The Legacy of the CE and BMET: Safer Healthcare Technologies

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The emergence of the biomedical equipment technician and clinical engineer professions in the early 1970s was ostensibly to provide for the maintenance and electrical safety testing of medical devices. Maintenance describes tasks such as changing defective electronic or mechanical parts or calibrating medical devices to assure their proper function. Maintenance is the method and functional safety is the result.

Functional safety of medical technologies is based on three fundamental characteristics inherent in all devices —accuracy, precision, and reliability. Every maintenance task addressing functional safety is performed to assure one of these three characteristics. If not assured, functions such as controlling the intensity of x-rays, assuring valid clinical laboratory readings, or properly analyzing cardiac arrhythmia patterns are not possible. Maintenance also incorporates tasks that assure electrical safety, such as tightening a ground screw, testing for failed components or circuits, and examining receptacles.

Since the 1970s, maintenance programs have addressed the safety issues crucial to protecting patients, staff, and assets. Essentially, prevention of all the hazards that can be associated with the use of healthcare technologies—whether functional or physical—is now incorporated within Medical Equipment Maintenance Plans (MEMPs). It is through these efforts that a safety layer is effectively placed between the patient and potential hazards from healthcare technologies. Continuous monitoring and improvement of this safety layer will maximize patient safety. Safer healthcare technologies will be the legacy of the biomedical equipment technician (BMET) and the clinical engineer (CE).

Check Points

If you would like to know if your department is following the safety "legacy," you should be able to answer "yes" to the following questions:

- ✓ After a "No Problem Found," are you continuing the investigation of the minisystem to determine the real cause of the failure?
- ✓ Is the department providing or requiring education and training on the fundamentals of human factors design as well as human error and basic systems engineering?
- ✓ In merging clinical systems into hospital information systems, is patient safety a primary discussion issue?

The Emergence of the CE and BMET Professions

While the discovery of the properties of x-rays over a century ago is a well known time mark, most people do

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not realize that medical devices were in clinical use prior to the introduction of the x-ray machine in 1895.[1] Early medical devices, such as microscopes, mercury thermometers, stethoscopes, and other extensions of the physician's senses were crude instruments that did not require much technical support. Such support was then provided by the inventor, their assistant, or the device operator (typically, the physician).

As devices like the x-ray machine became more complex, manufacturers either maintained them or trained others to maintain them. Because of the complexity and initial unreliability of these devices, direct technical support was usually required to maintain them. This need sometimes put professionals from various disciplines, such as a biophysicist-repair person, on-site. Maintenance skills and competencies varied widely.

As hospitals appeared and patients grouped in central locations, devices for general patient care were developed, such as mechanical beds, surgical instruments, microscopes, and laboratory equipment. These devices initially required mechanical maintenance support and were maintained by the hospital engineer, a local mechanic, or, in some remote areas, a handyman. Some were sent back to the manufacturer for repair.

Following the introduction of the x-ray machine, many other electro-mechanical devices were introduced: fluoroscopes[2] (also, 1895) mercury sphygmomanometers[3] (1886), EKG machines[4] (1901), electrosurgical units[5] (1925), pH meters[6] (1934), EEG machines[7] (1935), and heart-lung machines[8] (1937).

X-ray machines, EKG machines, and other equipment became smaller, lighter weight, and more practical for use in smaller healthcare facilities over this period and up to about the 1940s due to the invention and development of the triode vacuum tube along with improvements in electronic circuitries and components. Because of the characteristics of vacuum tubes and of the electromechanical circuits, the calibration and maintenance of these devices were a continuous problem. They were more complex than most handymen or mechanics could support. This restricted the usefulness of a handyman to only the simplest of device repairs and the manufacturer to the more difficult repairs. In the larger hospitals, electronic engineers and technicians began to appear and to provide support and repairs.

The early part of World War II saw the emergence of the first professionals trained as BMETs.[9] The Army wanted technicians to service x-ray machines, EKG machines, blood pressure apparatus, etc. in the battlefield hospitals and hospitals in the United States. By this time, a variety of medical devices had emerged and they found that more education and training was required to accomplish repairs than when devices were primarily mechanical. In 1942, Army schools were established to provide for the education and training of x-ray technicians and other repair persons. Although some safety issues were discussed, the primary, recognized need was to keep the devices functioning.

Technical Advances, Safety Concerns Solidify the Professions

The creation and dissemination of more sophisticated devices following World War II came as a result of the physicians and surgeons demanding the ready availability of medical devices in their clinical research, hospitals, and offices. In the 1950s, medical advances were being made on all fronts—open-heart surgery, heart catheterizations, expanded dialysis capabilities, and neurology, for example. An integral part of these clinical advances was the development of new healthcare technologies. Associated with the technologies were electrical hazards that were presented to a wider group of patients. Some of the hazards associated with them were recognized and some hazards were new and related to these new clinical technologies.

New healthcare technologies frequently originated in hospitals and research centers, where they were clinically tested for acceptability and then licensed to manufacturers for construction and dissemination. Physicians and bioengineers guided their development and, where warranted, electronic technicians and mechanical technicians were trained to provide maintenance support. The manufacturers also trained engineers and technicians to support their specific products.

In the 1960s, advances in organ replacement coupled with the introduction of cardiac pacemakers and the emergence of critical care units resulted in published articles and symposiums indicating that serious electrical safety hazards existed in hospitals.[10-12] In effect, safety and maintenance in hospitals ranged from non-existent in most hospitals to fairly good in others.

In 1970, an article about these hazards was written by Ralph Nader and published in the *Ladies Home Journal* magazine.[13] It suggested that 1,200 persons per year died in U.S. hospitals from small quantities of electrical energy known as microshock. The forces for the correction

of electrical hazards—government, accreditation, and an aroused public—finally came together to demand a change for a safer environment. Skilled biomedical equipment technicians and clinical engineers rose to meet the challenge of providing competent support of healthcare technologies.

Education and Certification Assure Competence, Skill

When technicians and engineers provide functions that have a significant public safety impact, they typically are subject to licensing, certification, and/or registration processes that are applicable to their field. These processes review their education and training and provide through examination a validation of their knowledge and skills. The certification process is periodically updated to remain current and assure that those examined are competent to perform requisite safety tasks.

Over time, it became clear that technicians and engineers who provided technical services including safety support to healthcare technologies should be expected to master specialized safety knowledge and training. As a result, BMET and CE educational programs were developed that incorporated appropriate safety knowledge. There was also a clear need for certification programs to assure that eligibility requirements were met and pertinent knowledge had been acquired and demonstrated. After successfully passing a certification examination, the professionals for the first time were to become certified as CBETs and CCEs.

AAMI identified the requirements for BMETs and developed the certification process in 1972.[14] To be eligible for certification, the BMET was required to have two years of college education and experience in BMET technology or an equivalent combination of education and experience. Up to the year 2005, over 6,000 BMETs have been certified.

A university group intending to establish a clinical engineering department at George Washington University Medical School first introduced the term clinical engineer in 1967.[15] AAMI identified the requirements for clinical engineers and established a certification process. It began certification of CEs in 1975.[16] To be eligible for certification, the CE must have a 4-year engineering degree, additional training in life sciences, and a one-year internship. The CE certification process was discontinued by AAMI in 2001 and re-established by the American College of Clinical Engineering Health Care Technology Foundation (AHTF) in 2004 (www.acce-htf.org).

MEMPs Focus on Systems Safety

Over three decades—1975 to 2005—CEs and BMETs have focused on the development and implementation of cost effective equipment management plans that assured the safe functioning of medical devices. The programs that have emerged after 30 years of adjustments are generically called Medical Equipment Management Plans (MEMPs). These programs define the responsibilities of administration, technicians, and engineers and technology operators.

Microshock, the silent menace of the 1970s, was generally proven to be a rare event but one readily avoided by changes in device designs, maintenance plans, and good operator techniques. Electrical shocks were greatly reduced and a report of such an incident due to a failed device is today quite rare. This safety level was initially accomplished by the efforts of BMETs and CEs, through implementation of the Medical Device Amendments[17] of 1975, and through design changes by manufacturers.

Maintenance and safety plans for equipment are generally managed by hospital departments called clinical engineering departments or biomedical engineering departments. The first departments created focused on the maintenance and safety aspects of the technologies already in use in a hospital. Inventories were taken and maintenance forms provided. Ground screws in power plugs were tightened and their integrity verified; accuracy and precision of the devices were checked; burnt lamps were replaced and cases were cleaned. Preventive maintenance guidelines and periods were established. Safety specifications for new equipment were written and included with purchase orders. It was assured that operators of healthcare technologies were taught the proper functioning and safe use of the devices.

Programs began to recognize that newly purchased equipment needed to be inspected prior to being used on a patient to ensure that it met the newly established safety requirements and had not been damaged during the shipping process. Later, in 1975, the value of pre-purchase evaluation was recognized as a safety tool for preventing devices with recognizable hazards or incompatible designs from being purchased. Each of these simple steps in a program was implemented and significantly improved electrical safety and provided a more functional device for use by the clinicians. However, this program

included only the safety aspects that applied once the hospital took ownership and possession of the device.

Safety Begins with the Manufacturer

As the programs were being implemented, it became clear that the safety of devices began with the manufacturer. The manufacturer determined three key safety elements: human factors design, selection of the component parts, and design of the circuits. The first related directly to human error, the second and third related to sudden component or circuit failures as well as the slower deterioration of components and, thus, the periods for preventive maintenance.

After the Medical Device Amendments were passed by the Congress in 1975, manufacturers of devices were required to demonstrate that their new devices were safe and efficacious. The law also mandated that devices be constructed following defined manufacturing processes and required manufacturers to implement recalls of devices that demonstrate unsafe designs. These requirements were intended to assure the safety of devices available for purchase and ready to incorporate in healthcare systems.

Achieving Functional Safety

If a device is used for diagnostic, monitoring, or therapeutic purposes, it must meet the specifications for accuracy, precision, and reliability established by the manufacturer. If it does not, a misdiagnosis may result in an injury, a monitoring device may fail to alarm during a heart abnormality, or a defibrillator may not deliver an adequate impulse for defibrillation. Each of these can be the result of a device being inaccurate, imprecise, or unreliable. When viewed by a patient, these are patient safety issues. From the point of view of a healthcare administrator, these may be considered a mixture of maintenance and safety activities.

The functionality of a device can be defined by these three factors—accuracy, precision, and reliability (see sidebar). Although maintenance actions are not generally defined in these terms, any maintenance action performed is designed to ensure at least one of these factors.

Accuracy can exist without the device being either precise or reliable and a device can also be either precise or reliable without being accurate. When a screw in a 115 vac power plug is tightened, it is assuring the reliability of the ground or the 115 vac connections. This is an electrical safety issue. Functional reliability of a device may be maintained by the periodic replacement of components such as the replacement of a defibrillator battery that precludes the failure of the defibrillator. The accuracy and precision of many clinical laboratory devices are verified by using a known standard just prior to measuring an unknown. Accuracy and precision are also measured during preventive maintenance periods as defined by MEMPs. This description argues that all MEMPs are actually safety programs and that maintenance is simply the method by which we achieve functional safety as well as physical safety.

Systems Approach to Safety

To deliver a clinical benefit, any device must be part of a minisystem.[21] Each minisystem typically contains five components: the device, a patient, a facility, adjacent minisystems, and a device operator. Any one of these systems components can fail or contribute to failure and result in the device not delivering its clinical benefit.

In the 1970s, most devices were quite unreliable so maintenance efforts of the clinical engineers focused on establishing some level of device reliability and safety. Hospital engineers were responsible for maintenance and reliability of hospital facility systems, including gas, suction, and electricity that support devices. The nurses, physicians, surgeons, and technologists were responsible for bringing patient, facility, and device together to function safely in an environment that includes many other minisystems.

With these split responsibilities for components within the same or other minisystems, it was assumed that the minisystem would function properly when all the components were finally brought together. Each responsible group or profession tended to defend the borders of their profession and preferred that other professions not scrutinize their borders too closely.

This compartmentalization limited incident or accident investigations if human error was suspected. The nurse, physician, or technologist then assumed responsibility for any correction. These were the circumstances in the 1970–80s.

In the 1990s, Leape[22] argued that human error contributes to approximately 70% of all adverse events and that hospitals must examine their systems and minisystems for the root causes of these errors. CEs and BMETs have encountered human errors when they investigated adverse, device-related incidents and

found that the device worked perfectly well. These were called No Problems Found (NPF) and although not all problems found were operator-caused, a significant number of them were. Subsequent to Leape's studies, the Joint Commission[23] required root cause analysis teams to perform complete investigations. The borders of the professions now were more readily crossed and each component of the total system more carefully examined.

Systems analysis is part of the domain of medical equipment professionals. CEs/BMETs have always been required to analyze and investigate failures in electronic and electrical systems. It was called troubleshooting and required logic and knowledge of the circuits and components. In addition, they have studied the physical causes of injuries and have studied human anatomy and physiology. These qualities have proven invaluable for investigating device-related systems and identifying causes, and are just as applicable to investigating incidents that do not involve a device.

With medical devices becoming more reliable and less time being spent on troubleshooting of devices, CEs/BMETs will spend more time analyzing deficiencies in systems, proactively improving high risk systems and investigating incidents. In effect, the focus of CEs/BMETs is moving from device-centered activities to systems-centered activities. This progression will in turn modify MEMPs, and they will also become more systems-centered. To accept the new responsibilities for analyzing systems, CE/BMETs will need to acquire additional education on human factors design, human errors, and basic systems.

Functional Safety Equals Accuracy, Precision, and Reliability

Functional safety of medical technologies is based on three fundamental characteristics inherent in all devices—accuracy, precision, and reliability. Every maintenance task addressing functional safety is performed to assure one of these three characteristics.

Accuracy: A measure of the deviation of some parameter of the device from a specific standard. As expressed by Feinberg,[18] "this term describes the algebraic difference between the indicated value and the true or theoretical value."

Example: A nurse complained that an IV pump was removing the fluid from the IV bag too rapidly. The BMET tested the flow rate of the pump and found that when set to 100 mL/hr the pump was actually pumping at a rate of 148 mL/hr. This was repeatable to within 4–5%. The design accuracy for the flow rate was ±20%. The rate inaccuracy was +48% of the set rate. In this instance, the flow rate was precise but inaccurate and the device required a repair.

Precision: "The degree of reproducibility of a measurement.[19]": Each time the same measurement is repeated it should be the repeatable within a specified range…even if the value measured is inaccurate.

Example: A study of home blood glucose monitors (HBGMs) was made (1994). The objective of the study was to analyze and statistically compare the accuracy and precision of the HBGMs produced by several major companies. Accuracy of each monitor was studied by comparing the glucose value reported by each HBGM with that determined by a reference method. Precision or reproducibility of results was performed by testing a single, known whole-blood glucose sample 20 times on each monitor. The precision of each device was tested on known low, normal, and elevated samples. Actual and absolute deviations from the reference standard demonstrate that three of the HBGMs passed this base-line standard for accuracy but one failed to pass due to imprecision.

Reliability: Application engineers use the following definition: "the probability that device will function without failure" over a specified time period or amount of usage. [20]

Example: An automatic external defibrillator was recently recalled by the FDA because "…an intermittent electrical connection within the device may result in failure or unacceptable delay in analyzing the patient's ECG, failure to deliver appropriate therapy." This defibrillator was not being recalled because it was inaccurate or imprecise, but because an intermittent connection made it …*unreliable.*

Conclusions

Since their roles were first defined by certification in 1970s, BMETs and CEs have focused on the safe use of healthcare technologies. That focus began with a reduction in electrical hazards and continues today with analysis of more complex hazards such as the potential for electromagnetic interference and the safe integration of clinical systems into hospital information systems. Over the past three decades, technology systems have become more reliable but also more complex. The increase in reliability has reduced some of the need for preventive maintenance. However, the increased complexity has brought new safety concerns associated with the man-machine interface.

Concerns such as human factors designs and use error are now in the forefront of system safety, designs, and support. With functional safety as the goal and maintenance as the means, the MEMP becomes a healthcare technology safety program. Slowly, as the need for maintenance is further reduced, some of the responsibilities of the BMETs and CEs are shifting from device-specific support to systems safety specialist. These shifts signal a need for greater education and training in basic systems engineering, human error fundamentals, and human factors concepts. It also highlights the need for the BMET/CE and their certification process to remain current with changes in healthcare technologies, if the current high levels of safety are to be maintained. Safer healthcare technologies will be the legacy of the biomedical equipment technician and the clinical engineer. ■

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