PART 8

CLINICAL ENGINEERING
36.1 BIOMEDICAL ENGINEERING

36.1.1 Historical Background

No discussion of what is now referred to as clinical engineering can begin without considering first
the development of biomedical engineering and, in turn, engineering. “In the past engineering was
defined as the facility to direct the sources of power in nature for man’s use and convenience.”
Today, modern engineering involves the application of scientific techniques, theories, and technology
for the solution of societal needs. This definition has implications that all engineers, and clinical
engineers in particular must address.

As professionals who wish to consider society’s problems, engineers must first address three issues.
It is essential that engineers must possess skills that are appropriate to the problem being addressed or
else exempt themselves from that work. Second, engineers must ensure that the solutions they
propose do not impose new and more serious problems on society. Third, engineers must meet the
real needs of society and must be instrumental in defining those needs. These issues are of particular
relevance for biomedical engineers and clinical engineers, as we shall see.

Biomedical engineering, rather than limiting the range of engineering brought to bear on a
societal problem, limits the range of problems addressed to those in the medical and biological area.
Indeed, we increasingly recognize the field more as the integration of engineering with medicine and
biology for better understanding and solutions of societal needs.

Although we may feel that this recognition is progressive, history shows that the established
boundaries of the various professional and scientific fields, and the medical and engineering sciences
in particular, are of modern origin. Indications are that the giants of scientific engineering
investigation throughout history either ignored or were insensitive to these boundaries. More likely,
they recognized that the same scientific and engineering laws applied to all of natural phenomena
whether in the physical or biological world.

The origin of biomedical engineering, while obscure, can be traced to ancient times. We know that
Alcmaeon, a student of Pythagoras, in the period around 500 B.C., became interested in applying
mathematics to the study of physiology. This propensity for crossing boundaries and recognizing common scientific principles persisted throughout most of recorded history. Both Plato (427–347 B.C.) and Aristotle (384–322 B.C.) investigated, observed, and systematized the world they studied around them. Their study of the human body included detailed explanations of the pumping action of the heart and the functions of other organs. Galen, who was the son of an architect and mathematician in Roman times, developed theories on hemodynamics that persisted to the time of the great physician Maimonides 1200 years later. Certainly, this integration of sciences and mathematics is consistent with modern biomedical engineering.

Leonardo da Vinci, one of the greatest engineers in history, also applied physical principles and experimental analysis to the study of physiology and medicine. Santorio invented an instrument to count the pulse—the “pulsilogium”—that was almost certainly the first recorded medical instrument. In addition, for his study of metabolic physiology, he built a metabolic balance chair to monitor body weight over long periods. Robert Hooke, who was a student of Robert Boyle, studied respiratory phenomena as he studied the relationship between pressures and volumes. Was this work biomedical engineering?

Stephen Hales, an English clergyman and physicist, carried out a classic experiment in 1732 to determine blood pressure. He connected a U tube to the carotid artery of a mare and observed the height that blood rose in the tube. Then, using fluid dynamic principles, he calculated the velocity of blood in the aorta, force of contraction, and stroke volume. This work has been the foundation of modern hemodynamics and was used by Bernoulli in his quite accurate calculation of cardiac output in 1737.

Lavoiser (1747–1794), during his studies of oxygen, extended that work to respiration. Galvani, recognized as a pioneer in electrical engineering, observed in 1780 the contraction of a frog’s leg muscle when stimulated electrically. Alessandro Volta, also a physical scientist, worked extensively with the “animal electricity” that Galvani had observed. Was this work biomedical engineering?

In the mid-nineteenth century, several fields of science saw explosive activity. Men like Orstead, Gauss, Weber, Laplace, Lagrange, Carnot, Faraday, Maxwell, and Helmholtz were contemporaries in physics and chemistry. Divergence and segregation of the fields gradually occurred at this time, but some workers, such as Helmholtz, crossed these boundaries.

Helmholtz, with his early interests in physics and mathematics, undertook a career in medicine in 1838. He applied his knowledge of thermodynamics to the study of conservation of energy and metabolic physiology in 1847. He estimated the velocity of nerve transmission, invented the ophthalmoscope, and investigated the physiology and psychology of hearing, a topic of investigation to this day. Surely Helmholtz was a biomedical engineer.

In 1837, Samuel Haughton quite clearly applied mechanical engineering principles and contemporary engineering technology to acquire new knowledge about biomechanics and cardiovascular physiology. In his Preface, he referred to “… the mutual advantages obtainable by Anatomists and Geometers from a combination of the Sciences they cultivate.” Using tools that we would consider hopelessly inadequate, he quite accurately deduced the velocity of blood in an artery, capillary resistance, blood pressure, cardiac work, and the time required for the circulation of the blood.

These investigators, scientists, and engineers, like Helmholtz and Haughton, recognized that the same laws apply to studies of physics, engineering, or biology—the unity of the sciences. This understanding represents the greatest challenge and potential both on the research and development side and on the applied side of the field of biomedical engineering today. This fact makes clear why developments in fields such as DNA sequencing and communications theory, which we think of as separate fields, can be successfully melded to yield outstanding gains in our understanding and treatment of disease. It also should make clear to us that techniques and technology, and not just instrumentation, that may derive from traditional engineering applications are equally applicable in health care. This application side defines the portion of biomedical engineering that has come to be called clinical engineering, where all aspects of engineering and technology come to play directly in the health care field.
36.2 CLINICAL ENGINEERING

36.2.1 Development

Clinical engineering developed in health care facilities around the world over the last four decades of the twentieth century. There was widespread recognition in professional and government circles of the technological explosion that had affected society in general and health care in particular. A series of workshops held in 1972 provided a forum for the discussion of the need for an engineering approach to effect some control on this technology. Let us consider three of the factors that can be cited as having had a great influence on the way in which clinical engineering has developed in the hospital:

1. The rapid influx of technology and its resulting instrumentation into the hospital primarily in the 1960s and 1970s
2. The recognition of an electrical safety issue associated with the increase in clinical instrumentation coming in contact with the patient
3. The move to develop a certification process for engineers in hospital clinical settings

These three factors served to encourage the development of the field and at the same time served to define the field itself. The increased prevalence of technology and medical instrumentation in hospitals meant that hospital organizations had to develop ways to take care of these devices. With this rapid proliferation of what were primarily electrical devices in the vicinity of the patient, some assurance of the electrical safety of the patient needed to be provided. Finally, the skills, training, and education of engineers and technologists who were to become involved in these activities needed to be vetted.

Perhaps the start of the new field, that was to become clinical engineering can be attributed to the establishment in January 1942 of the U.S. Army Medical Equipment Maintenance Course. This developed into the Army Medical Equipment School in Denver, Colorado, and the Air Force Training Wing at Sheppard Air Force Base in Texas. Thus maintenance of medical equipment became the first of the defined functions of what was to become the clinical engineering field.

Others recognized other problems in health care that were associated with this rapid influx of technology and that could be amenable to an engineering approach. Robert Rushmer understood the need for engineering involvement not just in maintenance but also in all parts of health care. He emphasized the need for optimization and improvement of the effectiveness, safety, and benefit of existing technologies as a means for their more efficient and appropriate use by health care professionals and the resulting improved patient care. He further recognized the need for medical engineers to help to define the technological applications beyond the critical-care applications of the day. He understood the need for the engineering approach and involvement in all parts of health care from hospitals to home care.

T. D. Kinney in 1974 broadened the role of biomedical engineering in the hospital as he anticipated the potential for savings in chemistry laboratories through the work of biomedical engineering. He estimated that 90 percent of advanced laboratories were automated in some way at that time.

Raymon D. Garret specifically addressed the computing needs of the hospital. While the solutions available in 1973 clearly were inadequate, the analysis of the hospital as a system remains valid today and serves as an excellent description of an opportunity for clinical engineering involvement.

This brief survey illustrates that there was recognition of the problems that existed in health care in that time period and that there was recognition of the potential for biomedical engineering to effect solutions to those problems. It is interesting to note that the initial understanding of the role engineering could play in health care did not come necessarily or solely from engineers. Rather, that
broader understanding came from visionaries such as Robert Rushmer, a cardiovascular research scientist, and Cesar Caceres, a clinical cardiologist, whose recognition of what the range of engineering involvement in health care could be defines, in essence, the role of clinical engineering.

Cesar Caceres offered perhaps the most insightful description of clinical engineering: “An engineer who is trained for and works in a health service facility where he or she is responsible for the direct and immediate application of engineering expertise to health and medical care.”11 Except for the constraint this definition places on the practice of clinical engineering to that being within the precincts of the hospital, this definition accurately outlines the role of clinical engineering. It is important to notice that this definition assumes both appropriate engineering expertise and direct benefit to patient care or health care, which are two of the important issues previously cited that engineers must address.

The next step in the beginnings of what has been called clinical engineering can be traced back to the late 1950s and a convergence of the first two factors. Concern arose over electrical safety for patients in hospitals resulting from the proliferation of electronic equipment in the vicinity of the patient devices.12,13 The results of a number of reports and analyses14,15 were that the need for biomedical engineering expertise in the hospitals centered for many years on the electrical safety aspect.16 S. Powers and D. G. Gisser, in discussing the issues related to monitoring of trauma patients in 1974, again brought forward the electrical safety issues.9 Indeed, some clinical engineering departments were built on electrical safety testing. Even today, the concern for safety sometimes masks other clinical engineering functions at some hospitals.

The other great influence on the development of the field of clinical engineering was provided by the efforts to establish peer recognition of this new group of engineers who practiced in health care institution. In the early 1970s, Cesar Caceres and Tom Hargest coined the name clinical engineering to describe the new field of engineering practice that had gradually been developing in hospitals over the previous decade. Since it was directed toward the improvement of patient care in the clinical environment, the somewhat curious name stuck. They also can be considered as pioneers in developing a certification program for vetting the competence of engineers wishing to practice this new field. Modeled after other speciality fellowship training and certification programs in other medical fields such as cardiovascular surgery, a certification commission was set up in 1974, with the Association for the Advancement of Medical Instrumentation agreeing to serve as secretariat.

Initially, two boards of examiners were established that reported to a certification commission. Subsequently, other boards of examiners were established, starting in Canada in 1979. The bylaws and terms of reference of each board, such as the U.S. Board of Examiners for Clinical Engineering and the U.S. Board of Examiners for Biomedical Technicians, were subject to review and approval by the certification commission. The boards in turn had the responsibility of establishing the examination process, setting appropriate examinations, and conducting the examinations for clinical engineering and biomedical technician applicants. Following completion of that process, the boards of examiners made recommendations to the certification commission, and certification was approved or not approved by the commission.

In parallel, the U.S. Board of Examiners for Clinical Engineering set up a similar, albeit much smaller, certification program. The two programs were merged in July of 1983 to form the International Certification Commission (ICC). Currently, the ICC has seven boards of examiners reporting to it.

Certification influenced development of clinical engineering in three ways. First, it established and crystalized the name of the field as clinical engineering. Second, it provided some assurance of the competency of clinical engineering practitioners to the health care facilities where they practiced. Third, however, it tended to result in clinical engineers defining themselves in terms of the certification process. The examination process in particular, which in the U.S. boards of examiners was heavily oriented toward electronics, had an effect on both the type of engineering people who went into the field and the educational programs that provided the training. The wide range of management and broad health care issues identified by such people as Rushmer and Caceres tended not to have as heavy an emphasis.

This background provides a basis for the understanding of the role clinical engineering occupies in health care today. Clinical engineering developed with an early large emphasis on the maintenance,
electrical safety, and electronics aspects of medical equipment. Some people, such as Scott and Rushmer, encouraged the consideration of broader safety aspects in health care. Gordon repeatedly emphasized that the assessment, evaluation, and management of health care technology rather than of medical equipment was key. Caceres consistently outlined the broadest possible role for clinical engineering in health care to include all aspects of management of technology throughout the spectrum of health care delivery. Let us then consider that role.

### 36.3 ROLE OF CLINICAL ENGINEERING

The application of engineering techniques, technology, and theory to the solution of health care problems and a management of technology in health care is, by definition, clinical engineering. The American College of Clinical Engineering emphasizes both patient care and management by defining a clinical engineer as “a professional who supports and advances patient care by applying engineering and management skills to health care technology.” More than two decades ago, Scott and Caceres separately identified a number of clinical engineering responsibilities that remain valid today. Their combined list of clinical engineering responsibilities includes development and management of medical systems, education, maintenance, safety, clinical research and development, and analysis and development for the more effective patient care systems. Betts, in considering the changing role of clinical engineering in the 1980s, emphasized the need for management skills in addition to the requisite technical knowledge. More recently, Bronzino identified technology management, risk management, technology assessment, facilities design and project management, and training as the key functions for a clinical engineering department. The clinical engineer must be directly involved with solutions in any of these problem areas at the delivery level if available solutions are to be effected.

He or she must provide education for nursing, medical, and paramedical staff to facilitate their understanding of present technology and future trends. In consultation with medical and administrative staff, he or she must ensure that equipment purchases and hospital designs and systems are optimal and that technology acquisitions are appropriate; he or she must engage in applied research and development at all levels to improve patient care and make provisions for the safe and effective use of technology. Accordingly, the following functions can be taken as descriptive of the role of clinical engineering.

#### 36.3.1 Education

- Prime responsibility for making provisions for training and education associated with technology and instrumentation used in the hospital
- Education of clinical engineering staff
- Education of health care facility staff

The objective is to provide to all medical equipment users with the understanding and knowledge necessary for the proper use of all patient care equipment, calibration, routines, instruments errors, safety procedures, and possible hazards.

#### 36.3.2 Clinical Research/Development

- Design of new equipment, patient aids, and techniques to aid in patient care
- Assistive devices

While the old adage “Don’t build if you can buy” certainly should apply in all clinical engineering departments, it is clear that in most hospitals there is a continuing need for what we could call
customized devices. A clinical engineering department in a rehabilitation health care facility may be heavily involved in the design or modification of assistive technologies. Other examples arise from the particular type of patient care or particular procedures encountered in a specific hospital. These may be as simple as the need to provide electrical isolation for an amalgam of devices, which would require an understanding of medical electrical system standards. More commonly, it would involve providing assistance to other departments in clinical research projects and the development of solutions to current clinical problems unique to the facility. Whatever the application, it is important that clinical engineering have the facility or be able to serve as an interface so that specialized devices, techniques, or accessories can be made available for more effective patient care.

36.3.3 Computing Applications

• Development and management of hospital and patient information and data-acquisition systems

Certainly the ubiquitous presence of computing in all functions of the hospital is well recognized. These functions range from what we recognize as mainframe computers and servers to word processors or personal computers and handheld computers and finally to processors incorporated within diagnostic and therapeutic devices. It is incumbent on the hospital, therefore, to provide some management of computing in the hospital. Traditionally, this constituted establishment of a department with such a function and starting with the large-scale accounting computing function. Increasingly, it is understood that the overlap of other computing needs such as patient records, patient information systems, medical device data and storage systems, and diagnostic and direct patient care computing systems requires a much broader approach. Such an approach is consistent with the role of clinical engineering.

36.3.4 Facility Planning

• Advising and consulting with administrative and health care staff on matters related to the impact of technological developments in health care facility planning

• Standards and regulations

Botz has emphasised that the application and proper use of technology entail the appropriate management of all resources, including equipment, personnel, supplies, and space. It is obviously important then that the requirements placed on a health care facility by a particular technology become part of the considerations for the technology and related equipment. However, it must also be reflected at a very early stage in the planning process in the planning and design of the facility itself. This may be as simple as planning for an appropriate electrical power supply or adequate heating and ventilation for the installation of a device. Ensuring that relevant standards are met is assumed. It may be the much more intensive planning required to ensure proper integration of the technology and all associated equipment in the architectural design.

36.3.5 Systems Management

• Systems analysis

• Design and evaluation of health care systems

• Quality management

System analysis and synthesis have long been a well-established engineering approach that has been used in many different branches of engineering. This formal way of examining the inputs, outputs, and transfer functions applied to a health care system or portion thereof has provided some important
insights and has identified opportunities for improvement. In a similar way, the relatively recent recognition of the applicability of quality-management approaches long used in engineering offers the same potential. Clinical engineering departments are uniquely positioned for involvement in these activities.

36.3.6 Equipment Management

- Consultation with other health care staff in the planning and purchase of equipment
- Prime responsibility for maintenance and modification of equipment

The large number of individual devices in modern hospitals present a unique set of problems in management and represent a major role for clinical engineering. This set can broadly be segregated into:

- **Planning.** Functional program review.
  - New equipment planning
  - Renewal equipment planning
- **Acquisition.** Definition of clinical requirements.
  - Survey of available equipment
  - Specification writing
  - Equipment evaluation
  - Generation of purchase documents
  - Vendor selection
  - Acceptance testing
- **Control.** Inventory management.
  - Maintenance
  - Repair
  - Test and calibration procedures
  - Scheduled inspection
  - Safety program

The technology planning function is one of the most cost-effective roles for clinical engineering. Equipment planning, which includes planning for new and renewal equipment, is an important part of this process. It begins at the functional programming stage of planning. It involves continuing participation in the organizational wide strategic planning process so that equipment-related issues can be appropriately identified. These issues include life cycle, new technology, obsolescence, capital costs, personnel and training requirements, maintenance requirements, operating costs, and facility design considerations. The hospital needs to have all the information to make a decision on the economic and technical viability of either new or existing equipment.

The acquisition of equipment is the next major part of effective equipment management. It follows and is indeed part of the equipment planning phase. Flowing from definition of requirements, specifications are developed. Based on those specifications, a subset of possible equipment is evaluated for conformance to the specifications or standards, and purchase of the most appropriate equipment is initiated. When the equipment arrives at the hospital, the acceptance or incoming inspection of the equipment is a very common function that clinical engineering fulfills.

For all the devices deemed necessary by the hospital to be utilized effectively, an inventory of those devices needs to be in place. Such a system, therefore, however it is maintained, must be able to provide for the hospital the type of device, the capability of each device, the location, the status, and some way to ensure its availability at the point of care. To meet these requirements, in turn, the devices must be adequately maintained and calibrated. All these functions are routine clinical engineering functions. To ensure that this takes place, some sort of inventory, tracking, maintenance
and repair log, and calibration activity has to be provided. Typically, safety testing is also part of this process.

36.3.7 Patient Safety/Risk Management

- Prime responsibility for safety of medical equipment and systems in-patient care areas

The management of the safety risk associated with the use of medical devices is an important function for clinical engineering. While in some facilities this may be incorrectly confined to incident investigation, the broader understanding of the function includes identification of hazards, establishing realistic estimates of the risks associated with those hazards, and instituting suitable control measures to minimize those risks. While the concepts of risk management are more than 400 years old, Leeming was the first to specifically apply the concepts to the clinical engineering field.26 His work in the electrical safety field allowed realistic estimates of the risk associated with the use of multiple electrical devices in the patient care vicinity and provided a basis for a rational deployment of resources and choice of risk-control measures. Much more recently, there is an increasing recognition of the risk-management approach in clinical engineering for technology management as well as for safety applications.27

36.3.8 Regulatory Activities

- Codes
- National and international standards
- Regulations and accreditations

Health care in all countries operates subject to a broad variety of standards and regulations. In many cases, these are technological in nature and should come under the purview of clinical engineering. Feinberg emphasized the importance of this point in hospitals in the United States in listing some of the codes and standards pertaining to the clinical engineer.28 In all jurisdictions, regulations such as municipal, provincial, or national building codes have an impact on health facility design, for example. Furthermore, technical standards affect every device in the hospital. These standards are increasingly international standards but may also be developed by a national or local standards body. Finally, in most countries, such as in the United States, extensive federal regulations govern virtually all aspects of medical devices design, distribution, and application. Clinical engineering, the department responsible for such devices, must be conversant with the appropriate standards and regulations.

Educational programs for clinical engineers and biomedical engineering technicians and technologists reflect the need for training specific to the perceived role of clinical engineering. Figure 36.1 illustrates a set of guidelines and provides a matrix of duties for graduate students during internship periods in one such program. It is provided as an example only.

With this background of the current role of clinical engineering in health care, we can consider the future role for the field and the way it will address the three issues cited earlier:

- Defining and meeting societal needs
- Ensuring that technological solutions are responsible solutions
- Continuing development of required professional skills

36.4 Future Development of Clinical Engineering

In keeping with the definition of clinical engineering as supporting and advancing patient care through application of engineering management and technology, it is important to recognize that the
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**FIGURE 36.1** Example of experience matrix guidelines for clinical engineering students in one clinical engineering master’s training program. *(From University of Toronto, Institute of Biomedical Engineering, Internship Guidelines, 2001.)*
field of clinical engineering will need to continue to develop as health care develops. This will include developments both in sophistication, such as physiological functional imaging or highly integrated information systems, and in scope, such as wellness care or distributed clinical care. Moreover, it will be important that every clinical engineering program or department obey the laws of entropy. These laws describe the natural tendency for systems to run "down hill" rather than evolve to something bigger and better. Very active development by individual departments and by the field will be required for the field to keep abreast of changes and issues in health care. Let us first consider some of these changing health care issues and how they may influence the role of clinical engineering in the future.

In a later chapter in this book J. Currie carefully discusses the impact that technology and other factors have on health care facility design (see Chap. 38). Figure 36.2 lists some of these factors. Advances in science and technology will lead to continuing developments in diagnosis and therapy. The ubiquitous and expanding presence of information-technology applications in health care is widely accepted. New modalities for treatment stemming from current research in areas such as tissue engineering and biomaterials will come to fruition. The incursion of new or newly important disease entities coupled with shifts in population composition will present challenges to health care systems everywhere. Finally, the economic impact of all these factors on health care systems needs to be taken into account.

More than a decade ago, Robert Rushmer described some of these same health technology issues for the twenty-first century. In reviewing research and development at the Imaging Research Center at the University of Washington, he provided a summary of sophisticated new imaging techniques ranging from three-dimensional confocal microscopy for displaying cellular structure to the more common Doppler imaging of flow (Fig. 36.3). These examples in just this one area of technology serve to illustrate three important related health care issues that were also brought out in Currie’s work, mentioned previously. These key issues are the rapid development of new technology, ubiquitous incorporation of computing technology, and the communication and information technology imperative.

First each of these new imaging techniques is based on either new or newly applied scientific principles in health care. Information on the structure, chemical composition, physiological function, and metabolic function of organs or cells can be generated. Imaging of the current density distribution in living muscle or neurological tissue provides a representation of the electrophysiologic function of tissues. Health care practitioners at all levels,
including clinical engineering practitioners, will need to become conversant with these underlying scientific principles if the new technique is to be introduced and utilized effectively. Current examples can be drawn from the differences in three of the commonly available scanning techniques, magnetic resonance imaging (MRI), positron-emission tomography (PET), and single-positron-emission computed tomography (SPECT). Since each is based on the recording of different emissions from tissues generated in different ways, each therefore has different clinical capabilities. This requires an ongoing educational and training effort by health care facilities, as well as consistent assessment of the suitability of the new technology in each particular health care environment.

Second, the previously cited examples of MRI, PET, or SPECT imaging are obvious examples of technologies that require extensive computing power for transduction, manipulation, and display of information. Less obvious is the ubiquitous presence of digital processors in virtually all medical devices that may be serving as either input or output stages or be running algorithms to generate diagnostic data. The signal from a finger or ear transducer requires the application of an algorithm to convert it to a representation of oxygen saturation. An appreciation by clinical engineering of the computational requirements for any of these devices is essential.

Finally, the data and information generated in all these imaging examples must be converted to usable information and communicated effectively to care providers around the health care facility if patient care is to be affected positively. Information must be accurate, timely, and appropriate to the user. This demands not only that the technological infrastructure be provided for moving and storing information but also that new, innovative user-friendly ways of presenting information must be available.

Mack, in discussing the development of minimally invasive and robotic surgery, brought out similar issues. The development of high-resolution CCD chips, together with high-intensity lighting and high-precision miniaturized handheld surgical instruments, has allowed the application of minimally invasive techniques for a wider variety of procedures. The further development into robotic and computer-assisted surgery will place a great reliance on communications and telemetry in particular. Griffith and Grodzinsky also recognized engineering advances in these same areas of microinstrumentation and virtual surgery techniques. New challenges will be presented for clinical engineering not only in keeping abreast of these new surgical technologies but also in integrating the related communications and computer technology into the hospital environment.

While these changes in health care are occurring, there are other external factors that will also affect the clinical engineering field:

- **Internationalization of science and technology.** The science and technology used in health care are universal. Coupled with global manufacturing and international companies, it is clear that science and technology are worldwide in application.

- **Integration of technology.** In the examples provided by some of the preceding authors, it is evident that health care technology is sophisticated and cross-disciplinary. The application of communications theory to improving the accuracy and speed of DNA sequencing is such an example. In addition, devices are increasingly interdependent and intercommunicate freely as they are combined into systems.

- **Communications technology.** Information is the new currency of modern health care delivery. The data generated at the instrument site must be transformed into information usable for diagnosis and therapy. The health care facility or system must have the ability to move that information to the patient care site. Considerations of information storage and transfer and the protocols for making such transfers are all now part of health care’s technology management decisions.

- **Regulation of health care technology.** The health care medical device field is heavily regulated in all countries of the world. The impact this has on the application of technology at an individual hospital level varies with the sophistication of the hospital. However, three examples of international standards that influence the safety and effectiveness of every medical device in the hospital illustrate the pervasive nature of these standards and regulations. These three standards are the medical electrical standard, IEC 60601, the ISO quality-management standard, ISO 13485, and the ISO risk-management standard, ISO 14971. Clinical engineering personnel need to be fully informed about each of these standards and the impact they have on their hospitals.
With the changing health care environment both within and without the hospital, what can we say about the future role that clinical engineering should play? Enderle et al. have offered some helpful insight into the possible future role for clinical engineering, including computer support, telecommunications, facilities operation, and strategic planning. It is perhaps most appropriate, however, first to return to the definition of clinical engineering as being the application of engineering techniques, technology, and theory to the solution of health care problems and a management of technology in health care. While the environment is changing, this definition is not. We understand that there is a moving technological horizon in clinical engineering. In the 1960s, the concern was electrical patient safety; in the 1970s and 1980s, it was equipment acquisition; and in the 1990s, planning came more to the fore. Gordon has consistently strongly emphasized that clinical engineering must concentrate on management. Botz voiced a similar theme, stating that management of technological resources necessitated the management of equipment, personnel, supplies, and space. Technology management, then, must be the overriding theme for clinical engineering departments in the future. Within this broad theme we can identify four key roles that clinical engineering must play that are consistent with those of Enderle et al. and that will ensure that the field deals effectively with the factors that have been previously cited in the changing health care field.

- **Strategic planning.** As new scientific advances are considered for implementation, a clear understanding of the resource, economic, and technical implications must be developed by the hospital planning team. Clinical engineering needs to be involved in all these aspects of planning for the hospital system from the generation of the functional program to the final implementation of the technology within the hospital.

- **Technology management.** Once a technology is in place in a health care system, it must be managed in the best interests of the patient, the users, and the hospital. This management function includes all the traditional maintenance and safety considerations but will increasingly include more advanced management functions such as benefit analysis, reliability, risk-management techniques, and sustainability.

- **Information technology.** The overwhelming presence of information and communications technology in health care will only increase. Incorporated in this broad role is computing support, network support, integration of systems, data transmission and storage considerations, and telemedicine. It is imperative that clinical engineering play a part in this key aspect of modern health care.

- **Standards and regulatory activity.** Health will continue to operate in a highly regulated environment. Standards and the regulations and accreditations that implement those standards affect the hospital explicitly or implicitly. Quality management and risk management are important aspects of technology management, which are now very well defined in national and international standards as well as in many accreditation processes. Technical standards now cover virtually every device used in the hospital. Effective use of these standards and regulations as part of the hospital management will be essential.

Health care and the technology supporting health care will continue to develop. This accelerating trend in scientific developments in health care will continue, and this will, in turn, drive the development in clinical engineering. Active development in clinical engineering will be required if the field is to continue to thrive.

**REFERENCES**


