CLINICAL ENGINEERING

Definitions

- Biomedical Engineering
  - Solving problems in biology and medicine using engineering methods and technology (e.g., research, design and development of biomedical instrumentation.)
- Clinical Engineering
  - Application of engineering methods and technology to the safe and effective provision of health care.

Definitions

- Technology
  - Broad class of related procedures and systems used to perform a common function. (e.g., Computer technology performs the function of data processing.)
  - Equipment
  - Specific device within a class of technology. (e.g., Macintosh or IBM PC)

Clinical Engineering

- Mission:
  - Ensure the safe and effective application of technology to patient care.
- Customers:
  - Clinical staff and patients.

Functions of Clinical Engineering

- Technology Planning (project management)
- Technology Assessment
- Acquisition and Application of Technology
- Equipment Control
- Preventive and Corrective Maintenance
- Service Contract Management

Functions of Clinical Engineering

- Development of New Technology
- Facility Planning and Development
- Safety and Risk Management
- Continuous Quality Improvement
- Education
- Clinical Equipment Application

Technology Planning

- What types of technology are best suited to satisfy the program needs of this facility?
- What are the future technology requirements?
- What technologies are under development? How will they impact patient care?
- How can technology be better utilized to improve patient outcome, control costs and improve productivity?

Technology Planning

- Continuing Education
  - Professional Journals and Newsletters
  - Professional Societies
  - Internet
  - Seminars and Conferences
- Awareness of Program Needs
  - Frequent communication with users
  - Involvement with technology related committees
- Awareness of Technology Resources
  - Equipment Control Program

Technology Assessment

Definition:

- Assessment of medical technology (devices, drugs, procedures, & systems)
  - Safety
  - Clinical effectiveness
  - Cost effectiveness
  - Ethical (e.g., reproductive technologies)
  - Legal

Technology Assessment

- Given one or more competing technologies, which is the most appropriate and cost effective for a particular clinical application?

Technology Assessment

Clinical Engineering Role:

- Information gathering
- Information dissemination
- Facilitation

Acquisition and Application of Technology

- What equipment do we need to do the job?
- Is it commercially available?
- Which of the available models is best?
- How much will it cost to buy? To operate?
- Where will it go? Will we need to renovate?
- Who will use it? Will they need training?
- Who will service it?
- How often will it need to be serviced?
- When will we need to replace it?

Acquisition and Application of Technology

- Needs Assessment
- Environmental Assessment
- Translation of Clinical Requirements into Technical Specifications
- Research
- Technical & Functional Evaluations

Acquisition and Application of Technology

- Recommendation and Purchase
- Incoming Inspection
- Add to Equipment Control Program
- Installation
- User Education

Equipment Control

- What equipment is in the hospital? (make, model, serial#)
- Where is it?
- Who does it belong to?
- Is it safe?
- Is it reliable?
- Is it effective?
- How is it utilized?

Equipment Control

- Is it easy to use?
- How frequently is it utilized?
- Is it time for replacement?
- What service procedures have been performed, when, what parts were used, how much did it cost?
- How frequently is preventive maintenance and performance assurance performed? What P.M. procedures are performed?

Preventive and Corrective Maintenance

- In-house or external service?
- Warranty management
- Level of in-house service (board level, component level)
- Corrective-maintenance service process
- Service facility (size, location, etc.)
- Size of technical staff

Preventive and Corrective Maintenance

- Staff training
- Staff organization
- Parts inventory
- Test equipment
- Equipment manuals & documentation
- Diagnostic software

Preventive and Corrective Maintenance

- Vendor support
- Frequency of PMs
- Scheduling
- PM procedures
- Service reports
- Billing rate

Service Contract Management

- In-house, vendor, third-party, maintenance insurance?
- Provisions of service contracts
- Service contract negotiation
- Monitoring and documentation service contracts
- Cost analysis

Development of New Technology

- Needs assessment
- Research
- Design and specification
- Prototype construction, testing and evaluation

Development of New Technology

- Construction, testing and documentation of final assembly
- Regulatory approvals
- User education
- Clinical trials, modification, documentation and reporting
- Add to equipment control program

Facility Planning and Development

- Specifying equipment requirements
- Liaison between contractor and hospital
- Project planning and management
- Ensure conformance to relevant codes & regulations

Safety and Risk Management

- Remain current on all pertinent codes & regulations
- Interpretation of codes & regulations
- Implementation and enforcement of codes & regulations
- Maintain system for responding to published equipment hazard reports

Safety and Risk Management

- Reviewing requests for new technology as to safety and effectiveness
- Identification of potential hazards
- Assessing degree of hazard protection required in relation to size of risk
- Preventing technological change when risk unwarranted or effectiveness not demonstrated

Safety and Risk Management

- Incident investigation and reporting
- Maintain incident database.
- Safety policy development
- Development of safety education programs
- Representation on hospital safety committee
- Liaison with manufacturers
- Liaison with hazard reporting agencies (ECRI, Government)

Continuous Quality Improvement

- Identify customers
- Identify and measure improvement needs
  - Identify critical processes
  - Identify quality indicators
- Examine problems and analyze the causes
- Decide on solutions and action plans to achieve them
- Implement proposed solutions, measure and evaluate
- Adopt and standardize improved processes

Education

- Education of Clinical Engineering
- Education of Clinical Staff
- Education of Patients
- Partnership with local Clinical Engineering Technology Programs

Education of Clinical Engineering

- Attend relevant conferences and seminars
- Attend vendor service courses
- Participate in Clinical Engineering professional associations (Alberta Clinical Engineering Society)
- Read clinical engineering magazines and journals
- Remain current on developments in medical technology (vendor contacts)

Education of Clinical Staff

- Development of in-service education programs
- User training on new equipment
- Annual refresher courses for clinical staff
- Informal user assistance and training
- Documentation of user training
- Education of clinical staff on new developments in medical technology

Education of Patients

- Provide in-service education to patients responsible for the operation of medical devices

Training Partnerships

- Advise local Clinical Engineering Technology programs on curriculum content
- Assist with training
- Provide hospital internship program

Clinical Equipment Application

- Provide assistance with set-up and operation of technically complex medical devices
- Assist clinicians with application of medical technology in tertiary care areas (ICUs, Diagnostic areas, and ORs)
  - Dialysis
  - Intraaortic Balloon Pump
  - Lasers & Electrosurgery

Evolution of Clinical Engineering

- Level 1 (1970-1978)
  - Associated with Physical Plant
  - Electrical safety
  - Corrective maintenance of basic electromedical equipment
  - Initiation of PM program
  - Equipment Control Program initiated
  - Initial involvement in equipment acquisition process

Evolution of Clinical Engineering

- Level 2 (1978-1984)
  - Center for hazard and recall network
  - Incident investigation
  - Significant involvement in acquisition process
  - Initial involvement in outside service contracts

Evolution of Clinical Engineering

- Level 3 (1984-1989)
  - Reports directly to administration
  - Computerized equipment control program with productivity and cost analysis capability
  - Maintenance of more sophisticated technology including medical imaging and clinical lab.

Evolution of Clinical Engineering

- Level 4 (1989-1993)
  - Integration of CQI/RM into technology management
  - Comprehensive service contract management
  - Computerized ECP with extensive analysis capability
  - Active participation in equipment planning and facilities development

Evolution of Clinical Engineering

- Level 5 (Future Projection)
  - Technology Assessment
  - Strategic Technology Planning
  - Integration of Clinical and Information Technologies
  - Home Care technology management
  - Increasing clinical involvement

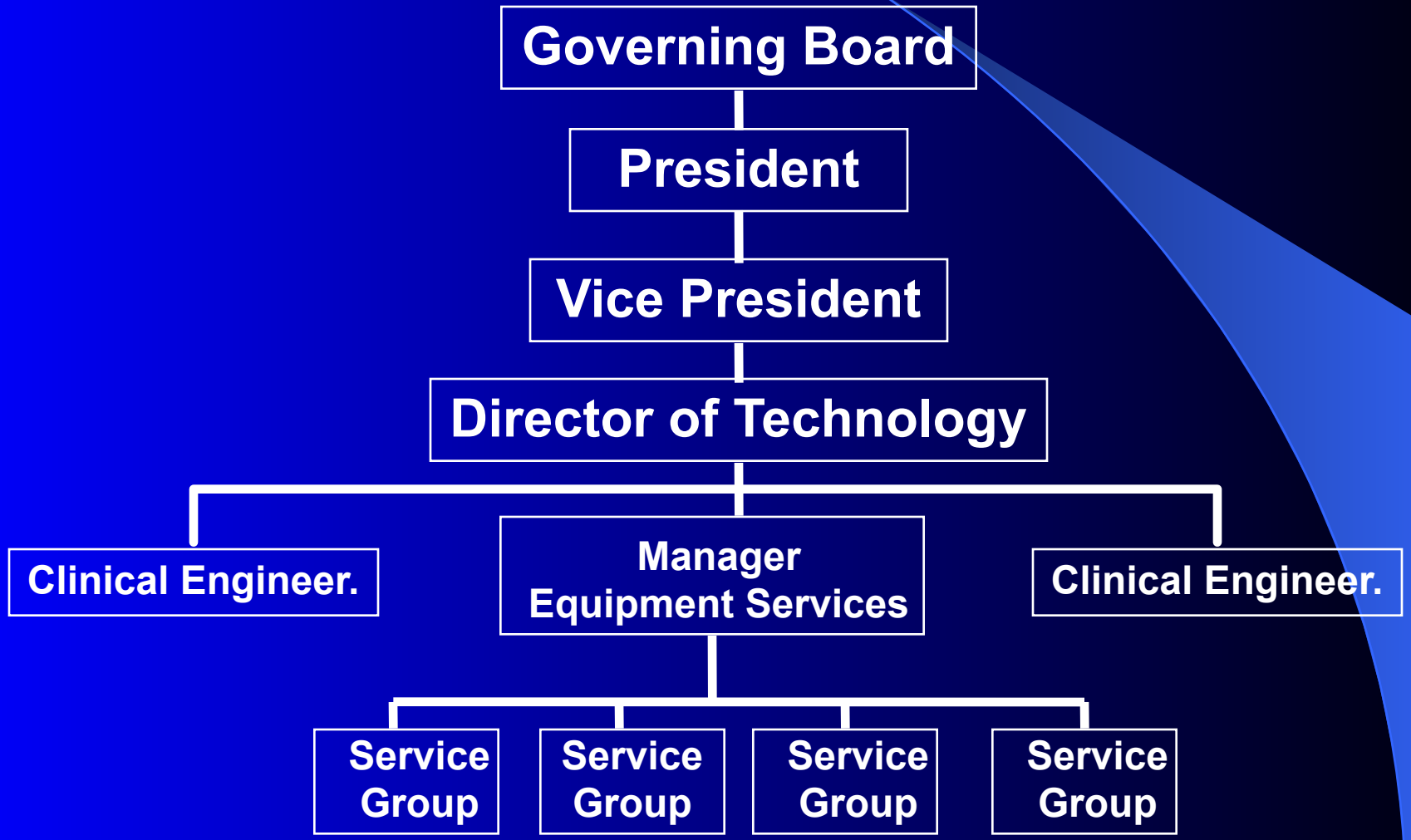
Clinical Engineering Program Structure

- Historically a function of Physical Plant
- A modern CE program should
  - report directly to administration
  - have autonomy (i.e., own personnel, capital equipment and operating budgets)
- Political strength with administration and medical staff is essential to accomplish program goals

Clinical Engineering Program Subdivisions

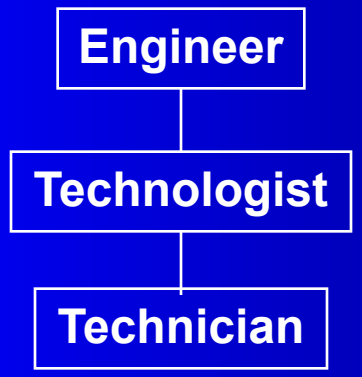
- Risk management/CQI
- Technology Planning and Assessment
- Technology Development
- Technical Support Services
  - Clinical Laboratory
  - Diagnostic Imaging
  - Medical Instrumentation Group 1
  - Medical Instrumentation Group 2
  - etc.

Clinical Engineering Program Structure

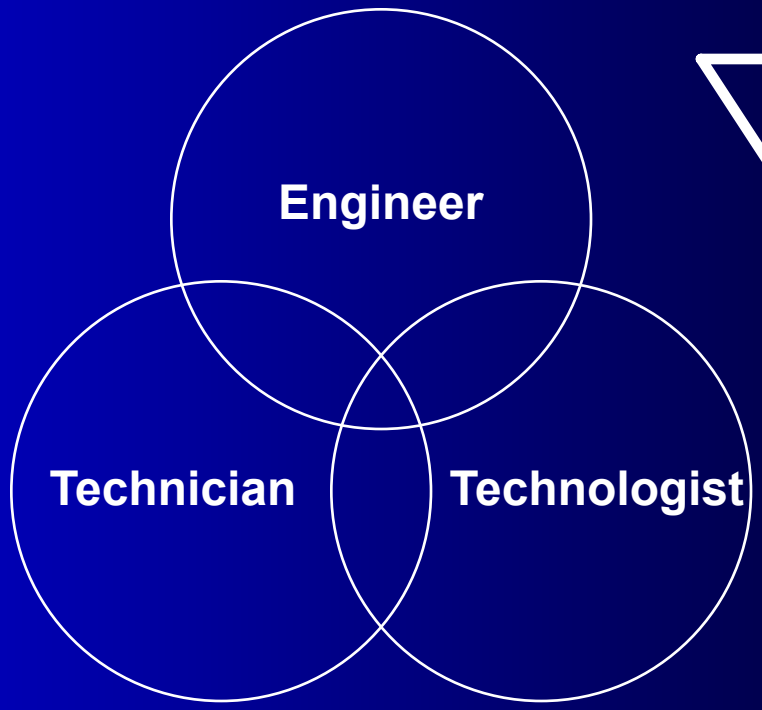


Engineer vs. Technologist vs. Technician

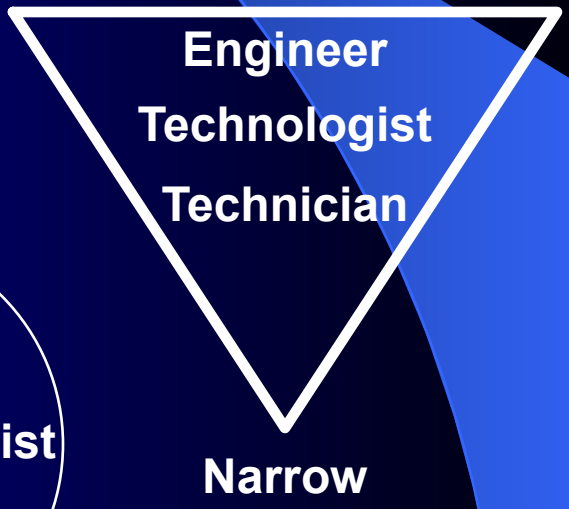
Administrative Model



Functional Model



Educational Model



Centralized vs. Distributed Service

- Centralized Service Advantages
  - Lower cost
  - Increased efficiency
  - Prevents duplication of function and personnel
  - Common resource and knowledge base
- Centralized Service Disadvantages
  - Lack of individual department control

Equipment Specialist vs. Generalist

- Specialist Advantages
  - Staff are more capable
  - More efficient
  - Job gets done faster
- Specialist Disadvantages
  - Staff are less flexible
  - No cross-training
  - Department is vulnerable
  - Uneven workload distribution

Single Team vs. Multiple Team (Area Specialization)

- Multiple Team Advantages
  - More efficient
  - Improved familiarity with equipment and users
  - Clear identification of responsibility by clinical staff and CE staff
  - Ownership (pride in work)
  - Accountability
  - Improved communication between clinical staff and CE staff

Single Team vs. Multiple Team (Area Specialization)

- Multiple Team Disadvantage
  - More vulnerable
  - Technologist may become bored with same range of equipment
  - Uneven workload distribution

Factors Causing Change in CE Program Structure

- Regionalization of Support Services
- Medical Program Rationalization
- Patient Focused Care
- Competition (private service organizations)
- Fee-for-service model