



The premier industry event
for healthcare technology
management professionals
and clinicians

The Business Operations of Clinical Engineers

Sunday, June 7, 2015 | 10am-11pm

Thomas Judd, MS, PE, CCE

The Differences between Japanese CEs and American CEs

Kaiser Permanente Clinical Technology
ACCE (American College of Clinical Engineering)

Who are US Clinical Engineers

- **Profession by the title of Clinical Engineer (CE)**
 - Coined in mid 1960s by Cesar Caceres, MD, later AAMI Board member
- **American College of Clinical Engineering began in 1990**
 - *"A Clinical Engineer is a professional who supports and advances patient care by applying engineering managerial skills to healthcare technology."* - ACCE Definition, 1992, see <http://accenet.org/>
- **Education**
 - Typically has at least a baccalaureate (4-year) degree in engineering or engineering technology from an accredited college or university
 - Of ACCE Individual members*, 60% have masters or doctoral degrees
- **Certification & Licensing**
 - CE Certification desirable after 3 years of experience; 31%* have CCE
 - Licensing as a professional engineer (PE) not required

US Clinical Engineers



Number*

- US CEs est. 20,000
- ACCE members ~800

Work Place**

- Hospitals 70%
- Consultant 15%
- Industry 10%
- Academia 5%

*Sources: [PayScale.com](https://www.payscale.com), Bureau of Labor Statistics, and CNNMoney research, 2012

**ACCE Body of Knowledge (BOK) 2010 Survey re Health Technology (HT) Definitions & Practices

US CEs: Activities & Knowledge Base

In the US, by many other health professionals operate clinical equipment: e.g., Nurses; Cardiovascular, Respiratory, Dialysis, Lab, and Radiologic Technologists, etc.

Categories of CE Work

% Time

- | | |
|--------------------------------------|------|
| 1. HTM | 32.2 |
| 2. Service Delivery Management | 16.8 |
| 3. General Management | 10.7 |
| 4. Education of Others | 10.6 |
| 5. Risk Management / Safety | 10.6 |
| 6. CE-IT (Information Technology) | 8.0 |
| 7. Testing, Evaluation, Modification | 4.9 |
| 8. Facilities Management | 4.7 |
| 9. Other | 1.2 |

CE Knowledge Category

- | |
|---|
| 1. Physiological Monitoring |
| 2. General Med./Nursing Equipment |
| 3. Surgical Equipment |
| 4. Computers, Networking, IT |
| 5. Presentation Skills |
| 6. Anesthesia |
| 7. Medical Imaging |
| 8. Respiratory Therapy |
| 9. Management Theory |
| 10. Medical Terminology, Anatomy/Physiology |

Source: ACCE Body of Knowledge (BOK) 2010 Survey

US CE BOK Categories of Work Defined

Health Technology Management (HTM)

- Technology, Usability/Compatibility assessment; Product & vendor selection
- Device integration planning, Life cycle analysis, Device / system upgrade planning
- Return on investment (ROI) analysis, HT strategic planning, Capital planning
- Coordinating device interoperability / interfacing, Clinical systems networking,
- Project management, Interpretation of codes and standards
- Clinical trials management (non-investigational), EMI / RF (wireless) management
- Clinical devices use and / or application, Pre-Clinical procedure set-up / testing, Participation in clinical procedures (e.g. surgery)
- Water quality management, lab, dialysis, pharmacy

Service Delivery Management (SDM)

- Technician/ service supervision
- Service contract management
- Equipment repair and maintenance, Equipment acceptance & performance testing
- Develop test/calibration/maintenance procedures
- Computerized maintenance management system (CMMS) Administration
- Parts/supplies purchase and/or inventory management
- Technical library/service manuals management

US CE BOK Categories of Work, cont.

Product Development, Testing, Evaluation, & Modification

- Medical device concept development / invention
- Human factors engineering, Medical device design
- New product testing and evaluation, Device modifications,
- Research and development, Product sales / sales support,
- Product / systems quality management, Regulatory compliance
- Documentation development / management

Information Technology (IT) / Telecommunications (aka CE-IT)

- Help Desk / dispatching / call tracking
- IT management, Telecommunications management
- Integration of medical device data

Education of Others

- Technician education
- Engineering education
- Device user / nurse training
- Develop / manage staff training plan,
- International HTM education

US CE BOK Categories of Work, cont.

Facilities Management

- Building design, Building plan review
- Medical gas system testing
- Supervise / manage / direct facilities management operations
- Facility / utility remediation planning, Emergency electrical power
- Facility emergency preparedness activities

Risk Management/Safety

- Patient safety, Expert witness, Risk Management
- Forensic investigations, Medical device incident reporting
- Root cause analysis, Failure mode effects analysis
- Product safety / hazard alerts / recalls, Incident /untoward event investigations
- Investigational Research (Human Use), Radiation safety
- Fire protection and safety planning,, Infection control, Industrial hygiene
- Work place safety practices, Hazardous materials
- Engineering assessment of medical device failure

General Management

- Staffing, Staff skills / competency assessment
- Budget development / execution, Revenue producing activities
- Personnel management / supervision
- Performance improvement / CQI, Policy/procedure management/development
- Committee management
- Business / operation plan development / management

Funding Mechanisms for CE Programs

- **Japan**

- Largely based on national Medical Insurance Fund reimbursement for clinical equipment operation;
- and to a lesser extent on service delivery management (SDM) activities

- **US**

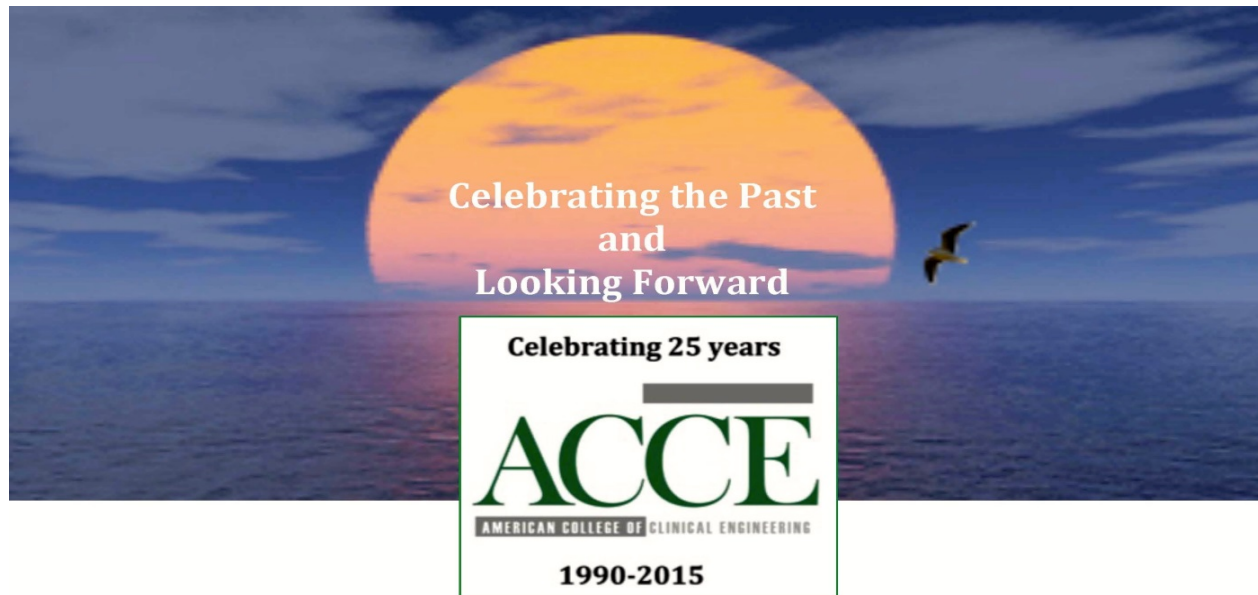
- Largely based on service contract elimination through use of in-house CE / SDM services, as well as wise use of HTM activities leading to efficiencies in care delivery, value additions to hospital budgets and cost reductions

Typical activities of ACCE

(American College of Clinical Engineering)

ACCE: Certification System

- The Certification in Clinical Engineering (CCE) system begun in the 1970s today is under ACCE oversight.
- The CCE process – for applicants with the right mix of education and experience – involves written & oral exams on the CE BOK topics introduced earlier, of a clinical, technical, and managerial nature.
- A key purpose of certification is to demonstrate the CEs clinical competence - e.g., ability to partner with physician and nursing leaders to improve patient care quality and safety - as well as to enhance the CEs ability to manage complex technologies through their lifecycle alongside hospital business leaders, at best possible cost.



Expanding the horizons of clinical engineering practice since 1990

ACCE <http://accenet.org>

- Addresses national health technology (HT) & health IT (CE-IT) concerns
- Partners with other health leaders to improve patient safety
- Over 700 individual leaders as well as 20 organizations, including over 150 internationals from nearly 40 countries
- 60% of our membership is 40 years old and younger as we continue to grow and to attract younger members
- Historical strong US educational role; often for leading edge topics and venues
- Created Advanced CE/HT workshops in 1991, with WHO-PAHO, now provided over 50 week-long seminars to developing country leaders from > 70 countries

Typical ACCE HTM Seminar

- HT Policy & Regulations (HTR)
- HT Assessment (HTA)
- HT Management (HTM)
 - Service Delivery Management (SDM)
 - Computerized SDM (aka CMMS)
 - Managing Donated Equipment
- Patient Safety, Risk Management, Use Error
- Healthcare Facilities & Medical Devices
- Human Resources Development (HRD)
 - Education
 - Professional Societies & Certification
- Emerging eHealth and CE-IT Issues

