CLINICAL ENGINEERING

OVERVIEW

Definition

Clinical engineering is a relatively new profession. The term *clinical engineering* was coined by Cesar A. Caceres, M.D. in 1967 to describe a George Washington University Medical School program in which he envisioned engineers and physicians working together to provide better patient care. This program, which was not medicine, engineering, nor statistics, contained elements of all of these disciplines. As the program focus was to be patient oriented, he chose to couple the term *clinical* with *engineering* to describe it, so as to distinguish it from the research-oriented activities of biomedical engineering (1).

In 1992 the American College of Clinical Engineers (ACCE) defined a clinical engineer as "a professional who supports and advances patient care by applying engineering and management skills to healthcare technology" (2). The Clinical Engineering Board of Examiners of the International Certification Commission for Clinical Engineering and Biomedical Technology endorses this definition.

Environment of Patient Care

At the heart of clinical engineering is the concept of providing engineering expertise to ensure that the environment of patient care (EC) is safe for both patient and clinician. Medical equipment used for patient care comprises a large part of this environment. It must be safe, efficacious (performing the function for which it was intended), and cost effective. Clinical engineers are the professionals who provide technical support services to ensure this. Their knowledge is invaluable to health-care provider institutions, such as hospitals, nursing homes, clinics, medical and dental offices, and ambulatory care centers.

Clinical engineers are trained in engineering principles, basic sciences, the life sciences and patient-care principles. They are knowledgeable of regulatory agency requirements, health-care codes, and medical equipment standards. This diverse body of knowledge and experience enables clinical engineers to understand how technology and patient care interact within the clinical setting (3). This knowledge is vital when medical equipment is integrated into the environment of patient care. It allows clinical engineers to interface medical systems to the patient, and to other medical systems including those used for data collection (4).

Employment

Primarily employed by health-care provider institutions (as part of in-house or shared-service clinical engineering departments), clinical engineers are also employed by original equipment manufacturers (OEM), third-party independent service organizations (ISO), independent testing laboratories, clinical engineering consulting firms, regulatory agencies, technical publishing houses, law firms, and academic institutions.

Clinical engineers hold positions in management, engineering, medical equipment sales, equipment test and evaluation, field service, health-care regulation, technical publishing, and education. They serve as expert witness of patient incidents and provide input to legislative bodies. They also serve on curriculum advisory committees on which clinical engineers from both industry- and hospital-based clinical engineering programs sit, allowing curriculum to keep pace with the most recent industry trends.

Biomedical Equipment Technicians

Closely associated with clinical engineers are biomedical equipment technicians (BMET). BMETs are skilled technicians who are specially trained to work with medical instrumentation. Although BMETs focus their activities on the repair and maintenance of medical equipment, they are called on to inspect, install, and modify medical devices, as well as to provide guidance in proper equipment usage and safety. Some take on managerial responsibility, supervising other BMETs.

Education

Clinical Engineering. As a minimum, new practitioners in clinical engineering require a bachelor of science degree in engineering. This degree should be obtained from an institution that is accredited by the Accreditation Board for Engineering Technology (ABET).

Formal clinical engineering curricula are offered by colleges and universities. Bachelor's, master's, and doctoral degree programs are available in biomedical and clinical engineering. The important difference between the curriculum for these programs and the curriculum for other engineering disciplines is the mix of engineering and life sciences that it offers. Included are traditional engineering courses (electrical, mechanical, chemical, computer engineering), as well as courses in the physical sciences, life sciences (biochemistry,

biology, physiology, and anatomy), mathematics, humanities, and management (5).

It is also possible to enter the clinical engineering field with a traditional bachelor of engineering degree (such as electrical engineering) and then acquire the necessary life sciences knowledge by taking supplementary courses, on-the-job training, and self-study.

Clinical engineers are qualified to pursue advanced degrees in such diverse fields as medicine, law, business administration, health-care management, and technology assessment.

It should be noted that prior to formal degree programs becoming available in the 1970s, early leaders in the field entered with backgrounds in the physical sciences or life sciences and are considered to be "grandfathered" into the profession.

The following sources of information are useful (6) :

Directory of Engineering and Engineering Technology: Undergraduate Programs from the American Society for Engineering Education

Peterson's Guide to Undergraduate Programs in Engineering and Applied Sciences

Peterson's Guide to Graduate Programs in Engineering and Applied Sciences

Biomedical Equipment Technician. BMET education leading to an Associate in Applied Science Degree (AAS) in Biomedical Engineering Technology is offered via seven accredited programs in the country. One such two-year program is offered by the State University of New York, College at Farmingdale. This program provides balanced course work in electricity and electronics, chemistry, physics, physiology, and biomedical engineering technology. Students have the option of continuing their education an additional two years earning a Bachelor Degree in Electrical Engineering Technology (7).

Continuing Education

Expositions. The environment in which clinical engineering functions changes daily as new technologies such as telemedicine, robotics, and wireless local area networks (LAN) are introduced into the clinical setting. In this dynamic field continuing education is the rule. One method of obtaining this education is by attending technical expositions and professional organization meetings. The Association for the Advancement of Medical Instrumentation (AAMI) and the American Society of Healthcare Engineering (ASHE) hold meetings and expositions that expose attendees to the latest medical instrumentation being introduced into the marketplace. The pulse of the health-care industry can be sampled in a relatively short time by attending roundtable discussions and member and industry presentations. Courses are provided in regulatory requirements, medical devices, instrumentation repair and maintenance, clinical engineering and BMET professional certification preparation, and clinical engineering management. Technical information is also presented at monthly meetings of the Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society, as well as local clinical engineering and BMET organization meetings.

Service Training. As new medical equipment is acquired, employee technical knowledge must be updated with regard to its operation, preventive maintenance, and servicing. Training is available from the manufacturer or from independent schools. Training can sometimes be included in purchase requisitions and request for quotations (RFQs) for new equipment. Service training not only benefits the clinical engineer and BMET involved in maintaining this equipment, it also benefits the equipment user each time clinical engineering is called on to assist them with equipment-related questions. Formal service training can be expensive. In addition to tuition there are travel and lodging expenses. To supplement, but not replace service training, clinical engineering staff can attend equipment operator training provided by vendors for clinical users of medical equipment, within their own institution. Training can also be obtained using the expertise available within the clinical engineering department (Fig. 1).

Self-Study. Formal training can be supplemented with self-study of technical journals, periodicals, and trade publications, as well as equipment operator and service manuals, VCR training tapes and computer-based training programs. A clinical engineering library provides an invaluable tool for the clinical engineering staff and for other health-care workers (physicians, nurses, laboratory technicians) to whom clinical engineering services are provided. Libraries could include technical video, equipment operator and service manuals, and technical publications (books and magazines). Such material also allows staff to keep pace with changes in regulatory requirements and biomedical standards.

Safety Training. Employee right-to-know and safety training that discusses the hazards encountered in the workplace is also necessary. This includes subject matter related to blood-borne pathogens, hazardous materials, proper protection when entering patient-care areas (gloves, masks, etc.), environmental hazards, fire hazards, patient's bill of rights, and other items. The latest trend makes use of interactive computer program modules. This allows training at a time convenient to the employee and no longer requires attendance at lengthy seminars.

Certification

Certification is provided for clinical engineers [Certified Clinical Engineer (CCE)] and biomedical equipment technicians [Certified Biomedical Equipment Technician (CBET)] by examining boards guided by the International Certification Commission for Clinical Engineering and Biomedical Technology. The Commission is composed of health-care community members including engineering, medical, industrial, and governmental groups and agencies. Certification provides formal recognition that an individual has mastered a body of knowledge that is useful in job performance. This knowledge, which is both theoretical and practical, includes theory of operation of medical equipment, physiological principles, and safety issues related to medical equipment (8).

Clinical engineering certification requires passing a written exam (multiple-choice and essay questions), and an oral interview, aimed at determining the candidate's depth and breadth of experience. BMET certification requires passing a written multiple choice examination. The Association for the

Figure 1. In-service education, ventilator tester. Inservice education can be provided by manufacturers and vendors, as well as by clinical engineering staff. Here a clinical engineering supervisor is providing training to other clinical engineers in the use of an automated ventilator tester. Such devices are used during preventive maintenance and repair. They reduce the number of individual test instruments required as they integrate several test functions into one device. This reduces service time leading to more rapid equipment turnaround. Such education also helps to satisfy JCAHO training requirements for clinical engineering staff.

Advancement of Medical Instrumentation (AAMI) assists candidates by providing certification training courses and study materials.

Certification renewal requires demonstration of continued training. Points are assigned and accumulated for various activities that contribute to one's ability to do his job.

Ethics

Confidentiality. Working in a health-care environment, clinical engineers and BMETs have access to information that must be kept confidential. If confidentiality is not adhered to credibility is soon lost.

For example, the following applies

Patient data must not be indiscriminately discussed.

Some service manuals are proprietary.

During the bid process in which new equipment is being purchased, bidder quotes and bid evaluations must not be shared with competitors.

Research activities must not be discussed until data are published.

Code of Ethics. The ACCE addresses these and other issues in their code of ethics (2), which states that a clinical engineer will act as follows:

- Strive to prevent a person from being at risk of injury due to dangerous or defective devices or procedures.
- Accurately represent my level of responsibility, authority, experience, knowledge and education.
- Reveal any conflict of interest that may effect information provided or received.
- Protect the confidentiality of information from any source.
- Work toward improving the delivery of health care to all who need it.
- Work toward the containment of costs by better utilization of technology.
- Promote the profession of clinical engineering.

Professional Organizations

Participation in professional organizations exposes a clinical engineer and BMET to the latest industry trends. These organizations provide up-to-date information, the sharing of ideas, and networking. National, regional, state, and local organizations exist.

National organizations include:

Association for the Advancement of Medical Instrumentation (AAMI)

American Society of Healthcare Engineering (ASHE)

American College of Clinical Engineers (ACCE)

Institute of Electrical and Electronics Engineers (IEEE), Engineering in Medicine and Biology Society

Instrument Society of America (ISA)

HISTORY

Mid 1960s–1970s

Clinical engineering's great impetus for growth occurred in the 1970s. This came about as follows.

Equipment Problems

During the mid-1960s the medical device industry as a whole did not yet have adequate performance or safety standards. Equipment designers were not fully familiar with the requirements of the hospital environment. Equipment design defects included inadequate energy from defibrillators, ungrounded equipment chassis, and alarms that could be falsely triggered. Quality control was also poor as evidenced by physiological monitors that were grossly out of calibration and equipment

that was cracked, broken, or missing components. New medical equipment that was purchased and delivered in supposedly ready-to-use condition was found to have incidence of defects ranging from 25% to 50% (9).

At this time the dangers of microshock and leakage current were starting to be recognized and discussed. Of special concern was the medical equipment used for coronary care and the procedures used to maintain this equipment.

Ralph Nader

Ralph Nader raised national consciousness about accidents that could occur in hospitals as a result of poorly designed or faulty medical equipment. His article in the March 1971 *Ladies Home Journal* claimed that "too many hospitals are hazardous electrical horror chambers." To eliminate these dangers, Nader suggested that hospitals hire engineers to provide advice on electrical equipment and its installation, as well as on electrical wiring (10). As a result, the clinical engineering profession was spurred forward as hospitals hired additional staff to test their equipment and verify electrical safety. This was also the beginning of independent service organizations (ISO), which provided an alternative to original equipment manufacturer (OEM) service. Nader's claims have since been refuted (11).

Kellogg Foundation. The W. K. Kellogg Foundation (established in 1930 to help people improve their quality of life by providing grants to solve identifiable problems) addressed the need for improved equipment maintenance prior to the Nader article when it funded the nation's first experimental preventive maintenance (PM) program for hospital equipment. A three-year grant starting May 1, 1970 was awarded to the biomedical/clinical engineering department of the State University of New York's Downstate Medical Center. The Downstate Medical Center has since changed its name to the Health Science Center at Brooklyn, University Hospital of Brooklyn. The department, the Scientific and Medical Instrumentation Center (SMIC) established in 1963, one of the first biomedical/clinical engineering programs in the nation, is still active today. The Kellogg Foundation also funded the nation's first shared clinical engineering program in 1972, the Northwest Ohio Clinical Engineering Center. The center provided equipment maintenance, consultation, and educational services to hospitals in that local (12,13).

Response of the Joint Commission on the Accreditation of Healthcare Organizations. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) also responded to the apparent need for additional safety testing. Their 1974 standard required quarterly leakage testing for electrically powered equipment. Their April 1976 *Accreditation Manual for Hospitals* required hospitals to establish comprehensive instrumentation programs that included preventive maintenance programs with written records of inspection testing and corrective action taken. It also required all new patient-related equipment to be evaluated for proper performance before being used clinically (9). The JCAHO requirements further hastened the establishment of in-house clinical engineering departments that strove to satisfy these requirements as well as to improve on manufacturer-provided maintenance.

During the 1970s professional organizations such as AAMI and ASHE became more prominent. They sought to promote safer use of medical equipment. AAMI and the National Fire Protection Association (NFPA) issued standards for leakage current and grounding, which further promoted electrical safety testing of medical equipment (14,15).

1980s

Medical Equipment Advances. During the 1980s medical equipment became more sophisticated. Designers utilized devices, techniques, and technologies that had been developed and then filtered down from NASA and military contract work and also focused more on safety. Included were ultrasound imaging techniques, charge-coupled devices (CCD) first used in spy satellites now used in endoscopic cameras, solid-state electronics, integrated circuits, denser multilayer board packaging, microprocessors, and dedicated computers. Health care became more equipment-dependent. The number of medical devices purchased increased, and sophisticated medical programs and procedures grew in number. The services that the clinical engineer was requested to provide expanded from just maintenance, repair, and safety testing of medical equipment to include activities now considered to be part of an equipment management program, namely patient incident investigation, medical device regulation reporting, equipment planning, and new equipment acquisition. This further increased the demand for clinical engineers.

Modification of Inspection Requirements

As the economics of health care started to change and funding became more scarce, the JCAHO modified its PM inspection frequency requirement, reducing it from quarterly to semiannually. This was done to reduce the cost of compliance to health-care institutions. In 1988 JCAHO introduced risk-based management. This allowed institutions to create more realistic PM programs. Gone was the requirement that all electrically powered equipment had to be tested regularly. AAMI and NFPA electrical leakage test parameter specifications also became less stringent.

1990s

Running Health Care as a Business. During the 1990s the effects of managed care, reductions in Medicaid and Medicare reimbursements, state budgetary problems, university budgetary limitations, and cutbacks in research funding all came to a head, putting tremendous financial pressure on health-care institutions. Institutions seeking ways to cut costs and remain competitive formed alliances, merged (16), and investigated the out-sourcing of support services including clinical engineering. These economic pressures often resulted in reduction of full-time employees (FTE) throughout the health-care institution, including within clinical engineering departments, necessitating reexamination of clinical engineering core services. Outsourcing provided further opportunity for third-party ISO to expand. The importance of running health care, including clinical engineering as a business, became the new paradigm (17).

CLINICAL ENGINEERING IN HOSPITALS

Resources

Health-care facilities of varying size tailor their clinical engineering programs to satisfy the needs of their own specific environments, while striving to meet regulatory requirements such as that of the JCAHO. For example, community hospitals with less sophisticated health-care systems tend to require less clinical engineering services than tertiary care teaching hospital centers.

The depth and breadth of services that clinical engineering can provide are directly related to the personnel and financial resources allocated to it. Smaller clinical engineering departments must select services that are feasible for them to provide, that is, concentrating their efforts mainly on the very core elements of equipment management such as PM and repair. As many clinical engineering services are geared toward risk reduction, each institution must realize that by choosing to limit these services, they are at the same time increasing their risk exposure and the possibility of lawsuits.

Institutions that cannot afford in-house programs turn to shared services in which several neighboring institutions share their specialists, or to independent service organizations.

Report Structure

An institution's structure determines to whom clinical engineering reports. Some clinical engineering departments report to facilities engineering and are grouped with other engineering services. Some report to hospital administration. Others, viewed as university departments, report to a university vice president. Generally, the higher up in the reporting structure, the more resources are made available to clinical engineering. The department status is also more credible. These resources include staff allocation, other-than-personnel service funding (OTPS), and physical plant space.

Department Structure

Full service clinical engineering departments could include clinical engineers, BMETs, machinists, equipment designers and prototype builders, and possibly an optics specialist (for lasers, microscopes, and other optical devices). The technical staff is supplemented by administrative, secretarial, and clerical staff. Such departments have the capability to be involved in sophisticated equipment maintenance and repair, equipment modification, and research activity.

Staff Duties. The director responsible for all managerial aspects of the department interfaces with hospital administration and other departmental managers both local and national, and sits on institutional committees. The director negotiates on behalf of the institution with vendors, manufacturers, and other service providers. He or she sets the course for the department, adopts policies that provide cost-effective quality service, and tracks industry trends and standard practice to benefit the institution. The director also ensures compliance with regulatory and investigatory agency requirements.

The administrator, a key position, handles personnel issues, as well as matters related to financial analysis, budgets, billing, tracking of capital equipment purchases, and supervision of the secretarial and clerical staff (Fig. 2).

The clinical engineering managers are responsible for ensuring smoothness of day-to-day operation, assigning jobs, managing on-call and recall, providing engineering consulta-

Figure 2. Administrative support, purchase order processing. The clinical engineering administrative function including secretarial support is critical to a successful department. The administrator serves a key function and is heavily involved in tracking the institution's clinical capital equipment purchases and clinical engineering's own purchases. The administrator is also involved in budget preparation, monthly financial report analysis, and preparation of clinical engineering annual reports. Shown here, purchase requisition information is being reviewed to assure timely processing so as not to delay equipment service. Such delay loses income for the hospital.

tion, and in-service education. They also assist in setting standards, policies, and procedures.

The clinical engineers are involved in acceptance testing, PM, repair, on-call and recall, providing emergency assistance, design and prototype construction, and in-service education.

The BMETs are primarily responsible for performing PM, repair, and calibration of equipment, per procedures set by clinical engineers.

The clerical staff assists with data entry and documentation filing.

Job Titles. *The Journal of Clinical Engineering* conducts an annual nationwide survey of salaries and responsibilities for hospital biomedical and clinical engineering and technology personnel (18). This survey includes a set of generic titles and generalized job descriptions that provide a convenient industry overview. These titles follow:

Jr. BMET
BMET
Sr. BMET
Equipment Specialist [Laboratory (RES) or Radiology (RES)]
BMET Supervisor
Clinical Engineer (CE)
Clinical Engineer Supervisor
Director or Department Manager

Goal and Responsibilities

Goal. A hospital-based clinical engineering department's goal is to support its institution in its mission (typically patient care, education, and research), and while so doing ensure the safety and efficacy of the hospital's medical instrumentation. This goal is achieved by providing appropriate technical services. These services can range from the basic maintenance, calibration, and repair of medical equipment, to the more sophisticated research activities of design and development of medical equipment and devices usually associated with biomedical engineering, thus resulting in some overlap between these two disciplines (Fig. 3).

Equipment Responsibilities. Clinical engineers apply engineering and management principles to issues that relate to medical equipment's entire life cycle. They help determine what equipment to purchase and how long it is cost-effective to keep this equipment in service, and when to turn to newer technologies. Such guidance saves hospitals money and reduces liability.

Clinical engineers manage a diverse group of medical devices located throughout their institutions. This includes instrumentation used in cardiology, intensive care, clinical laboratory, respiratory therapy, anesthesiology, neurology, physical therapy, ultrasound, and the operating rooms. Some clinical engineering departments also provide service for x-ray or ionizing radiation devices used in radiology, radiation therapy, or nuclear medicine that are typically managed by radiation physics staff. Others may service purely mechanical devices such as stretchers, hospital beds, and wheelchairs, but these are usually managed by facilities engineering.

Clinical engineers provide emergency instrumentation troubleshooting expertise. This can take place within an operating room during cardiothoracic surgery, a patient-care area (Fig. 4), or in a researcher's laboratory during animal experimentation. Typically clinical engineers do not operate the medical equipment or select levels of treatment (i.e., balloon pump inflate or deflate timing), or give fluids to or take

Figure 3. Research design and development, optical tomographic system. Research activities enhance a clinical engineering department's image and keep the staff current with the latest technological developments. Special-purpose devices that are not available commercially or are cost prohibitive are constructed. A team with diverse expertise in electronics, mechanics, electromechanics, and physiology is required. A precision machinist plays a prominent role. Shown, a positioning device is being modified for incorporation into an optical tomographic laser system, which one day may prove as clinically beneficial as MRI.

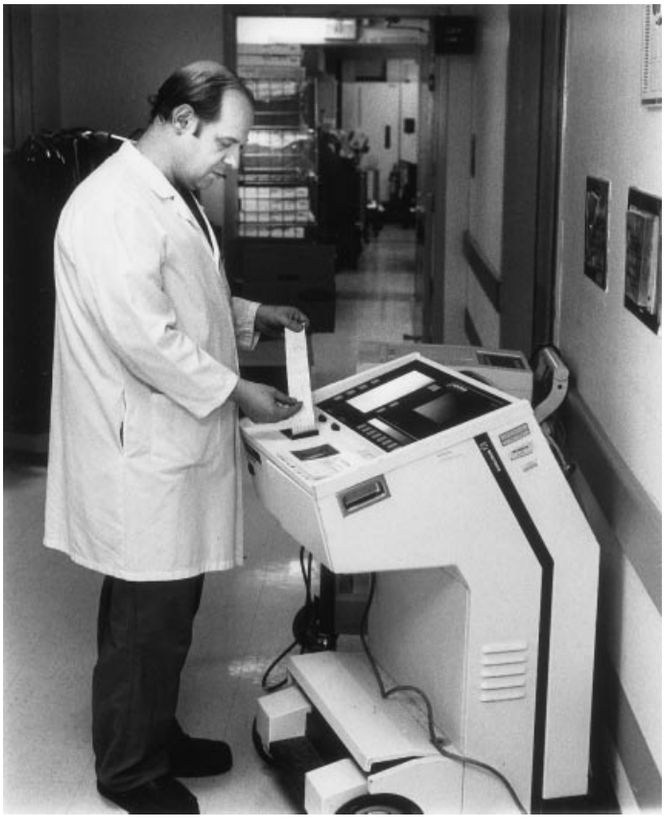

Figure 4. Emergency support, balloon pump. Clinical engineering plays a key role in providing emergency support to troubleshoot and answer questions relating to equipment operation and capability. Here a clinical engineer is running a test to assure that a balloon pump located outside a Cath-Lab is functioning properly. This device provides support to critically ill patients by reducing their heart's workload until it strengthens. Balloon inflate/deflate timing and mode of triggering assure optimal patient assistance.

fluids from patients (i.e., cell saver). This is left to clinical specialists, perfusionists, and licensed technicians specially trained for these purposes. However, clinical engineers do provide instrumentation troubleshooting expertise during these procedures and provide guidance on the operation and performance of the equipment.

Typically clinical engineers do not maintain the physical plant. They deal with medical equipment external to the walls. This equipment may require connection to utilities including electricity, gases, and water, as well as to other electrical systems that may not fall within clinical engineering's domain [e.g., patient line isolation monitors (LIM) within headboards or nurse call systems which interface with bedside monitor alarms]. Knowledge of the physical plant and such systems is, however, helpful especially during equipment selection and installation, when analyzing the cause of equipment failure, and when setting policies for equipment use during utility failures. A useful reference guide is the National Fire Protection Association (NFPA) Health Care Facilities Handbook (15).

Changing Responsibilities. As health care changes, some hospital-based clinical engineering departments are starting to investigate the feasibility of providing a broader range of services. They are becoming areas of excellence for items that were previously outside their domain, including x-ray devices, computers, telecommunications, and nurse-call systems. Some also take on risk management and many clinical engineering departments have technology assessment responsibilities.

Clients

As a service department, clinical engineers interface daily with staff from most other departments and entities within a health-care institution, all of which are considered to be clinical engineering clients. A partial list includes facilities engineering and planning, hospital administration, cardiothoracic surgery, central sterile, expenditures, contracts, risk management, OPD administration, clinics, clinical laboratories, ambulatory surgery, pharmacy, surgery, anesthesiology, off-site satellite clinics, clinical areas, nursing units, the personnel department, purchasing, and cardiology. Interaction between researchers and educators also occurs.

Committees

Clinical engineering participation in committees is important for a successful clinical engineering program. It provides clinical engineering with greater exposure to other hospital departments and administrators and vice-versa and provides information about how the department is doing which supplements the formal survey process. Equipment-related problems and questions voiced allow clinical engineering to provide immediate feedback to the clinical user. This keeps open and improves channels of communication between clinical engineering and their clients. It allows clinical engineering to become essential members of the multidisciplinary team of health care delivery and have an input on decisions relating to that delivery. It also allows trends to be spotted that clinical engineering staff may be unaware of, for example, equipment that is down but was not yet formally reported to clinical engineering.

Committees include:

Safety committees such as safety and laser safety.

Clinical committees such as neonatal interdisciplinary, special care units, adult critical care, cardiopulmonary resuscitation (CPR), infection control, and the Institutional Review Board.

Equipment-related committees such as capital acquisition, product standardization, and sole source (some of which may be chaired by clinical engineering).

Quality assurance and investigatory planning committees such as clinical departments, quality assurance, and those related to JCAHO such as Environment of Care.

Ad hoc special committees such as those for efficient lighting studies, research activities, year 2000 (Y2K) compliance and so on.

Physical Plant Requirements

To ensure efficient services, clinical engineering must be allocated adequate facilities to allow all clinical engineering functions to be performed. This includes sufficient space to store new equipment delivered, equipment awaiting servicing, and

equipment awaiting delivery back to the user, as well as equipment sequestered because of its involvement in a patient incident. Space must also be adequate to house all of the tools, test equipment, computers, office equipment, parts and if possible a machine shop. As clinical engineering is the central repository of all regulatory-related medical instrumentation history files both active and inactive, adequate accessible storage for them is needed as well as for the equipment operator and service manuals and technical library.

Test space must be such that it allows performance of acceptance testing, PM, and repair. It must contain appropriate electrical power, suction, compressed air, secure gas tank storage, proper lighting, ventilation, sinks, fume hoods, workbenches, and storage cabinets.

Test Equipment, Tools, and Test Fixtures

Required test equipment includes electrical safety analyzers, physiological simulators, oscilloscopes, power supplies, multimeters, ventilator testers, electrosurgery analyzers, waveform generators, photometer or radiometer lightmeters, laser power meters, etc.

Tools required include screwdrivers, pliers, wrenches, drills, soldering stations, etc. A machine shop equipped with a drill, lathe, grinder, and milling machine is useful.

It is beneficial for the clinical engineering staff to construct setups of equipment, which are readily available for equipment testing purposes during acceptance testing, PM, and repair. These devices can sometimes be purchased, but most times they can be put together in-house. All such devices should be inventoried in a test-fixtures manual for ease of access.

Full-Service In-House Department

Service Overview. A full-service clinical engineering department provides a multitude of services. As example, the biomedical/clinical engineering department (Scientific and Medical Instrumentation Center) of the State University of New York, Health Science Center at Brooklyn, University Hospital of Brooklyn has a broad-based clinical engineering program that includes biomedical engineering components such as support for research and education (19).

Its program includes the following:

- Clinical engineering consultation
- Design, construction, and modification of clinical instrumentation and devices including electronic, electromechanical, and mechanical
- Education
- Research and Development assistance
- Patent and grant assistance
- Institutional Review Board (IRB) approval assistance
- Equipment planning for clinical areas and new programs
- Generating reports to administration including clinical capital equipment purchase tracking
- Computerized clinical instrumentation inventory
- Centralized patient-care instrumentation history files
- Centralized instrumentation technical manuals library
- Equipment evaluation library
- Instrumentation pre-purchase evaluation
- RFQ generation
- Purchase requisition review
- Bid evaluation
- Vendor and manufacturer interface
- Coordination of outside services
- Acceptance testing (initial checkout, incoming inspection, incoming test) of new equipment safety, operation, and technical specifications
- Clinical equipment installation coordination and supervision
- Defect resolution and documentation
- User in-service training
- Preventive maintenance test procedure generation and update
- Testing of rental, loaner, demonstration, patient-owned, and physician-owned equipment for hospital use
- Scheduled PM
- Equipment repairs
- Equipment upgrades
- Oversight and evaluation of equipment service contracts
- Emergency clinical engineering support to all patient-care areas
- On-call and recall for critical care areas
- Specialized clinical engineering support dedicated to cardiothoracic surgery
- Quality assurance and risk management
- Regulatory agency survey support
- Equipment related patient incident investigation
- Hazard and recall alert notification
- Clinical engineering participation on hospital and health center committees
- Represent hospital on the University Healthcare Consortium (UHC) Clinical Engineering Council
- Represent hospital in the New York City Metropolitan Area Clinical Engineering Director's group
- BMET internship programs
- NYC Board of Education Substitute Vocational Assistance (SVA) internship programs
- Volunteer training
- Clinical engineering staff and departmental development.

Equipment Modification. At times clinical engineering is called on to modify instrumentation. Modification must not be done indiscriminately. Care must be taken so as not to violate the integrity of the equipment. It is best to limit modifications to external operations. Nonmanufacturer approved internal modifications must be approached with extreme caution and are best not done as they may void warranties and violate FDA guidelines. This includes securing devices to a cart so they will not fall off in transit or be stolen, assembly of devices into working systems, and modification of equipment to allow easier PM. For example, a monitor used in an endoscopic video system may have to be secured to a cart, or, a medication cart may have to be modified to allow its use as a crash cart. Crash carts typically are medication carts that house a defibrillator, suction device, O_2 tank, and supplies. Purchased as separate entities, integration is required. Elec-

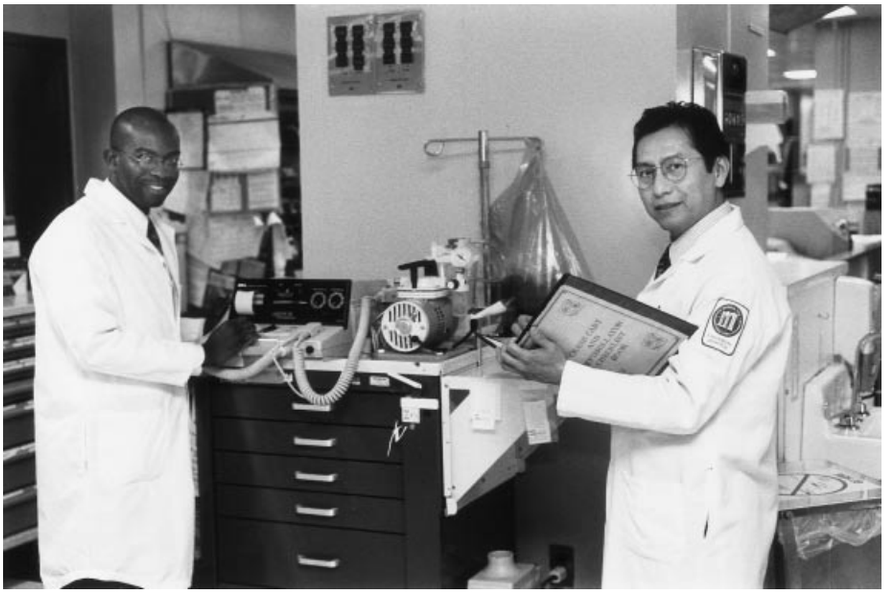

Figure 5. Equipment modification, crash cart. Equipment modification takes many forms and runs the gamut from modifying a specific device to assembling separately purchased components into functioning systems which may not be available commercially, or which must have specific characteristics to satisfy institution requirements. Shown here, a medication cart was modified by clinical engineering to accept an electrical outlet strip and retractable reel (with 25-ft line cord), O_2 cylinder, a defibrillator, and an aspirator so that it can be used as a cardiac arrest crash cart, which is brought to the patient bedside for resuscitation during patient cardiac or respiratory emergencies.

tric reel extension cords, auxiliary power outlets, as well as on/off switches and tie-down straps to prevent defibrillator removal must be added (Fig. 5). Another example is the construction and assembly of an operating room (OR) transport cart connected to the patient bed upon transport from the OR to the Cardiothoracic Intensive Care Unit (CTICU), which houses a ventilator, monitor, defibrillator, and dc to ac supply. An example of a modification that assists in PM is the external provision for a jumper (with manufacturer approval), which when removed allows the backup thermostat of a hyperthermia blanket to be tested, without the need for dismantling the unit. Equipment controls may also be physically constricted so as to prevent inadvertent operator-induced error. Examples include covering of stylus heat adjustment controls (after optimization), limiting rotation of a ventilator alarm control to prevent complete alarm shut-off, and plugging an unneeded ECG sync-pulse phone jack output to prevent its use with a defibrillator as it induces too much signal delay.

Research and Education. Most health-oriented universities with teaching hospitals have education, research, and health care as their mission. Clinical engineering is capable of providing support for all of these goals. Clinical engineering assistance with health care has already been discussed. With regard to education, in addition to providing in-service education, clinical engineers are called on to teach courses in the health-related professions. Clinical engineering support for research activities includes assistance in the selection of experimental equipment, setting up a laboratory, measurement technique, grant writing, patent applications, and IRB approval. Also included are the design, prototype development, and final construction of special-purpose devices that are not readily available commercially or that can be more cost effectively built in-house.

Involvement in research and educational activities are beneficial to a clinical engineering department. These challenging opportunities help to keep the staff technically competent and involved at the forefront of technology. Such activities also bring prestige to the department, enhancing its professionalism and reputation, helping it to gain additional resources.

REGULATORY REQUIREMENTS

It is necessary that clinical engineers become familiar with mandated standards, voluntary standards, accreditation body requirements, and licensing agency requirements that apply to their particular health-care institution and to the medical equipment for which they are responsible. Typical examples are shown below (20). An in-depth list of Biomedical Standards is available in *The Guide to Biomedical Standards* (21).

Voluntary Standards Organizations

- American Association of Blood Banks (AABB)
- American Dental Association (ADA)
- American National Standards Institute (ANSI)
- American Society of Histocompatibility and Immunogenetics (ASHI)
- Association for the Advancement of Medical Instrumentation (AAMI)
- College of American Pathologists (CAP)
- National Fire Protection Association (NFPA)
- Underwriters Laboratories (UL)

Governmental Agency Standards

- Federal Communications Commission (FCC)
- Food and Drug Administration (FDA)

Standards for the Operation of Hospitals

- Local and state requirements, such as the Department of Health
- American Hospital Association
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Joint Commission

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) runs voluntary three-year accreditation programs for health-care facilities aimed at improving the quality of patient care. Information gathered about a hospital can be released to the public. Accredited health-care facilities are eligible to receive federal Medicare reimbursement. Many state governments recognize accreditation as a requirement for licensure and Medicaid reimbursement (22).

The environment of care (EC) in which today's health care is provided is complex. It includes plant facilities, medical equipment, drugs, information, finance, staff, third-party services, and diverse technologies (23). JCAHO is concerned that this environment be managed so as to provide a hazard-free environment that reduces the risk of human injury.

JCAHO requires management programs to be set up that deal with safety, security, hazardous waste, emergency preparedness, life safety, medical equipment, and utility systems. Clinical engineers tend to be most involved with activities that constitute a medical equipment management program, the purpose of which is to promote the safe and effective use of the institution's medical equipment. The medical equipment management program encompasses equipment acquisition, technical management, and education for both equipment operators and maintainers. As part of this program, JCAHO requires clinical engineering to submit periodic reports to the institutions safety committee. Performance standards (quantifying factors relevant to program effectiveness) are developed and selected indicators (activities) such as those dealing with timely PM and repair performance are tracked. Changes observed in the indicators are used to spot and correct deficiencies in the clinical engineering program. The aim of this activity is to improve the quality and cost-effectiveness of the clinical engineering services provided (24).

Safe Medical Devices Act

The Safe Medical Devices Act (SMDA) of 1990 and its 1992 amendment requires health-care institutions to report equipment incidents resulting in serious injury or death to a patient or employee. An institution's risk manager determines whether the incident is reportable, using a documented decision-making process. Medical-device-related deaths must be reported within 10 days to the FDA and to the manufacturer. Medical-device-related serious injuries or illnesses must be reported within 10 days to the manufacturer, or if the manufacturer is unknown, to the FDA. Periodic summary reports are also required. The SMDA also requires that specific medical devices be tracked, and that medical equipment be properly disposed of when it is taken out of service (25,26). SMDA compliance is also a requirement of the JCAHO.

However, as a result of a reform bill, the FDA Modernization Act of 1997, in a few years all hospitals may no longer be required to submit reports to the FDA when patient deaths or serious injuries involving medical devices occurs. Instead the FDA will rely on a small sample of representative hospitals and nursing homes called "sentinels" to collect the data.

Patient Incident Investigation

When a patient incident occurs, incident reports from nursing, physicians, and others are submitted to the risk management department. A clinical engineering technical evaluation is also prepared and submitted. Risk management staff uses this material to determine what caused the incident (e.g., was the equipment at fault or was operator error indicated). The intent of the investigation is to prevent a recurrence and to determine if the incident must be reported under the SMDA of 1990.

Clinical engineering should be notified about an incident as quickly as possible to allow a thorough technical evaluation to be made. Doing so may allow investigation and on-site testing to be done with the equipment setup still intact (making note of how the unit was used, dial settings, etc.) and with peripheral equipment still in place. Subsequently the instrument, accessories, and disposables are taken out of service and sequestered. Further inspection and testing may be required within the clinical engineering laboratories (Fig. 6), or by a third party. Such determination is made by clinical engineering working with the risk manager. The manufacturer should only be contacted with the risk manager's approval. Sometimes during investigation, minor equipment problems are detected, that could not have caused the incident. Prior to repairing these, the risk manager should be consulted to determine the legal ramifications. Determination must also be made as to whether the equipment needs modification to prevent future recurrences. The clinical engineer' report will be important should a lawsuit ensue. For this reason imprecise language must be avoided, so as not to jeopardize the institution's legal position. For legal reasons, the equipment must be stored in a secure location and not put back into service until the risk manager concurs.

User Error; Equipment Abuse; No Fault Found

It is important that clinical engineering workers track service requests whose resolution indicates no fault found (NFF), equipment abuse, or user error. This information should be submitted to risk management for analysis even if patient injury did not result. User errors are typically more common than true equipment malfunctions. JCAHO requires that user errors that have a potential for harm receive the same type of review that hazardous equipment failures receive. Risk management analysis may indicate the need for additional user in-service education to alleviate future problems.

Informal one-on-one training is provided by clinical engineering staff to the user when returning such equipment back to service, by demonstrating the proper equipment operating technique. Through this educational activity clinical engineering helps improve patient care and reduces the possibility of lawsuits.

Hazard Alerts and Recalls

The clinical engineering department acts as the hospital's hazard and recall coordinator. Typically the manufacturer notifies clinical engineering and risk management about recalls and alerts. At other times the clinical engineering department, upon review of commercially available listings, notifies appropriate hospital departments including risk management. Hazard alerts and recalls are available from the FDA, as well as from private publishers such as the Emergency Care Research Institute (ECRI) and Quest.

The clinical engineering department queries the equipment inventory list to locate equipment affected, and when

Figure 6. Incident investigation—fiber optic light. Equipment-related incident investigation is conducted by clinical engineering whenever there is the possibility that a medical device may have caused injury to a patient or clinician. This requires investigation at the scene, as well as additional testing within the clinical engineering laboratories. Picture taking (a digital camera is most useful) documents observations. Clinical engineering staff may also anticipate and resolve equipment problems before they result in an incident. Shown here, an examination lamp bracket was found to not meet the lamp OEM specification, which could result in the lamp being easily dislodged and falling. The bracket manufacturer in coordination with the lamp OEM worked with clinical engineering to resolve the issue and supplied newly designed brackets.

required removes it from service and sequesters it until remedial action is taken. Should equipment retrofiting be required, the manufacturer may choose to provide an upgrade kit with instructions, opt to send a field-service engineer on-site, or require that the equipment be picked up or sent to the factory. Appropriate paperwork must be provided to the institution for inclusion in the instrument's history folders, and entries made into the computerized equipment records. Updated operators' manuals and additional user in-service training may also be required.

MEDICAL EQUIPMENT

Patient-Care Equipment

Equipment used "on" patients or "for" patient care in healthcare facilities is both varied and numerous. It runs the gamut from simple thermometers to sophisticated MRI machines. Equipment used "on" the patient, such as an electrocardiogram (ECG) monitor, is readily visible in the patient's immediate physical vicinity. Equipment used "for" patient care, such as a clinical chemistry analyzer, may be housed in a laboratory at a location remote from the patient. Both types are important when considering the environment of patient care.

Medical equipment falls mainly into three different categories. These categories are diagnostic, therapeutic, or assistive. Diagnostic equipment such as a monitor acquires data and uses transducers to enhance and supplement human senses. Therapeutic instruments such as high-voltage X rays, pacemakers, and defibrillators arrest or control physiological processes affected by disease or trauma. Assistive devices supplement diminished or lost functions, and include life-support (ventilator) and life-sustaining (dialysis unit) devices (27).

The equipment that a typical university hospital clinical engineering department such as the Scientific and Medical Instrumentation Center is responsible for (excluding x-ray or ionizing radiation devices) runs to 10,000 active items. These include capital and noncapital devices. Capital devices are classified as costing greater than or equal to $500 per item. Noncapital devices cost less than $500. To describe this equipment approximately 500 different equipment nomenclatures are used. This alone shows the diversity of knowledge that a clinical engineering staff must have.

Patient Monitoring

Medical instrumentation used for patient monitoring has become quite sophisticated. This microprocessor-controlled equipment provides multiphysiological parameter monitoring with alarm generation and recording capability. It incorporates telemetry, S–T segment analysis, and full physiological parameter disclosure capability (which stores selected waveforms for recall), allowing clinical study of abnormalities. It also includes automatic arrhythmia detection at the bedside, which until a few years ago required a large stand-alone computer housed in a specially cooled room. Using individual personal computers, patient data can also be collected and archived for additional statistical studies.

The patient's physiological parameters are viewed on bedside monitors as well as on remote slave displays. Parameters monitored include ECG, heart rate, respiration rate, cardiac output, noninvasive blood pressure, invasive blood pressures (arterial, pulmonary artery, central venous, etc.), oxygen saturation (S_AO_2), pulse rate, end-tidal carbon dioxide (ET CO_2), and temperature.

In critical care areas, the bedside monitors are hard-wire connected to central nursing stations allowing centralized

Figure 7. Central nursing station. Physiological monitoring has grown quite sophisticated. Patient information gathered at the bedside is routed to a central nursing station providing clinical staff with a comprehensive viewing area. Each central station monitor typically shows waveforms and parameters for four different patients and has the ability to zoom in on a specific patient to show all monitored parameters. Recorders provide documented printouts of alarm conditions including detected arrythmias. Closed circuit TVs visually monitor patient isolation rooms as well. Clinical engineering is involved with the entire life cycle of such equipment from prepurchase selection through acceptance testing, PM, repair, and eventual obsolescence retirement.

viewing at one location (Fig. 7). Nursing stations may be connected together via local area ethernet-type networks, allowing remote patient viewing between nursing stations and sharing of full disclosure equipment. Telemetry information is likewise routed to a nursing station for centralized viewing of ambulatory patients. In this case, the telemetry transmitter takes the place of the bedside monitor, transmitting a signal to an antenna system that routes it to a receiver and display unit.

Equipment Classification; Nomenclatures

Equipment classification nomenclature systems bring order to the vast array of medical equipment presently in use. These systems simplify the gathering and distribution of data relating to medical devices. Complete nomenclature listings are found in ECRI's *Health Devices Sourcebook* (28), and the *Medical Device Register* (29). Another nomenclature system was developed by the U.S. Food and Drug Administration (FDA) as part of its regulatory responsibilities for medical devices. ECRI and the FDA are presently attempting to standardize their two systems.

In the sample nomenclature listing below, note the two ways of listing an ECG monitor.

Cart, resuscitation
Pacemaker, cardiac
Heart rate monitor, ECG
ECG monitor
Diathermy unit

Equipment Inventory List

To be effective an equipment management program requires maintenance of an up-to-date, complete inventory of medical equipment used in the health-care institution. This equipment inventory list helps identify equipment for product recall and hazard alerts, as well as to locate equipment due for PM. As much information as possible should be included for each piece of equipment in the list (30), such as the following:

Unique identification number, which could be a property control asset number, but is usually assigned by clinical engineering and is generally not the serial number
Equipment manufacturer, model, serial number, and description (nomenclature)
Equipment location
Purchase order number
Departmental owner
Service organization responsible for the equipment (in-house, contract, etc.)
Acceptance date, when approved for clinical usage
Warranty expiration date
Equipment acquisition cost
PM frequency and PM procedure number to be used
Additional information the organization believes useful for proper equipment management

Equipment Records

Equipment history files are maintained to provide information for equipment management and technology assessment purposes, as well as to satisfy regulatory requirements. When equipment is taken out of service and is disposed of, its history file should be maintained for a minimum of three additional years (31), or longer if an institution's legal council or risk manager deems it necessary. This will offer the institution some protection in the event that a patient incident lawsuit is initiated at the time of equipment disposal, of which clinical engineering or risk management is unaware. Records for equipment involved in patient incidents are usually sequestered by the risk manager so as to avoid possible tampering.

ELECTRICAL SAFETY

Ongoing Testing

Medical equipment is tested for electrical safety throughout its lifetime. Baseline tests are run during acceptance testing. Tests are also run during PM, following equipment repair, upgrade, or patient incident. The measurements are recorded and compared to previous readings. Changes indicate possible electrical degredation that must be investigated to eliminate electrical hazards before an incident can occur. Training of equipment users in electrical safety concepts is also important.

Electrical Safety Analyzers. Electrical safety analyzers are used to determine that electrical devices, ac receptacles, and conductive surfaces meet required safety standards and are safe for use. These solid-state instruments incorporate true rms measurement capability. They allow testing of portable medical equipment and fixed (hard-wired) installations. Internal circuitry [AAMI test load (14)] simulates the human body's impedance to current flow. The measurements made are representative of the leakage currents (if present), which could flow through the body. Normal and reverse polarity tests, as well as current source tests, are run (32).

Micro- and Macroshock

Electrical safety as related to medical instrumentation concerns itself with limiting the amount of electric current allowed to pass through the body to a few microamps. This limits the current density (current per unit area) to values below a threshold that could affect or damage tissue and vital organs such as the heart and brain (33).

In a health-care setting patients are compromised when their skin is punctured and catheters are inserted, or when their skin is prepped (rubbed and cleaned with alcohol) prior to the placement of electrodes, and where moist environments exist. The electrical resistance of patient's bodies to current flow is reduced from its normal range of 10,000 Ω to 100,000 Ω, to a range of 1000 Ω to 10,000 Ω. Under normal conditions 110 V ac applied to the skin results in currents of 1 mA to 10 mA. Under these compromised conditions larger currents of 10 mA to 100 mA result.

Macroshock (current above 1 mA) can be hazardous when delivered at the body's surface. For example, 100 mA applied at the skin could cause ventricular fibrillation. Microshock (current below 1 mA) can be hazardous when delivered directly or close to heart tissue. For example, current in the order of 0.1 mA may cause ventricular fibrillation. Currents such as these that can injure the patient are usually too low to affect the uncompromised equipment operator.

Ac Leakage Current

Ac leakage currents are found in electrical instruments other than battery-operated direct-current (dc) devices. Leakage currents are produced as a result of the ac signal coupling to the chassis of the instrument due to capacitance effects. Such currents flow from chassis to ground when a low-resistance path is made available.

The ground wire within the equipment's three-wire line cord provides a safe low-resistance path for the leakage current. It is for this very reason that two-wire line cords are prohibited for hospital use. The ground wire is connected to the chassis of the instrument on one end and to the ground pin of the ac plug on the other. While this connection is intact the leakage current is safely conducted away from the patient, as it flows from the chassis through the ground wire to ground via the ac wall outlet. Should this path open or present a high resistance from chassis to ground due to a loose wire connection in the plug, or an improperly grounded ac outlet, the leakage current seeking other pathways could flow through the compromised patient. Leakage currents can also flow between patient leads and ground due to poor lead isolation. The large number of medical devices that surround and could route electrical current to the patient compounds the problem.

Manufacturers limit leakage current by (34):

- Incorporating patient isolation circuitry utilizing isolation amplifiers, optical coupling, and infrared transmission techniques
- Doubly insulating some devices with an outer nonconductive plastic housing so that even if touched, they cannot conduct electricity
- Using specially constructed low-leakage ac line cords
- Incorporating isolation transformers into systems, which have components whose total leakage current exceeds safety standards

Hospital Grade Plugs and Outlets

Safety is also provided by use of heavy-duty hospital grade ac plugs (with a green dot). These plugs are mechanically keyed to prevent polarity reversal. Explosion-proof plugs previously used due to the explosive nature of some anesthetic gases are no longer prevalent. Prior to opening new clinical areas, in addition to having the clinical gases certified, all ac outlets should be tested with a tension tester to verify that the ac outlets will tightly grip equipment plugs when inserted and with an ac polarity checker to ensure that the wiring has been properly done.

PROCUREMENT OF MEDICAL DEVICES

Reasons for Equipment Acquisition

Equipment is acquired by a health-care facility for a multitude of reasons, including the following:

- Replacement of obsolete equipment that cannot be repaired as parts are no longer available or that is not cost-effective to repair as a new unit would be comparable in price to the repair cost. Included is equipment that breaks down frequently, resulting in lost patient revenue to the institution. Such equipment replacement increases the hospital's cost-effectiveness and reduces its risk exposure.
- Replacement of technologically obsolete equipment that is not as precise as newer microprocessor equipment, to improve diagnostic and therapeutic efficiency.
- Introduction of new types of technologies, such as magnetic resonance imaging (MRI) and Catscan to provide enhanced services.

Requirement of additional units of a type already being used in the facility to reduce equipment downtime and patient waiting.

Attracting highly qualified physicians including new department chairmen.

Provided free of charge to the institution as part of a disposable contract.

Brought into the facility by clinicians for specific practice purposes.

Loaned to, or rented by, the institution.

Clinical Capital Equipment Committee

Equipment acquisition usually starts with a perceived need expressed by a clinician, a hospital administrator, or clinical engineer and a request is forwarded to the institution's Clinical Capital Equipment Committee. However, equipment is sometimes purchased on an emergency basis based upon medical contingencies or for political reasons without committee input.

The Clinical Capital Equipment Committee is made up of clinical department chairpersons, physicians, hospital administrators, as well as representatives from nursing, clinical engineering, finance, and purchasing. The committee reviews the equipment requests. Clinical engineering staff provides equipment inventory lists, instrumentation repair trends, and other equipment management information requested to expedite the decision-making process. Priorities are determined, a purchase list is generated, and requesting departments are notified. They prepare appropriate purchase requisitions, and necessary hospital administration signatures are obtained. The purchase requisitions are then submitted to clinical engineering for technical review.

"Turn-Key" Installations

Large "turn-key" installations require a request for quotation (RFQ) to be prepared for a bid process. Turn-key installations require the vendor to provide all equipment, materials (cables, mounting devices, etc.), and labor to install the system completely, and, when ready, to turn it over to the institution for acceptance testing. The RFQ document includes equipment specifications, environmental specifications, and legal requirements that address issues of noncompliance and penalties. During installation, such systems may require extensive vendor–clinical engineering interaction and problem-solving, as fully detailed documentation is not always possible. They also require extensive acceptance testing. Subsequent to the bid award, a detailed purchase requisition is generated.

Purchase Requisition Review

Assists the clinician in obtaining needed equipment, ensuring that everything required (peripheral items, supplies, etc.) is being ordered and that all items are compatible with each other and with existing equipment. It also ensures that the physical plant is ready (e.g., water, gas, special electrical requirements) so that equipment installation and use will not be delayed.

Requisitions are first reviewed to determine the following:

If equipment falls within clinical engineering jurisdiction (i.e., items used in the health-care facility for which clinical engineering is responsible).

If the FDA has approved the equipment for clinical use. If approved only for investigational purposes (i.e., a research phase requiring clinical trial to prove its efficacy), clinical engineering staff could assist the clinician in obtaining IRB clearance for clinical trials.

If the equipment utilizes a new technology requiring an engineering evaluation and clinical trial period prior to purchase. Evaluation may also be required if several vendors have viable products that should be compared. Visits to other health-care institutions are sometimes required to view the equipment in use. Larger systems such as replacement of all of an institution's obsolete physiological monitoring equipment necessitates input from future users including physicians and nurses.

If the equipment requires special physical plant utilities or has physical attributes (size, weight) that the facilities engineering department must be made aware of. If so, the facilities engineering manager's purchase approval is required.

If equipment or accessories require special treatment to not pose an infection threat to patient or user (i.e., sputum chamber certification). If so, the infection control department should be notified so that appropriate hospital policies will be generated.

If equipment is year 2000 (Y2K) compliant. If not, the impact of this equipment on patient care must be determined.

If sole-source justification (exemption from advertisement) is required. Sole-source acquisition is justifiable if the unit must be compatible with an existing item, a vendor holds a service contract and must supply parts, the unit has unique features needed by the requester, or no competition by manufacturer or vendor exists.

Purchase requisitions are next checked to ensure the following (35):

All needed accessories have been specified and are compatible.

Vendor or manufacturer will uncrate, assemble, or calibrate the unit (if required).

Vendor will assist with acceptance testing (if required).

Vendor will install the equipment (if required, i.e., mount to walls, etc.).

Vendor will provide (or loan) test kits or fixtures (i.e., phantom for diagnostic imaging) or simulators specifically geared to the unit.

Vendor will provide user in-service training.

Vendor will provide sufficient number of operator and service manuals.

Vendor will provide VCR training tapes.

Vendor will provide acceptance testing and PM protocols.

Vendor will provide clinical engineering service training.

Vendor will provide an equipment loaner in the event of delayed delivery.

Vendor will provide system isolation transformers (if required).

Specification of the correct delivery location (clinical engineering). This is true even for large items so that the clinical engineering department will be aware of delivery, at which time the receiving department could be notified to route the unit to the intended user site.

Contact person has been specified should the vendor have to make arrangements with the clinical engineering department or for training purposes.

Sufficient start-up materials are specified both for acceptance testing and for start of clinical use.

Warranty period is specified and service contract specified (if required).

Although clinical engineers must concentrate on the technical issues, they might also verify quotations, specify discounts if appropriate, ensure that buying service pricing is adhered to, determine if special promotions are offered, see if trade-in of obsolete equipment is feasible, and check on availability and delivery dates.

The requisition is next submitted to the purchasing department. A copy of the entire paperwork package, including all technical information gathered, is stored in clinical engineering's open purchase requisition file awaiting equipment delivery. After delivery and acceptance, it will be stored in the equipment's history file.

Bid Review

This review assists the clinician and purchasing department in determining if a low bidder offering an "equivalent" unit to what has been specified meets clinical requirements.

Depending upon the institution, equipment cost, and if a sole source is not justifiable a bid process may be required. Following bid opening a purchasing department bid analysis is sent to the clinical engineering staff and to the clinical requester. Working together, they determine if the "equivalent" device proposed by the low bidder is a viable alternative that meets clinical needs and the important specifications of the desired unit. If not, the more expensive unit may be justifiable. This process requires comparison of the low bidder's equipment to the unit originally specified and bid comparison to ensure that items have not been excluded that could artificially lower the price. The low bidder may have to supply a loaner unit for engineering test and clinical trial. Subsequently, a letter of justification is written, the award is made, and the equipment delivered.

Equipment Acceptance Testing

Equipment acceptance testing, also know as initial checkout or incoming inspection, ensures that all items ordered have been received and are undamaged, the equipment functions as per the manufacturer's performance specifications, and the equipment is safe for both the clinical user and the patient.

Acceptance testing uncovers equipment defects including those not readily apparent, prior to the equipment being used on or for patients so as to reduce liability to the institution. Such testing is usually more in-depth than PM testing and is much more than just electrical safety testing (leakage current and grounding resistance). All medical equipment (whether purchased, leased, rented, loaned, physician owned, used as a demonstration model, or donated) should undergo acceptance testing. Short-term items are given a "loaner tag," while long-term items are assigned an inventory number.

Figure 8. Acceptance testing, endoscopic system. Acceptance testing assures that medical equipment functions properly, meets manufacturers' specifications, and is safe for use. It also verifies that all items ordered have been received, and appropriate in-service education is provided to the clinical and engineering staff. Shown here, an endoscopic video system is undergoing an acceptance test. Such devices allow intra-body images to be displayed on monitors for ease of viewing and allow their documentation via video recording or printout.

Acceptance testing should be thorough (36). A visual inspection externally, as well as internally (when justified), ensures that the instrument was not damaged in transit and has no loose or extraneous components. The visual inspection also verifies that the device is new, of the latest model, and has not been previously used (occasionally factory refurbished demonstration units may be purchased). Devices are checked for electrical safety, mechanical safety, and functionality and to assure that they meet the manufacturer's own performance specifications (an important concept). Built-in diagnostics are run to provide future confidence in them (Fig. 8).

A report is generated documenting test results, conversations with the manufacturer, and information learned about the device, such as electromagnetic compatibility. These data serve as a baseline for future repair and PM testing and to help answer questions posed by the clinical staff. Acceptance testing also provides a practical training ground for the clinical engineering staff, keeping them current should emergency clinical situations develop or a patient incident occur involving this equipment. All defects uncovered and the steps taken to resolve them should be documented in a defect log, which

becomes part of the equipment history file. Until the defects are resolved, the equipment should not be released for clinical use. There is typically a 60-day period starting with equipment delivery in which acceptance testing is expected to be concluded. Should there be a defect (or should only a partial shipment of equipment be received) expenditures processing must be notified immediately so that they can inform the vendor that the payment clock has been stopped to avoid the institution paying a penalty. Also, equipment warranty must not start until acceptance testing is successfully concluded. The documentation showing that the hospital did thorough testing is invaluable to the institution during a lawsuit.

EQUIPMENT MAINTENANCE AND REPAIR

Service Options

An institution must manage its medical equipment well in order to provide high-quality medical care at competitive prices. For this reason, the clinical engineering department should avail itself of the many methods of providing service to its institution. A clinical engineering director must be flexible and fully aware of the skills of the clinical engineering staff and the budgetary constraints of the department in order to select the proper cost-effective mix of services. The intent is always to provide quality service while striving to reduce overall costs. When outside services are selected to supplement in-house capabilities, they must be monitored to ensure quality, correctness of charges, and receipt of appropriate documentation for entry into the equipment history files and computerized system (30). Several service options are discussed below.

In-House Service

Advantages. In-house service is cost-effective, provides very short response times (measured in minutes rather than in hours (20), and allows for single-point (one phone call) service. Informal (not always chargeable) service requests can sometimes be accommodated. Specialized service such as support for a cardiothoracic surgery program is also feasible (Fig. 9). Providing in-house service for complex state-of-the-art equipment requires an adequate number of well-trained staff. If staffing levels permit, in-house service should be substituted for service contracts whenever possible.

Considerations. Maintaining equipment in-house requires consideration of the critical importance and downtime that can be tolerated for each device. Consideration must also be given to the availability of backup equipment, tools, spare parts, test equipment, diagnostic software, and manuals, as well as how the equipment will be repaired should it fail off-hours (30). Some equipment such as ECG machines lend themselves to in-house repair as they are not one of a kind, parts are easily obtained, and backup units are readily available.

Original Equipment Manufacturer (OEM) Service

Advantages. Manufacturer's service has the advantage of parts availability, servicer familiarity with the equipment, possibility of equipment upgrade as part of the service, and possibly remote diagnostic capability (37).

Figure 9. Cardiothoracic support, bedside monitor setup. Clinical engineering support for cardiothoracic surgery assures a specially trained engineer is available in the operating room throughout the surgical procedure to check the physiological monitoring equipment prior to patient connection as well as to troubleshoot equipment problems should they develop. The engineer is shown checking the patient bedside monitoring setup in the Cardiothoracic Surgical Intensive Care Unit (CTICU) to assure its functionality. He also verifies that all patient cables are available for quick connection upon patient arrival to the CTICU following surgery.

Service Contracts and Clinical Engineering Screening. Service contracts are available that include parts, materials, and labor. Yearly cost can be roughly estimated by taking 10% of the equipment acquisition cost (the closer to 5% the better the deal). Original equipment manufacturers often bundle PM and upgrades with repair service as an enticement to select them as a service provider. Decisions must be made as to whether these items should be unbundled, and their value and need for determined separately (17). Clinical engineering screening lowers service contract cost. Screening requires that the clinical engineering department verifies that the equipment malfunctioned and the problem was not due to user error, prior to a service call being requested. For easily rectified problems the service provider may opt to supply the parts for clinical engineering to install. Screening keeps the clinical engineering staff familiar with a wider variety of instrumentation, allowing them to better assist during emergency situations. Screening may not be feasible for equipment that must be up continuously and requires the service contractor to be called in immediately to reduce downtime and minimize revenue lost to the institution. Equipment lends itself to a service contract if it is relied on heavily, only limited downtime is acceptable, and backup equipment is not readily available. Intra-aortic balloon pumps could fall into this category.

Fee-for-Service. OEM service is also available on an as-needed basis (fee-for-service). Fees include travel time (to or from the institution), labor, parts and materials, or, using printers as an example, a flat fee may be specified. Repair and/or PM service can be provided. Service may be provided either on-site (infusion pump) or at a remote depot or facility (glucometer). A vendor-supplied repair estimate assists in determining if the repair is cost-effective. Fee-for-service may be chosen for sophisticated repairs of equipment or when clinical engineering staff cannot find the cause of a problem after a reasonable troubleshooting time period has elapsed.

Third-Party Service Providers

Independent service organizations (ISO) tend to be less expensive than OEM. Service vendors should be selected based on the quality and timeliness of past service. Service contracts and fee-for-service are available. Repair and/or PM service can be provided. It should be determined if parts other than OEM will be used and whether the manufacturer might void the warranty or negate product liability if a nonfactory authorized service provider is used. The equipment has less chance of getting factory upgrades and product recall retrofits.

Shared-Service Providers

Services can also be obtained from shared-service providers, which can be for-profit or nonprofit. These organizations are formed by health-care institutions usually located close together that do not have the resources necessary to maintain an equipment management program on their own. Instead they pool their resources and have a common entity provide service to all of them. They share in the capital cost of setting up such an entity and then pay for services in proportion to their use (20). The logistical problems of providing such services must be overcome.

Some clinical engineering programs after becoming successful within their own institution expand and provide shared services to neighboring institutions as well. As an example, Thomas Jefferson University Hospital in Philadelphia, Pennsylvania, has a full-service in-house program as well as a shared-service component.

Maintenance Insurance

This insurance protects against catastrophic failures by smoothing out service cost. Service is done on an as-needed, fee-for-service basis. The insurance company either pays the vendor directly or reimburses the institution for the service. Some programs pay clinical engineering personnel to handle those repairs it wishes to in-house. Proper clinical engineering screening of service calls and good equipment management decisions can result in year-end rebates. However, the paperwork in managing an insurance program often requires dedicating at least one full-time employee (FTE) to this task. Maintenance insurance backup provides a reasonable way for clinical engineering to start assuming equipment maintenance duties in areas in which they may not as yet be involved, such as radiology and clinical laboratories.

Preventive Maintenance (Scheduled Maintenance)

Purpose and Methodology. Scheduled maintenance ensures that equipment previously acquired continues to function properly, has not deteriorated (due to usage and aging), and is safe for use. An attempt is made to uncover and correct problems that have not been reported or of which the user is unaware. Problem correction at an early stage can prevent incidents from occurring.

Figure 10. Preventive maintenance cell saver. Depending on the medical instrument, preventive maintenance can be more involved than just a functional and safety test. Problems that are uncovered must be rectified, and some instrumentation requires that components be replaced due to wear or number of hours of use. This, as well as observed spills, may necessitate opening the unit. The cell saver shown is used to salvage blood shed during an operation allowing its return to the same patient.

Testing done during PM tends to be more functionally oriented and is not as inclusive as that done during acceptance testing. Equipment that is mechanical in nature is tested to ensure that moving parts are structurally sound. If electrically operated, ac safety tests are performed (Fig. 10).

Some equipment requires replacement of parts normally expected to deteriorate with use, such as O-rings, gaskets, and brushes. In fact, some PM (i.e., for dialysis machines and some ventilators) is scheduled not by period (yearly, etc.), but by number of hours of equipment operation. PM kits are obtainable from the manufacturer. Other sensitive medical equipment (audiometer) requires extensive calibration during PM.

PM procedures specifically geared toward each instrument are used, except when the instrument is simple enough that a generic PM procedure can be used. Procedures can either be written in-house or purchased commercially. A PM worksheet keyed to the instrument's unique identification number is filled out and filed in the equipment's history folder.

Most equipment is maintained on-site in the user facility or clinical area, while others must be done in the clinical engineering laboratories. Precautions should be taken to ensure

that the equipment has been properly cleaned and/or sterilized before work on it is attempted. The infection control department has guidelines on cleaning prior to repair. Notation must be made in the computerized maintenance management system (CMMS) of equipment that is temporarily taken out of service, its storage location, and whether PM must be done while it is stored. The unit should be tagged indicating that clinical engineering staff must inspect it prior to its being put back into service. Clinical engineering's test equipment used to maintain and calibrate the medical instrumentation must also be periodically checked and calibrated. Certification against standards traceable to the National Bureau of Standards may be required.

A recent trend is to use laptop computers to collect test data on-site which are then imported into the CMMS. Computer-compatible test equipment can also be used to somewhat automate the test process. Such systems are available from Bio-Tek and DNI Nevada Inc.

PM Risk Management. Risk factors are used to determine if equipment requires scheduled PM, and if so, how often. This allows health-care organizations to concentrate their resources on equipment presenting the greatest risk. All patient-care equipment is evaluated, independent of the manner in which the institution acquired it.

During risk analysis, consideration is given to equipment function, physical risk associated with clinical application, and equipment maintenance requirements. A weighted numbering system is used and an appropriate threshold is set. Clinical engineering experience (incident history and frequency of use) is used to modify the initial assessment as required (22). Some low-risk devices with no PM requirements only require acceptance testing when first acquired, and a zero PM frequency assigned. The following is one example of assigning risk levels.

Equipment Function. This assessment considers how a device and its data are used and the possible consequences of its failure. It is important whether a device is used for life support, routine treatment, diagnosis, monitoring, or for minor functions.

Equipment function is weighted as follows (38):

Therapeutic	
Life support	10
Surgical and intensive care	9
Physical therapy and treatment	8
Diagnostic	
Surgical and intensive care monitoring	7
Additional physiological monitoring and diagnostic	6
Analytical	
Analytical laboratory	5
Laboratory accessories	4
Computer and related	3
Miscellaneous	
Patient related and other	2

Physical Risk. This assessment considers the possible consequences to the patient and/or operator in the event of an equipment failure or malfunction.

Physical risk is weighted as follows:

A device malfunction could result in—

Patient death	5
Patient or operator injury	4
Inappropriate therapy or misdiagnosis	3
Patient's discomfort	2
No significant risk	1

Maintenance Requirements. This assessment considers whether the device requires periodic parts replacement, recalibration, lubrication, and clinical engineering tasks necessary to supplement user maintenance.

Maintenance is weighted as follows:

Extensive	5
Above average	4
Average	3
Below average	2
Minimal	1

Cannot Locate. Equipment that cannot be located (CNL) is an ongoing problem that most clinical engineering departments face when attempting to do PM. Movable equipment often winds up in locations other than those indicated in the inventory records. The equipment may even have left the institution with the patient upon transport. This requires extensive search time, entails hospital sweeps, and if unsuccessful, notification to the user and the Safety Committee. Should the device not turn up in a reasonable time period set by the institution (i.e., within three PM periods, two years), the clinical owner and property control personnel should be notified and the device removed from the active equipment inventory list.

Reduction of PM Requirements. From 1974, when the JCAHO first required that all electrically powered equipment be tested four times a year, through 1988, when the JCAHO introduced risk-based equipment management, which encouraged health-care facilities to develop more realistic equipment management programs, there has been a decline in the requirement to do PM (39).

Today (1998), as competition between health-care institutions intensifies and resources dwindle, further PM reduction is being discussed. At issue is the extent that PM contributes to patient care, patient and user safety or quality. PM is labor-intensive and uses personnel resources that are in short supply. Advances in the manufacture of medical devices (including the use of solid-state integrated circuits) produce instruments with longer mean times to failure rates and better electrical isolation. It is questioned if PM further improves these failure rates and whether clinical engineering resources would be better spent in providing additional training to equipment operators to improve their skills, thus reducing patient incidents and enhancing patient care (39). It remains to be seen if this approach will be adopted. For now, time spent on PM should be limited to what is required by law or as determined by prudent practice (17).

Repair (Unscheduled Maintenance)

Purpose and Methodology. The purpose of repair is to restore equipment so it meets original equipment manufacturer

Figure 11. Repair, infant warmer. Repair of medical instrumentation requires electrical troubleshooting skills. Here, an infant warmer is being evaluated using a multimeter to assure that the thermostat controls will function properly so as to prevent harm to the infants.

specifications. This is accomplished by determining the malfunction and fixing it so as to retain the efficacy and safety of the device (Fig. 11).

Prior to doing repair a determination should be made as to whether the device is under warranty or service contract. If so, the appropriate service provider should be contacted. If under contract, clinical engineering screening may be required to verify that a problem does exist and warrants a vendor service call. Determination should be made as to whether it is cost-effective to repair the device or if it should be retired from service (due to lack of parts availability or expense) and a replacement purchased.

Depending upon severity repairs can be done either in the clinical engineering laboratories or on-site in the user facility. In general, unless one has a good reason not to, original OEM parts should be used. During repair, built-in diagnostics are helpful, and the instrument operator and service manuals from the clinical engineering technical library, as well as the devices history file, prove invaluable.

On-site emergency support during the day allows the engineer to witness the problem first-hand. On-call/recall for emergencies during off-hours allows instrumentation problem troubleshooting by phone. This coupled with substitution of spare equipment often eliminates the need for return to the institution.

Work reports are filled out in a similar manner as for acceptance test and PM. Included should be the problem, steps taken to resolve the problem, parts used, and pertinent test data. These reports keyed to the instrument's unique identification number are filed in the instrument's history folder, and suitable computerized data entry is made.

Parts and Service Manuals. A problem faced when repairing medical devices is that manufacturers are sometimes unwilling to provide necessary replacement parts, insisting that more costly field replaceable units be purchased instead. They argue that proper repair requires automatic test equipment verification that is only available at the factory, and that they will be liable should the device malfunction after such repair (40). Also, although required under the FDA Federal Medical Device Amendments of 1976 to provide service literature containing installation, operation, and maintenance information, some manufacturers are unwilling to provide service manuals with proper schematics, arguing that their technology is proprietary, or they require a nondisclosure document be signed. Prior to signing any such agreement it is best to check with the institution's legal counsel to determine the ramifications of doing so. It must be stressed that the time to resolve the manuals issue is during pre-purchase requisition review. Not only is repair impacted by not having operator and service manuals, but equipment acceptance testing is as well, as equipment specifications and detailed test information is to be found there. Some clinical engineering departments do not even schedule acceptance test unless these manuals are first received.

Equipment Retirement

Equipment is retired from service when it:

- Is obsolete and can no longer be cost-effectively repaired due to lack of parts or expense.
- Becomes unreliable and prone to constant failure.
- Poses a hazard to patient or user.
- Is replaced by newer technologies.
- Is no longer the choice of the clinical staff (3).

Depending upon the institution and the equipment condition it could be:

Cannibalized for parts.
Traded in for a newer device.
Sold.
Offered to a sister institution.
Donated to a school.

In any case, appropriate disposal procedures must be followed, including notifying property control and making entries into the CMMS and equipment history files.

MANAGEMENT

Health-Care Technology Management

Health-care technology includes all of the components needed to diagnose and treat human disease (illness). This includes medical equipment (devices, systems, and software), supplies, pharmaceuticals, biotechnologies, and medical and surgical procedures as well as the health-care facilities (hospitals, etc.) that are used to house the patients and medical equipment (23). Health-care technology management deals with all of the health-care technology components. Included in health-care technology management is equipment management, technology planning, and technology assessment.

Equipment Management

Definition and Purpose. Equipment management deals specifically with the medical equipment and is the cornerstone of an effective clinical engineering program. An equipment management program that encompasses the more traditional clinical engineering duties (23) controls the risks associated with using medical equipment for patient care by detecting and correcting hazards before injuries can occur. Proper equipment maintenance (a core component of equipment management) maximizes the useful life of medical equipment and minimizes its lifetime cost.

Although equipment management includes the core services of equipment maintenance (PM and repair), it goes beyond these services to include most phases of equipment lifespan. It is involved with equipment acquisition, which includes equipment assessment, equipment specification, RFQ generation, and vendor selection. It encompasses installation planning, acceptance testing, user in-service education, selection of service provider, product recalls and alerts, and incident investigation, as well as PM and repair. It also includes equipment replacement analysis, removal, and salvage (30).

Better equipment management decisions save money. They reduce equipment downtime, eliminate the need to pay for emergency equipment rentals, and allow better equipment replacement decisions to be made that consider past equipment failures and expenses in addition to equipment capabilities. Equipment and consumable standardization is also encouraged (3).

An equipment management program must be compliant with JCAHO guidelines and regulatory requirements such as those of the Department of Health (DOH), College of American Pathologists (CAP), and American Association of Blood Banks (AABB).

Centralization. Ideally, a centralized equipment management program capable of handling all patient-care equipment (including anesthesiology, clinical laboratories, and respiratory care) is desired. More sophisticated institutions are placing all medical equipment maintenance funding in the clinical engineering budget. Consolidation makes economic sense as it allows an institution to more easily track its true equipment maintenance costs. Cost-effective service contracts can be negotiated and unnecessary ones eliminated. Interface between the institution and equipment vendors and manufacturers becomes simpler (30). Record-keeping is standardized, demonstrating to JCAHO that a uniform level of service for all medical devices exists as well as a centralized data repository. Centralization also makes it clearer to an institutions' staff that the clinical engineering department should be consulted for all equipment-related services.

AAMI Recommended Practices. AAMI is presently finalizing the recommended practice *"Required characteristics for a medical equipment management program"* (41), that reflects existing good practice, addresses program structure, required documentation generation, staffing, and resource allocation. It acknowledges that many clinical engineering programs already exceed these minimum requirements. AAMI's goal is that others strive to exceed them as well. This document should help newly formed, smaller clinical engineering departments (and health-care facility managers) to define what is expected as a starting point better.

Technology Planning

Technology planning supplements an equipment management program. It helps to further ensure that appropriate equipment that is cost-effective, efficacious, and safe is available, allowing the institution to meet quality patient-care demands. Technology planning includes greater clinical engineering involvement in the determination of equipment replacement needs, equipment acquisition, facility planning and design (to ensure equipment needs are accommodated), as well as continuous technology assessment (23).

Technology planning allows an institution to remain competitive by choosing new technologies that complement existing hospital services and present strategic advantage to the institution against competitors. It also reduces liability risk for the hospital and clinical staff by helping to identify legal standards of care requirements requiring purchase of new or additional equipment. As example, the requirement that pulse oximetry (S_AO_2) monitoring, end-tidal CO_2 monitoring, or both be provided during general anesthesia (3).

Technology Assessment

Technology assessment (a component of technology planning) analyzes all of the consequences of introducing a new technology [i.e., bone marrow transplant or picture archiving and communications systems (PACS)] into a health-care institution, prior to any equipment being purchased. Analysis includes consideration of the equipment required, techniques to be used, FTE personnel requirements, size and makeup of patient base, community impact, and financial considerations.

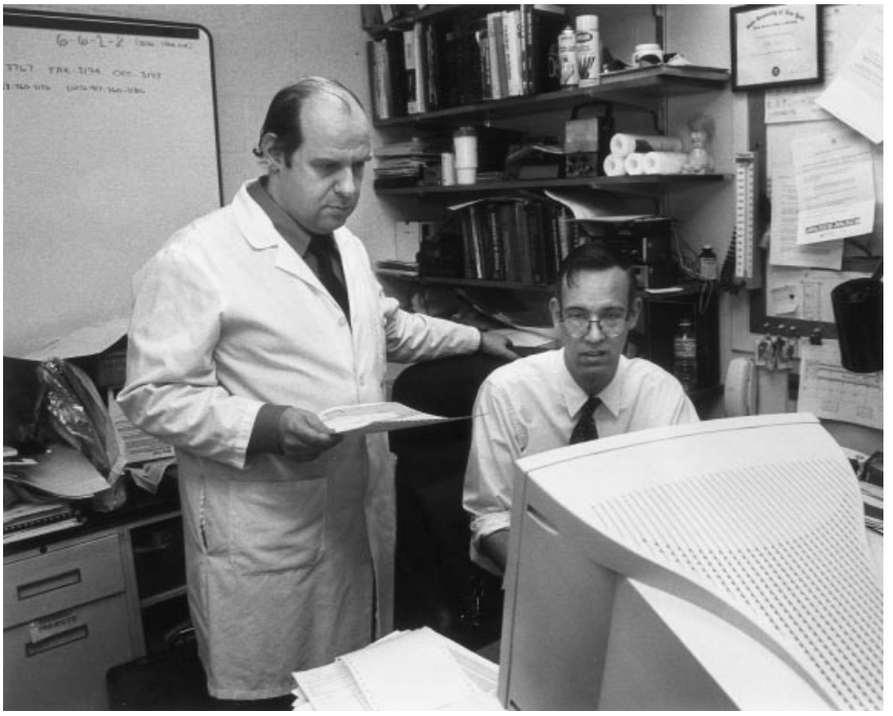

Figure 12. Computerized Maintenance Management System. Computerized Maintenance Management Systems (CMMS) are used by clinical engineers to track their workload. This includes repairs, preventive maintenance scheduling, and other requests for engineering assistance. CMMS also maintain an equipment inventory and maintenance history information. The two clinical engineering supervisors are querying the system to obtain lists of equipment of specific clinical areas so that they can plan and assign workloads for the staff.

The goal of the analysis is to reduce the possibility of purchasing expensive and inappropriate equipment that cannot generate income for the institution. By assisting in this task, the clinical engineering staff's awareness of new and emerging technologies aids in more wisely allocating capital resources (3).

Computerized Maintenance Management Systems

Computerized maintenance management systems (CMMS) software is a powerful technology management tool used to collect, store, and analyze data (Fig. 12). To utilize such programs, some clinical engineering departments rely on their institution's mainframe computer or a file server and local area network maintained by the information services department, while others maintain their own file server and local area network taking on the responsibility for data backup and integrity. Some use internally developed CMMS software, while others purchase commercially available packages. CMMS systems generate reports relating to all aspects of the operation of a clinical engineering department, including equipment management. Technology assessment software is also available.

Functions of CMMS are as follows (30):

- Maintain an equipment inventory and nomenclature system
- Select and schedule PM (based on risk factors)
- Track work including repair, user in-service training, construction and research projects
- Prioritize work load
- Track equipment and vendor services provided under warranty or service contract
- Track loaner and leased equipment
- Identify medical equipment needing replacement due to constant breakdown and large downtime
- Select new equipment for purchase based on past performance and cost effectiveness of similar equipment
- Detect trends that pinpoint the need for additional user training due to operator error, NFF, equipment damage, or abuse
- Detect trends that pinpoint the need for additional service training such as repeat repairs
- Generate work-completed reports for customers, including lists of equipment that cannot be located (CNL)
- Bill customers
- Maintain parts inventories
- Generate reports for hospital administration
- Analyze clinical engineering performance (financial, quality, and productivity)
- Assist in long-range forecasting

Benchmarking

Purpose and Methodology. A management tool for continuous quality improvement, benchmarking allows comparison of an organization to other similar organizations so that better techniques can be ascertained and adopted to improve performance and customer service.

Benchmarking can be informal or formal. Informal benchmarking consists of gathering information about similar institutions by contacting colleagues and comparing clinical engineering parameters and functions. Formal benchmarking requires filling in a detailed questionnaire and submitting it to an outside organization for analysis. Such analysis is provided as a service to university hospitals throughout the country that are members of the University Healthcare Consor-

tium (42). This benchmarking process allows member institutions to compare their operations. Institutions that submit data have agreed that all other member institutions may gain access to it for purposes of improvement.

Caution in Use. Benchmarking can be helpful (43) and the possibility of improvement exists. However, the results must be properly used. It is important when comparing institutions not only to consider the number of FTE, which may not be an absolute number as it may be based on overtime or be normalized (i.e., to a 40 h week), but also to compare fully the services each clinical engineering department provides. This is critical if such data are used to make operational decisions that relate to staff size. Analysis may well show that those chosen as "better performers" do not provide services that are vital to another institution. It is also important to consider the acquisition cost of equipment being maintained. Some departments are required to handle more sophisticated equipment that is both time consuming and costly to repair, thus increasing FTE requirements.

Finally, some point out that comparison of in-house clinical engineering departments to each other, using the ratio of number of engineers per bed, is a wasted effort as their real competitor is not each other, but outside service providers, who could replace them both (17).

Clinical Engineering Oversight

Oversight Function. Clinical engineering provides an important oversight function whose primary purpose is to reduce risk of injury to patients and staff as well as liability to the institution for which they work. While carrying out their mandate duties of the clinical engineering department can sometimes cause client irritation. As an example, review of equipment purchase requisitions, questioning clinical users about preferred equipment choices, coupled with the bid process, and need to provide justification to purchase other than the low bidder's equipment lengthen the equipment ordering process. On occasion, clinical engineering management may even disallow the purchase or use of devices found to be unsafe due to extremely poor workmanship, inherent design defects, or dangerous failure modes. Acceptance testing, which disallows immediate clinical usage of equipment, tends to frustrate clinicians anxious to use the equipment and causes them to question the need for acceptance testing (only wanting electrical safety tests to be run). They sometimes prematurely schedule patients, in-service education, and removal of old equipment upon equipment arrival into the institution, leaving little if any time for testing. These issues make it critical that clinical engineers understand that as they strive to satisfy regulatory requirements, safety requirements, and ethical considerations, they must also strive to streamline their operation to provide services as quickly as possible, so as not to alienate their clients. It is important to demonstrate to clients through timely feedback and education that clinical engineering is a vital resource and not an impediment.

Dangers in Bypassing Oversight Function. There are times even with hospital policies in place, that clinical engineering is not consulted for what is felt to be expediency. The result is often increased cost, delays, and increased risk to the institution.

Not involving clinical engineering during the prepurchase evaluation process is counterproductive. This is particularly true while planning for new clinical areas or renovating existing ones. Having to open newly constructed walls to add electrical outlets or to provide additional reinforcement to allow required medical equipment to be mounted, all of which should have been planned for prior to construction, is both costly and time-consuming.

Problems also arise when equipment is ordered, and physical plant conditions are not suitable for its operation. For example, a type of endoscopic sterilizer requires clean water, and a specified minimum water pressure (often not found in certain urban areas especially during summer months). Without these environmental conditions being met, the unit will not function and additional external filtration (which quickly clogs) does not remedy the situation. Studying specifications and having clinical engineering personnel interact with facilities engineering staff prior to such equipment being ordered reduces the chance of such expensive nonfunctioning installations.

Clinical engineering involvement in purchase requisition review reduces the possibility that incorrect equipment is ordered. Ordering nonstandard equipment requires additional user training and increases the chance of patient injury due to user equipment unfamiliarity. This also compounds maintenance requirements and the types of accessory supplies required.

Clinical engineering acceptance testing prevents unsafe equipment with defects being put into service and eliminates premature payment authorization that results in loss of leverage in defect problem resolution. Also, this assures the equipment is entered into the equipment inventory, PM scheduling is done, eliminating problems during regulatory inspections, such as untested devices turning up just prior to inspection when limited time is available to process them. To minimize problems it is important that clinical engineering work closely with the purchasing and expenditures processing departments to assure that medical equipment falling within the mandate of the clinical engineering department is not ordered or paid for without clinical engineering approval.

CLINICAL ENGINEERING CHALLENGES

Competition

Clinical engineering departments face the challenge of improving productivity and quality even though their resources are shrinking. The threat of downsizing, out-sourcing, and in-sourcing is very real. Competition with ISOs of the field service industry has intensified over the last 10 years, requiring in-house clinical engineering programs to organize themselves as businesses, so as to reduce costs and to be competitive (17).

Justification

Clinical engineering departments must continually demonstrate their value to their institution. This is especially true as hospital staff changes. New people, both administrative and clinical, come on board who may be unfamiliar with the benefits of clinical engineering services. Continuous advertising (brochures, newsletters, Web sites) and attendance at

meetings is required to educate them as to clinical engineering's vital role within the institution.

Remote Service

As health-care institutions merge and collaborate, and as additional satellite clinics are established to provide hospitals with clients, clinical engineering is faced with the logistics of providing services to remote locations.

Regulation

The FDA is considering extending good manufacturing practices (GMP) rules and regulations to medical equipment refurbishers, reconditioners, and servicers. This would require them to meet requirements similar to those of original medical device manufacturers and remanufacturers. Clinical engineering departments as equipment servicers may be impacted (44).

Home Safety

Clinical engineers may have to become more involved in safety issues related to the increased use of medical equipment for home care and how to provide such services. For example, home dialysis requires preliminary inspection of the patient's home site to ensure adequate electricity and water and then periodic visits for PM and repair.

Year 2000 (Y2K) Compliance Healthcare devices and systems (information systems, medical equipment, and general hospital systems) that use software or contain microprocessors may be prone to the Year 2000 problem. If so, as the date changes from Dec. 31, 1999 to Jan. 1, 2000 they may incorrectly represent the year 2000 as 1900 (or some other date). Some equipment might operate erroneously, others not at all. Such failure could affect patient safety, produce incorrect printouts and archiving, and increase risk to the institution. Clinical engineering involvement and allocation of resources are required to ensure equipment compliance (45).

Seeking New Opportunities

Clinical engineering departments must be flexible, adapting to the times and conditions of the ever-changing health-care institutions they serve. The feasibility of providing additional services for X-ray and ionizing radiation equipment, computers, computer networks, patient information systems, telecommunications, and nurse call systems should be investigated. Although with proper training, clinical engineering staff should be able to repair these items just as they repair other sophisticated equipment falling within their domain, a realistic approach must be taken with consideration given to available resources (i.e., funds for training and FTE allocation), as well as the political realities of "turf" within their particular institutions. Clinical engineers should also strive to become more involved in technology assessment issues for new technologies including telemedicine, robotics, PACS, and wireless LAN, helping to determine the value of introducing them into their institution.

Such flexibility will ensure that the relatively new profession of clinical engineering will mature and continue to provide value to the institutions it serves, as it moves forward into the 21st century.

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BIBLIOGRAPHY

1. Phone conversation between Dr. Caceres and the author, November 1997.
2. Anonymous, *What's a Clinical Engineer?,* Pamphlet, Houston, TX: ACCE.
3. Anonymous, *Special report on technology management: preparing your hospital for the 1990's, Health Technol.* **3** (1): Plymouth Meeting, PA: ECRI, Spring 1989.
4. M. J. Shaffer, The reengineering of clinical engineering, *Biomed. Instrum. Technol.,* **31** (2): 177–178, 1997.
5. T. J. Bauld, The definition of a clinical engineer, *J. Clin. Eng.,* **16** (5): 403–405, 1991.
6. Anonymous, *Frequently asked questions: biomedical engineering,* Department of Biomedical Engineering, Tulane University, http://www.bmen.tulane.edu/BMEFAQ/Welcome.html, 5/23/96.
7. S. Thanasas and Y. Dathatri, Course description of the Biomedical Engineering Technology Associates in Applied Science Degree, Farmingdale, NY: SUNY Farmingdale, January 1997.
8. Anonymous, *Certification Program for Clinical Engineers,* Virginia: International Certification Commission for Clinical Engineering and Biomedical Technology, February 1996.
9. S. Ben-Zvi and W. Gottlieb, *Inspection and maintenance of medical instrumentation.* In B. Feinberg (ed.), *Handbook of Clinical Engineering,* Boca Raton, FL: CRC Press, 1980, Vol. 1, pp.57–78.
10. W. J. Curran, P. E. Stanley, and D. F. Phillips, *Electrical Safety and Hazards in Hospitals,* New York: MSS Information Corporation, 1974.
11. J. M. R. Bruner and P. F. Leonard, *Electricity, Safety and the Patient.* Chicago: Year Book Medical Publishers, 1989.
12. D. Roth, *The History of Medical Equipment Service, Part I,* 24x7, **2** (4): 24-27, 34, April 1997.
13. D. Roth, *The History of Medical Equipment Service, Part II,* 24x7, **2** (5): 32, 34–35, May 1997.
14. American National Standard, *Safe current limits for electromedical apparatus,* ANSI/AAMI—1993. Arlington, VA: AAMI, December 2, 1993.
15. B. Klein (ed.), *Health Care Facilities Handbook.* 4th ed., Quincy, MA: NFPA, 1993.
16. E. B. Fein, N.Y.U. Center and Mt. Sinai resume talks, *The New York Times,* B1, B6, September 24, 1997.
17. G. Gordon, *Breakthrough Management, A New Model for Hospital Technical Services.* Arlington, VA: AAMI, 1995.
18. G. F. Nighswonger, 1997 survey of salaries and responsibilities for hospital biomedical/clinical engineering and technology personnel, *J. Clin. Eng.,* **22** (4): 214–232, 1997.
19. M. Wilkow and I. Soller, The Scientific and Medical Instrumentation Center Brochure. Brooklyn, NY: SUNY Health Science Center at Brooklyn, University Hospital of Brooklyn, 1995.

20. Guideline for establishing and administering medical instrumentation maintenance programs, AAMI MIM—3/84, Vol. 1: *Biomedical Equipment, AAMI Standards and Recommended Practices.* Arlington, VA: AAMI, 1989, pp. 3–42.
21. L. C. Brush et al., *The Guide to Biomedical Standards.* 20th ed., Brea, CA: Quest Publishing Company, 1995/1996.
22. *Inspections and enforcement chapter 1510 JCAHO accreditation, BNA's Health Care Facilities Guide,* No. 36, 1500:1001–1500:1106, The Bureau of National Affairs, 1997.
23. Y. David and T. M. Judd, *Medical Technology Management,* Redmond, WA: Space Labs Medical, 1993.
24. O. R. Keil, Accreditation and clinical enginering, *J. Clin. Eng.,* **21** (6): 410, 412, 440, November/December, 1996.
25. M. Shepherd, SMDA '90: User facility requirements of the final medical device reporting regulation, *J. Clin. Eng.,* **21** (2): 114–118, March/April, 1996.
26. *Safe Medical Devices Act: Medical Device Tracking Regulations.* Plymouth Meeting, PA: ECRI Advisory, July 1997.
27. L. A. Geddes and L. E. Baker, *Principles of Applied Biomedical Instrumentation.* 3rd ed., New York: Wiley, 1989.
28. *Health Devices Sourcebook Medical Product Purchasing Directory with Official Universal Medical Device Nomenclature System.* Plymouth Meeting, PA: ECRI, 1997.
29. *Medical Device Register,* The Official Directory of Medical Suppliers. Montvale, NJ: Medical Economics Data Production Company, 1994.
30. T. Cohen, *Computerized Maintenance Management Systems for Clinical Engineering.* Arlington, VA: AAMI, 1994.
31. Conversation between C. Yeaton (SUNY University Hospital of Brooklyn, Risk Manager) and the author, October 1997.
32. *Digital Safety Analyzer Model 501 Operator's Manual,* Rev. C. Burlington, VT: BIO-TEK Instruments, 1993.
33. S. A. Rubin, *The Principles of Biomedical Instrumentation A Beginner's Guide.* Chicago: Year Book Medical Publishers, 1987.
34. R. Aston, *Principles of Biomedical Instrumentation and Measurement.* Columbus, OH: Merrill Publishing Company, 1990.
35. I. Soller and L. Klebanov, *SMIC checklist for the purchase of scientific and medical instrumentation.* Brooklyn, NY: SUNY Health Science Center at Brooklyn, University Hospital of Brooklyn, September, 1992.
36. S. Polaniecki, *SMIC guide for the performance of initial checkout.* Brooklyn, NY: SUNY Health Science Center at Brooklyn, University Hospital of Brooklyn, August, 1989.
37. *Siemens-BJC multivendor service breaks new ground with remote diagnostics,* 24x7, **2** (9): September 7, 1997.
38. L. Fennigkoh and B. Smith, *Clinical Equipment Management.* Plant Technology and Safety Management Series, implementing the 1989 PTSM standards: case studies, Number 2, 1989, The Joint Commission.
39. O. R. Keil, Is preventive maintenance still a core element of clinical engineering?, *Biomed. Instrum. Technol.,* **31** (4): 408–409, 1997.
40. K. Beckley, *SpaceLabs explains service stance,* 24x7, **2** (11): November 7, 1997.
41. Recommended practices for a medical equipment management program, final draft standard, AAMI EQ56-1997, June 1997, Arlington, VA: AAMI.
42. *Clinical Benchmarking,* Oak Brook, IL: University Healthcare Consortium, 1993.
43. M. S. Gordon, The long and short of benchmarking, *Biomed. Technol.,* **6** (3): 20–26, May/June, 1995.
44. *FDA eyes GMP regs for refurbishers and servicers,* 24x7, **2** (9): September 7, 1977.
45. *Medical devices and the year 2000 problem,* Health Devices Alerts Number 1998-F2, Plymouth Meeting, PA: ECRI, February 27, 1998.

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CLINICAL MONITORING.

See PATIENT MONITORING.