sets normally belonging to information technologists. Conversely, information technology experts may acquire skill sets in the field of clinical engineering.
- In summary:
    - Medical device systems have evolved from being vendor specific proprietary solutions to integrated network-attached systems with the capability to send and receive patient data with IT systems. Thus, the boundary between Biomedical Technology domain and Information Technology domain is blurred.
    - The Electronic Medical Record (EMR/EHR) initiatives that many health care institutions are undertaking are driving us towards an increasingly integrated medical device environment. We must begin to view patient monitoring and medical devices as part of a larger, enterprise wide information system.
    - The trend towards “paperless and filmless”, as well as a variety of medication safety initiatives, are accelerating the rate of medical device integration over the shared network infrastructure, both wired and wireless
    - Clinical systems and applications using medical device interfaces are life-critical (life-support, life-critical, care-critical), with specific requirements for infrastructure availability and performance (i.e. closed-loop medication systems, robotic surgery, imaging-guided surgery).
    - Regulatory scrutiny of clinical information systems and software-enabled medical devices is increasing along with medico-legal risks.
    - Care delivery models are changing very rapidly (“The Home as Hub of Health Care” see IEEE article, http://www.ieee.org/portal/site/tionline/menuitem.130a3558587d56e8fb2275875bac26c8/index.jsp?&pName=institute_level1_article&TheCat=2201&article=tionli

ne/legacy/inst2006/jul06/fd2h2.xml&), along with consumer expectations and the rapid evolution of new medical devices primarily driven through the adoption of consumer technologies.
    - Clinicians have developed a great trust and reliance on biomedical and information technology, and the people who manage that technology, to provide care for their members and patients.
    - Clinical Engineers have a responsibility to act with a sense of urgency, professionalism and unity to maintain and grow that trust, by upgrading our education and skills to reflect the changes in the care environment, as well as educating our Information Technology colleagues about clinical systems, medical technology assessment, and patient safety considerations.

QUALIFICATIONS

- Qualified Clinical Engineer (see ACCE definition of Clinical Engineer, ACCE web site, http://www.accenet.org/default.asp?page=about&section=definition). Clinical Engineers and Information Technologists working as a team to implement clinical information technology.
- Unique skill sets required for Information Technology and Clinical Information systems
    - Clinical workflow knowledge appropriate for the clinical application being deployed. For example, knowledge of the workflow activities of nursing and intensivists in the critical care environment for critical care information system.
    - Clinical Engineer should be conversant with the information technology terminology involved with applications programming, networking and infrastructure, databases, etc.
    - Clinical Engineer should have a working knowledge of clinical information and computer based applications as well as the clinical practice of the impacted clinical department.

GUIDELINES

1. Education and Training
    - Networks and network architecture; database platforms and architecture; device interface including a working knowledge of network infrastructure (LAN, WAN, VLAN, VPN, etc) as well as the 7 layer OSI model (see http://en.wikipedia.org/wiki/OSI_model, link to source document for ISO Standard 7498-1:1994 and other useful references).
    - Real-time data issues (e.g. timing, bandwidth, frequency response, etc).
    - Standards: HL7, DICOM, IHE, et al.
    - RF and wireless communications including spectrum management, WMTS, 802.11 a, b, g, h, bluetooth, and security standards (WEP and WPA).
    - HIPAA and data security/confidentiality.
    - High availability techniques including UPS, RAID, hot swappable components, remote access and tools, etc.

2. Background including work experience
    - Knowledge and experience with enterprise architecture; understanding of quality of service requirements for clinical IT infrastructure.
3. Personal experience including working with and implementing clinical information technology systems
    - Knowledge and experience with the impact of clinical information technologies on clinical workflow; sensitivity to criticality and impact of the application on patient care; understanding of the need for reliable and clearly constructed application support infrastructures.
4. Role within organization working with information technology department(s)
    - Clinical engineering should take an active and prominent role in implementation of information technologies impacting areas traditionally served by biomedical engineering supported medical devices. As medical devices become more integral to the clinical IT applications, the integration of Clinical Engineering and IT becomes more critical to successful implementation.

REFERENCES

APPROVAL DATE (ACCE board): 6/16/07

REVIEW DATE

ADDENDUM

IT

- **Enterprise IT Infrastructure focus including deploying and managing large scale and complex computing environments**
- **Technology and information systems assessment and planning**
- **Business system background, staff typically come from non-medical industries**
- **Manage IT system lifecycle for facilities, member support, and EMR support**
- **IT Departments have a broad IT knowledge-base but medicine is a new field for many. Unfamiliar with the differences between medical & non-medical devices in regard to patient care and medical safety standards.**

Biomed

- **Clinical environment focus including deep understanding of hospital setting, clinical systems, clinical roles, processes, priorities**
- **Biomed system technical assessment and planning**
- **Close, long-standing ties to clinicians; are tightly integrated with hospital processes**
- **Manages lifecycle of diagnostic, ED, OR, bedside and outpatient technologies**
- **Familiar with federal & state medical safety regulations: [FED] JCAHO, HIPAA, FDA, NFPA, etc. [STATE] e.g. Title 22 (CA), State Safe Minimum Electrical Standards.**

Similarities

- From the outside Biomed and IT systems may look alike
- Biomed systems use many of the same computing components as IT systems
- Biomed systems may run on the same OS as IT systems
- Biomed systems are no longer standalone, they are networked
- Biomed systems may even send and receive data from IT systems
- Biomed systems are frequently hosted in the same facility computer room

Differences

- Biomed systems are selected based on their ability to meet clinical requirements
- The best Biomed solution may not conform to IT standards
- Biomed systems interact directly with patients to provide care
- Biomed systems are strictly regulated by FDA; small changes may affect FDA certification
- Biomed Hours of Operation may be different from IT's
- The impact of Biomed systems failure can range from clinical disruption to loss of life
- Failure can truly be a matter of life-and-death