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Healthcare Technology: A Strategic Approach to Medical Device Management

A thesis

presented to

the faculty of the Department of Engineering Technology

East Tennessee State University

In partial fulfillment

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Master of Science in Engineering Technology

by

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ABSTRACT

Healthcare Technology: A Strategic Approach to Medical Device Management

by

Chad A. Kinley

The constant evolution of medical technology has increased the demand for managing medical devices to ensure safety and effectiveness. In this paper I will investigate how biomedical engineering has addressed the issue of equipment management and identifies strategies to successfully maintain an inventory of medical devices.

Through research, on-the-job experience, and in-depth discussions with various biomedical engineering managers, I have been able to document possible equipment strategies and best practices for managing medical devices. There is really no “one size fits all” to medical equipment management due to the various clinical environments, but there are many aspects that remain necessary to ensure proper equipment safety and function while meeting or exceeding various regulatory requirements.

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HEALTHCARE TECHNOLOGY

Medical technology is constantly evolving to improve and prolong the lives of people. There are many new medical devices and procedures available that contribute to saving countless lives. Medical devices also help improve the quality of life for many people. With the constant evolution of medical technology comes the constant challenge of managing the technology to ensure proper safety and function.

Healthcare technology deals with patient care including devices ranging from simple thermometers to complex systems such as MRIs. With such a wide range of equipment and a growing demand for efficiency and safety, servicing these devices has become a very complex task. The service industry for medical devices is known as biomedical or clinical engineering. Recently there has been a push to unite the field by renaming it healthcare technology. This field is evolving at a steady pace, but many obstacles and challenges are increasingly becoming more prevalent.

Early medical devices had high failure rates due to the inconsistencies of the technology available which consisted of vacuum tubes, mechanical relays, and other nonsolid state devices. Also, there were no rules and regulations to regulate manufacturing practices or equipment management. This created inconsistencies in reliability, performance, and safety. Patient safety is the biggest concern when dealing with medical devices. First, the equipment must be electrically safe, meaning patients will be free from experiencing potentially painful or lethal electrical shock. Ultimately the equipment must perform its intended purpose flawlessly and safely.

Patient care has greatly improved within the past 50 to 60 years when electrically powered equipment was first heavily introduced in the hospital environment. In its infancy healthcare technology was very unstable, as the technology was primitive compared to what is

available today. According to the Penn Biomedical Support, Inc. in 1971, “Electrical safety in hospitals was in serious doubt. An article in Ladies Home Journal, by Ralph Nader talked about unsafe hospitals, and the danger of Micro-shock. They even quoted some experts estimating over 5000 undetected electrocutions in hospitals every year.” (Penn Biomedical Support, Inc., 2011) This article identified potential hazards within healthcare associated with electronic devices and pushed these ideas publicly to increase patient safety. With the safety hazards exposed of electronic healthcare devices biomedical engineering technology was officially created. The need for technicians to keep the equipment safe and functioning properly will be ever present. These technicians would soon be referred to biomedical equipment technicians (BMETs) and clinical engineers (CEs).

BMET Job Descriptions

Biomedical technicians can work in a wide variety of classifications. Most employers have different levels of biomedical equipment technicians. The entry level is considered a BMET I. This position deals with less complex equipment mostly infusion pumps, patient warmers, and thermometers. The next levels of employment would range from BMET II, BMET III, and lead tech. These classifications deal with more complex equipment often allowing the techs to specialize in certain areas. Specialty biomed equipment that requires training and expertise includes ventilation, anesthesia, surgical lasers, sterilizers, balloon pumps, dialysis, and heart-lung machines. A lead tech is usually the “jack of all trades” with a high level of seniority. Lead techs usually are working managers or supervisors who support the lower level techs while maintaining an inventory of high level equipment. Salaries for BMET classifications including BMET I, BMET II, and BMET III range from \$32,549 to \$72,761 (Bowker, 2011, p. 11)

Another tech classification is the field service engineer that usually refers to a radiology or laboratory equipment specialist. These techs deal mostly with radiological, also known as imaging equipment, or laboratory equipment. Servicing imaging and laboratory devices in-house has become a new trend in the biomedical field. In the past most hospitals had contracts on their imaging and laboratory equipment through either OEMs (original equipment manufacturers) or ISOs (independent service organizations). These contracts consume large amounts of capital and the response time of a service representative could take hours if not days. Taking imaging and laboratory devices in-house can reduce equipment downtime and can greatly reduce service costs for the healthcare facility. Most radiology equipment specialists specialize in one of the following modalities of imaging technology: x-ray, CT (Computed Tomography), MRI (magnetic resonance imaging), PET (positron emission tomography), nuclear medicine, linear accelerators, mammography, cath labs, or ultrasound. Salaries for imaging specialists range from \$63,318 to \$94,695 (Bowker, 2011, p. 11).

Laboratory equipment also requires a specialist to provide service and support. Just as imaging equipment has several different modalities so does laboratory equipment. These laboratory modalities would include histology, pathology, and hematology. Histology is the study of cells. Pathology is the study of diseases, and hematology is the study of blood. In each of these different lab modalities there are complex analyzers used to obtain clinical results. These analyzers are very complex. Eliminating contracts and servicing radiology and laboratory equipment in-house requires time and careful selection from the director of clinical engineering. The right technicians must be hired to properly service the equipment. Field service engineers can be previous OEM or ISO employees or a clinical engineering manager can help develop a current BMET into one of these roles by providing training to develop their staff.

Clinical Engineers are more advanced than biomedical technicians. Most clinical engineers have college degrees and perform more complex work such as project and equipment planning and supervisory duties. Clinical engineers focus on the entire inventory of a hospital and look for improvements, provide training, and may control service contracts, while biomed techs directly support individual pieces of equipment through repairs and preventative maintenance. Clinical engineers are more apt to give suggestions on capital purchases and perform installations of complex devices and systems. In most cases a clinical engineer is the manager of the department. Clinical engineer salaries range from \$61,000 to \$85,000 with supervisory positions ranging from \$62,000 to \$92,000 (Suban, 2011, p. 32). Formal education requirements will vary from system to system, but most high level jobs such as management most likely require a college degree. Most tech jobs may require an associate's degree in electronics or military equivalent. This field relies highly on experience and on-the-job training (OJT).

AAMI, Association for the Advancement of Medical Instrumentation (2012), has created job descriptions for the following medical equipment service titles:

A BMET I is an entry-level or junior biomedical equipment technician (BMET) that works under close supervision, performs skilled work on preventive maintenance, repair, safety testing, and recording functional test data, is not certified, and usually has less than four years of experience. A BMET II is a BMET who usually has a two-year degree or higher, has good knowledge of schematics and works independently on repairs, safety testing, and preventive maintenance (PM), maintains records, writes reports, and coordinates outside repairs and has an average experience of eight years. A BMET III is a

highly experienced or specialized BMET usually having an AS (two-year) degree or higher, has substantial experience and may be certified (CBET), and does highly skilled work of considerable difficulty, and has comprehensive knowledge of practices, procedures, and types of equipment with an average experience of 12 years. An equipment Specialist is a highly specialized BMET having special training or equivalent experience in lab equipment (LES) or radiology equipment (RES), usually has an AS (two-year) degree or higher, performs highly skilled work of considerable difficulty and may hold certification as CLES or CRES. A BMET supervisor is a BMET who supervises others, has a significant amount of training, education, or equivalent experience, most have a BS (four-year) degree or higher, schedules and assigns work to subordinates, but also continues to do highly skilled repairs, has comprehensive knowledge of practices, procedures, and types of equipment, has an average experience of 13 years. A clinical Engineer is a graduate engineer holding a BS, MS, or PhD that performs engineering-level work of considerable difficulty, has the ability to modify devices and do analysis of devices and systems (Association for the Advancement of Medical Instrumentation, 2012, para. 1-6).

Certifications

There are few certifications available in the biomed field. AAMI offers three different certifications: CBET certified biomedical equipment technician, CRES certified radiology equipment specialist, and CLES certified laboratory equipment specialist. Each certification has its obvious differences, but all have similar requirements such as work related experience, education, and ultimately passing a rigorous test. These tests contain five key areas: anatomy and

physiology, public safety in the healthcare facility, fundamentals of electricity and electronics, medical equipment function and operation, and medical equipment problem solving.

Anatomy and physiology is a very important concept that all biomed must know. Biomed must understand how the human body operates so they can relate to the function of the medical equipment that gives them a better understanding of how the device works. Public safety in the healthcare facility helps the biomed technician know and understand various rules and regulations present in a hospital environment. Most of these are fire and safety codes found in NFPA 99, National Fire Protection Agency. The fundamentals of electronics and electricity section provides necessary knowledge when repairing electronic medical equipment. This section focuses on electronic principles such as voltages and resistances and other concepts of electricity. The medical equipment function and operation section ensures that the technician understands the theory of operation for many medical devices. In order for a technician to properly troubleshoot a piece of medical equipment they must know how it works. Medical equipment problem solving proves that the certified technician is competent in properly troubleshooting medical equipment and solving equipment related problems. In this section schematics will be shown and an issue will be addressed. The object is to identify the most likely cause of the given problem. For example a schematic of an infusion pump will be given and the known problem is that the alarm speaker is not working. The technician is expected to read the schematic to identify possible causes of the alarm speaker failure.

The difference between the three certification tests is in the medical equipment function and operation section and the medical equipment problem solving section. The CBET test focuses mainly on patient care equipment such as patient monitoring systems including ECG (cardiac wave forms), SpO₂ (blood oxygen concentration), and NIBP (blood pressure). The

CRES test focuses on radiological equipment such as x-ray machines and magnetic resonance imaging (MRI), and the CLES test focuses on lab equipment such as hematology equipment and various chemical analyzers. AAMI certifications are highly respected in the field. Most employers will give incentives for gaining certification, such as a pay raise or promotion. Also, many employers prefer certification upon employment.

Another certification is the certified clinical engineer or CCE. The CCE certification is given by the American College of Clinical Engineering (ACCE). The ACCE defines a clinical engineer as “a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology” (American College of Clinical Engineering, 2012, para. 1). Obtaining a CCE certification is more difficult than obtaining an AAMI certification. The CCE certification deals with technical information similar to an AAMI certification but also deals with supervisory information. Also, the professional and educational requirements are more stringent. AAMI does not require a degree if the applicant has at least 4 years of related work experience.

The ACCE requires a license as a professional engineer (PE) with 3 or more years of experience, a BS degree with 4 years of experience, or a BS in engineering technology with 8 years experience. The CCE certification process consists of a written exam as well as an oral exam. Content of the exam includes technology management, service delivery management, product development, testing evaluation, modification, information technology, telecommunications, educating others, facilities management, risk management, safety, general management, and other related topics. All certifications require a continuing practice journal to be completed and submitted in certain time intervals as well as a renewal fee. This keeps the certification from expiring ensuring that the certified person is continuing an acceptable practice.

If the journal is not completed, the certification will expire and the applicant must retake all necessary measures to regain certification.

“Various surveys have shown that in general, those BMET’s and CE’s who have a higher education, more experience, and hold a certification earn more than their peers who do not,” says Arif Subhan, chief biomedical engineer for VA Nebraska – Western Iowa Health System (Suban, 2011, p. 32) The certification for both the CCE or AAMI certifications are both time consuming and costly, any person who obtains a certification should see a return on investment with a pay raise, new job opportunities, and a great sense of accomplishment.

Electrical Safety

Unsafe leakage currents can cause electric shock to patients. Electricity always flows through the path of least resistance therefore electronic medical devices must have a measured resistance to ground of no more than .5 ohms. This helps insure that any leakage currents will flow to ground through the device rather than being transmitted to the patient. AAMI has set recognized standards for these patient safety aspects. AAMI recommends that ground resistance of a medical device be no more than .5 ohms. Medical device chassis leakage is not to exceed 100uA in patient care areas (Atles, 2008, p. 627). A patient connection would be any type of exposed metal lead that is connected to the patient such as EKG leads or defibrillator paddles. In order to maintain these standards an electrical safety analyzer is required and will be found in any biomed shop. Electrical safety checks must be performed during the equipments initial inspection, during preventative maintenance, and after every repair.

Test Equipment

Biomedics must have many tools available to them in order to properly repair and test medical devices. A biomedics tool box may contain simple items such as screw drivers, wrenches, and a soldering iron, but there are many times where complex test equipment is required to verify that a medical device is properly working and is safe to use. Test equipment is also very important when calibrating medical devices. One of the most common pieces of test equipment is an electrical safety analyzer. A safety analyzer allows a technician to test and verify the electrical safety of any electrical device using a standard power cord. The safety analyzer will show electrical leakage currents in the equipment's chassis, ground wire of the power cord, and patient leads. Also the analyzer will show the equipment's resistance to ground. Another common piece of test equipment would be a patient simulator used to test patient monitoring equipment. Most patient simulators will simulate cardiac rhythms, blood oxygen saturation, blood pressure, temperatures, and respiration rate.

A defibrillator test device will allow a technician to discharge defibrillator pads or paddles to simulate a real life scenario to ensure that the selected energy is delivered within critical time constraints. Electrosurgical units require ESU test equipment to safely measure the electrical outputs of ESUs. Electrosurgical units use electricity to cut and coagulate tissues usually in a surgically invasive situation. Ventilator verifiers connect to the patient circuit of a ventilator to show the actual flow, pressure, and percent oxygen present. There is even more sophisticated equipment for testing radiographic equipment, such as dosimeter, which will show the mA, KV, mAs, and dose of an x-ray exposure. The list of test equipment can almost be endless. There is a piece of test equipment for every different type of medical device. Of course there are different manufactures of test equipment with several different models. The important

thing when dealing with medical test equipment is to make sure that it is properly calibrated and in working order. It is required that all test equipment has a documented calibration at least once a year. Each piece of test equipment should be entered into the computerized maintenance management system (CMMS) with its own asset ID therefore the test equipment can be accurately maintained and documented.

Patient Safety

The whole concept behind biomedical engineering is to ensure that all medical equipment is safe to use and will not harm any patient in any way. The biomedical engineering department manager is usually required to give safety reports at the monthly hospital safety meetings, also known as EOC, environment of care, meetings. All department managers as well as some administrative staff should attend these meetings, which are a requirement of Joint Commission. In these meetings the data presented by the biomedical engineering department should include the percentage of preventative maintenance completed and should give reasons for the devices that did not receive the required maintenance. If the reason is that the equipment was in clinical use, the biomed manger should request that the department leaders notify the biomed department when the equipment becomes available for maintenance.

Even more importantly the biomed manager should report the items that were unable to be located. Many PMs are not completed because the biomed tech simply cannot find the device. If department leaders are aware of what items cannot be located, they can help find the items or alert their staff to help locate the items. The hospital should have a policy about the requirements of retiring a device that cannot be located for a certain amount of time. For example if the biomed staff and the hospital staff cannot locate a device for a certain amount of time the device

should be noted as retired and removed from service. If the device is located after that period of time, it can be fully assessed by the biomed department and reactivated in the system. A common life support device that is difficult to locate is a hand held cardiac pace maker. These devices are mobile and can easily fit in drawers which make them difficult to locate.

Alerts should be reported on a scheduled basis. Alerts are usually given by the OEM and/or ECRI and provide information that a device may be potentially harmful to patients or cause death. The biomed manager must report these devices so that all hospital staff are aware of the issue and to explain the steps being taken to resolve the issue. A patient incident would include any device failure that lead to patient harm or death. These incidents should be reported to the safety committee along with a course of action on how to prevent duplicate occurrences. In some cases incidents need to be reported to the FDA, Food and Drug Administration, for further investigation which could lead to a recall on an entire fleet of devices.

BMET Workload

The main workload for a biomedical technician consists of preventative maintenance (PMs), repairs, and incoming inspections. Preventative maintenance is a process where equipment is checked during specific intervals to ensure proper safety and function. These intervals can either be related to time, such as annual, or can be focused on usage, such as hours used or cases performed. Some PMs require parts, cleaning, lubricating, etc.

Preventative maintenance requirements need to be explained in the hospitals Medical Equipment Management Plan (M.E.M.P.) which is required by Joint Commission. Most facilities use original equipment manufacturers (OEM) recommendations, Emergency Care Research

Institute (ECRI) recommendations, and evidenced-based planning to create policies regarding PM intervals and procedures.

Preventative Maintenance Work Orders

Preventative maintenance, PM, is one of the main functions of the biomedical engineering department. Preventative maintenance is the process of ensuring medical devices are working within manufacturers specifications through a recurring maintenance schedule. Most devices are required to have an annual PM. Life support devices and some lab equipment are required to have a PM semiannually or quarterly. PMs can be as simple as a functional check to verify the device is working properly. Some PMs can be very time consuming and may require calibrations and parts to be replaced. Common PM replacement parts are o-rings, batteries, filters, and various sensors.

PM stickers should be placed on all medical devices. The PM sticker should include the technicians identification, usually initials, last PM performed date, and next PM due date. PM stickers help biomed staff easily find equipment that is past due for inspection. A great way for quick identification is to use a color scheme for PM stickers, such as color coding for various months of the year. Some hospital systems made up of several individual facilities may use color scheme PM stickers to easily identify equipment that does not belong to the facility. Each facility will have its own color to identify ownership of equipment.

Upon completing a PM, technicians can document any necessary information such as any found problems and any corrective actions. Certain devices needed to be thoroughly documented such as centrifuges and blood warmers, per CAP, College of American Pathologists. Documentation would include temperatures, RPMs, recorded times, and tested verification of

alarm limits. For example when performing a PM on a centrifuge the verified speed and time need to be documented in the PM work order. Also, documentation for a blood warmer should include running temperatures and over temperature alarm verification. For some items it may be acceptable to simply record pass or fail when closing the PM work order. This pass or fail procedure is sometimes referred to as exception testing. These policies regarding documentation of PM work orders needs to be explained in the MEMP.

Some medical devices may simply require a functional check, also known as performance assurance or performance verification. This means no parts are to be replaced. A rule of thumb would be to check if the inputs vs. outputs are within plus or minus 10%. For example, to check an infusion pump would involve setting flow rates and measuring the actual output of fluid and time elapsed vs. the set output in time. If the IV pump was set to deliver sixty ml/hr and the measured output was 4.8 ml delivered in 5:03 minutes the device would be considered to have an acceptable operation though the output should have been exactly 5ml delivered in 5 minutes, the recorded output was well within a 10% range. This is only an example and all acceptable percentage limits should be verified in the preventative maintenance procedure. Functional checks and electrical safety checks should always be performed after any repair to ensure that the repair did not hinder the performance, accuracy, or safety of the device.

Evidenced based planning, also known as risk-based planning, is a recent trend in the field. With newer and more stable technologies the need for preventative maintenance decreases. Older pieces of equipment may require quarterly preventative maintenance schedules due to their instability, while newer technologies with insignificant failure rates can have increased time between preventative maintenance or no scheduled maintenance at all. It is possible for PMs to cloud the vision of biomedical technicians. Instead of focusing exclusively on PMs, biomed

departments should also focus on equipment uptime. Equipment uptime is when a device is in proper working order. Biomedics can greatly affect equipment uptime by making sure clinical staff is properly trained which reduces user errors, and by giving input on future equipment purchasing which prevents equipment with a known high failure rate from being purchased.

The initial step in evidence or risk based planning is tracking equipment history, which is a very easy process with the implementation of a computerized maintenance management system (CMMS). Some CMMS programs have a built in mean time before failure calculation to identify equipment failure rates. If no problems are seen in a certain time frame when reviewing the history of a device, confidence can be gained in knowing that that particular item does not need to be regularly examined thus increasing uptime of the equipment and allowing techs to allocate their time to more beneficial activities. The increase in equipment uptime is because the device is not removed from service for a PM to be performed. Though evidenced-based planning may work in some cases it is not fit for all items, especially life support devices. The life support category includes such devices as defibrillators, ventilators, anesthesia machines, and any blood related device such as blood warmers. Basically any item that directly sustains and or prolongs a patient's life is known to be life support. These items are usually required to be checked quarterly or semi-annually.

In December of 2011 article "Ref: S&C: 12-07-Hospital" was released from the Center for Medicare and Medicaid Services that required all preventative maintenance procedures on critical devices to be performed by manufacturers' recommendations (CMS, 2011). Critical devices would include all life support devices and any other devices that are critical to outcome of a patient's health and safety. CMS is not clear on the exact meaning of "critical," so the definition and selection of devices known to be critical will be up to the Environment of Care

Team in each individual hospital. Also all new equipment must be maintained per manufacturers until sufficient historical information is obtained to alter the schedule. Sufficient history would be between 12 and 18 months. The notice specified that all preventative methods must follow OEM techniques regardless of the maintenance frequency. Noncritical devices will be eligible for altered preventative maintenance schedules with a sufficient history based risk assessment. The purpose of this regulatory alert is to ensure that all equipment maintains a sufficient level of quality and safety.

Corrective Work Orders

Corrective work orders are also a main component of the biomedical engineering department's responsibilities. Corrective work orders would involve repairing medical devices that are reported broken by clinical staff. Preventative maintenance helps to reduce the amount of corrective work orders but unfortunately all equipment is subject to normal wear and tear, user error, and abuse that results in a corrective work order.

The first step in reducing corrective work orders is ensuring that all clinical staff and other end users of medical devices are properly trained. Having properly train users prevents inappropriate use that may damage a device and also prevent user error that results in a false corrective work order submission. When techs respond to a work order that is a result of user error, time is wasted troubleshooting equipment that is fully functional. In the event that user error is identified training should be provided to the clinical staff to ensure they are familiar with how to properly operate the equipment.

How clinical staff report failures can drastically improve turnaround time for a broken device. Some hospitals may have clinical staff bring equipment to the biomed shop, while others

may make phone calls or send emails. An intelligent approach to reporting equipment failures is with a computer system, such as a hospital intranet system where clinical staff would enter required information that would then generate a work order for the biomedical engineering department. Certain fields would be required such as the unique hospital identification code as well as a detailed explanation about the problem. A problem many biomedics face is when clinical staff report a failed device as “broken” or “doesn’t work”. This is unacceptable in a professional healthcare setting. It also increases the downtime of the equipment because biomed techs have to spend extra time trying to figure out the problem with the equipment.

If a detailed explanation is initially given, the biomed tech can start troubleshooting much faster because they have an idea of the problem. This type of hospital intranet reporting system should be integrated with the CMMS so that work orders can be immediately put in a prioritized queue and techs can be quickly notified. The faster techs are notified the faster they can respond which will decrease equipment downtime. The priority will be determined by the type of equipment. There are two basic types of medical equipment, life support and nonlife support. Life support equipment will always have top priority. If the item is an IV pump where there are plenty to go around, the damaged pump can be immediately replaced and repaired at a more convenient time. Also, the internet based corrective work order application should allow clinical staff to track the repair process either through an automated email process or a web based end user system. This would allow the clinical staff to know the repair status, such as parts ordered, or parts received. Once the repair is completed the item will be removed from the cue which will let clinical staff know the repair has been completed and the equipment is ready for use.

Some hospitals choose to contract their biomed services to third-party companies. Some of the larger third-party biomedical engineering companies have a call center that receives phone

calls directly from clinical staff having equipment issues. One such company has a very robust system where a call center operates 14 hours a day, with plans of becoming available 24 hours a day 7 days a week. When a piece of equipment is having issues the clinical staff calls the call center giving the operator their name, phone number, asset ID number, and a brief explanation of the problem. The call center has access to the CMMS system and generates a work order to the assigned tech. The work order that is then e-mailed to the biomed tech can be received on a computer or mobile device. Also, the work order is held in the biomed techs queue in the CMMS database until the work is complete and the work order is closed. This system also allows for clinical staff to receive emails about the status of the repair to keep them fully aware of the equipments status. Keeping clinical staff informed of their equipment status helps build relationships and trust between the clinical staff and the biomed department.

Laws and Regulations

Healthcare is heavily regulated by various organizations. The main organizations are: JC (Joint Commission), CMS (Center for Medicare Medicaid Services, FDA (Food and Drug Administration), ECRI (Emergency Care Research Institute), NFPA (National Fire Protection Agency), OSHA (Occupational Safety Health Administration), ASHE (American Society for Healthcare Engineering), AMMI (Association for the Advancement of Medical Instrumentation), ACR (American College of Radiology), CAP (College of American Pathologists), and various state organizations.

Joint Commission, commonly referred to simply as JC, is one of the most prominent accreditation organizations in the healthcare industry. JC provides a method of accreditation for hospitals that covers more than just biomedical engineering aspects. Joint Commission's

Environment of Care, Essentials for Healthcare publication includes expectations of the biomedical engineering department. The following Joint Commission standards are found in Joint Commission's Environment of Care, Essentials for Healthcare sixth edition published in 2006. Each one of the following standards directly relates to equipment management. Standard EC.6.10 refers to medical and laboratory equipment. This standard states, "Equipment must be maintained by qualified individuals." EC.6.10 has nine elements of performance (EP's). EP 1 states, "The organization must have a plan to manage the effective, safe, and reliable operation of equipment." EP 2 states, "The organization identifies and implements a process for selecting and acquiring equipment." EP 3 states, "The organization establishes and uses risk criteria for identifying, evaluating, and creating an inventory of equipment to be included in the equipment management plan before the equipment is used." This criterion addresses the following: equipment function, physical risks associated with use, maintenance requirements, and equipment incident history. EP 4 states, "The organization identifies appropriate inspection and maintenance strategies for all equipment on the inventory for achieving effective, safe, and reliable operation." EP 5 states, "The organization defines intervals for inspecting, testing, and maintaining appropriate equipment benefiting from scheduled activities to minimize the clinical and physical risks that are based on manufacturers' recommendations, risk levels, and current organization experience." EP 6 states, "The organization identifies and implements processes for monitoring and acting on equipment hazard notices and recalls." EP 7 states, "The organization identifies and implements processes for monitoring and reporting incidents in which a medical device is suspected or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990." EP 8 states, "The organization identifies and implements processes for emergency procedures that address the following: what to do in the

event of equipment disruption or failure, when and how to perform emergency clinical interventions when medical equipment fails, availability of backup equipment, and how to obtain repair services.” EP 9 states, “At a minimum, defined protocols and schedules for infection control in the procedure and recovery areas include the following: anesthetic apparatus is inspected and tested before each use by the practitioner who will administer the anesthetic. If found defective, the equipment is not used until the fault is repaired; repair of equipment is documented, temperature control for sterilizers, refrigerators, and other machines is monitored, and a preventative maintenance schedule is established and maintained that includes periodic calibration, cleaning, and adjustment of all equipment, as appropriate.”

Joint Commission’s standard EC.6.20 also deals with medical device management and contains 15 EPs. EP 1 states, “The organization documents a current, accurate, and separate inventory of all equipment identified in the equipment management plan, regardless of ownership” EP 2 states, “The organization documents performance and safety testing of all equipment before initial use.” EP 3 states, “The organization documents inspection and maintenance of equipment used for life support that is consistent with maintenance strategies to minimize clinical and physical risks.” EP 4 states, “The organization documents inspection and maintenance of non-life support equipment on the inventory that is consistent with maintenance strategies to minimize clinical and physical risks.” EP 5 states, “The organization documents performance testing of all sterilizers.” EP 6 states, “The organization documents chemical and biological testing of water used in renal dialysis and other applicable tests based upon regulations, manufacturers’ recommendations, and organization experience.” EP 7 states, “The organization documents and retains a historical record for each instrument or piece of equipment in the organization.” EP 8 states, “The organization documents and retains, for at least two years,

any daily, weekly, monthly, quarterly, or semi-annual performance testing and function checks. EP 9 states, “The organization documents and retains major repairs, parts replacement, and annual maintenance for the life of the instrument or equipment.” EP 10 states, “The organization inspects, tests, and maintains equipment including performing preventative maintenance, periodic inspection, and performance testing of equipment and instruments.” EP 11 states, “The organization inspects, tests, and maintains equipment including evaluating analytical measuring equipment and instruments with respect to all critical operating characteristics.” EP 12 states, “The organization inspects, tests, and maintains equipment including evaluating automated volumetric equipment.” EP 13 states, “The organization tests and operates instruments within temperature and humidity required for proper performance.” EP 14 states, “The organization documents monitoring of temperature controlled spaces and equipment.” EP 15 states, “The practice ensures preventive maintenance and inspection of medical equipment according to a schedule based on manufacturers’ recommendation, with time frames modified by current practice experience” (Joint Commission, 2006).

All of these Environment of Care requirements must be carefully followed and documented to receive accreditation from Joint Commission. JC will perform an initial survey to grant accreditation. Then on-site surveys will occur approximately every 3 years to continue accreditation.

Medical Equipment Management Plan (MEMP)

As mentioned previously, a biomed department needs to create and maintain a Medical Equipment Management Plan (MEMP). This document will outline all policies and procedures required for the biomed department which also sets expectations for the department. Most

policies and procedures will be based upon the Joint Commission Environment of Care Standards discussed previously.

The MEMP is usually written by the director of the biomed department with input from other management and BMETs. Once the document is completed, it is reviewed by the facilities Safety Committee and subjected to approval. The Safety Committee may decide to alter various policies and procedures to better suit the facilities needs. Once the MEMP gains approval by the Safety Committee, it becomes the guidelines for the biomed department.

General topics for the MEMP would include:

1. Mission Statement
2. Scope and Description of Services
3. Medical Equipment Management Plan
4. Equipment Selection for Inclusion in the Biomedical Equipment Control Program & Risk category assignment
5. Computerized Maintenance Management System - CMMS
6. Incoming Equipment Inspection Procedure
7. Preventative Maintenance Inspection (PM's) of Clinical Medical Equipment Procedures & Scheduling
8. Medical Device Alerts & Recall Plan
9. Medical Device Incident / Failure / Repair Reporting
10. Procedure for Medical Equipment Failure
11. Performance Testing of Sterilizers
12. Chemical and Biological Testing of Water Used in Dialysis

13. Use of Personal Electrical Equipment by Patients and Staff

14. After Hours Biomedical Engineering on-call Policy

15. Reporting to Other Departments

Some MEMP topics should directly reference individual Joint Commission standards. All topics listed for the MEMP should be thoroughly explained in great detail. This eliminates the possibility of “gray areas,” such as delegating services between various departments. Biomed departments are constantly faced with “gray areas.” Usually these gray areas are formed between the biomed department and either the facilities engineering department or the information technology department. For example the facilities engineering department may service the nurse call or television system at one hospital, but biomed may take care these systems at another hospital. A thorough MEMP will help ensure that all Joint Commission requirements are maintained and the expectations of the biomed department are thoroughly outlined.

The idea of the MEMP is to show how the department will manage the medical devices through preventative maintenance and repairs in an effort to eliminate any patient safety risks associated with medical equipment. All of Joint Commission regulation codes that are associated with medical devices are discussed in the MEMP. Topics discussed should include the equipment acquisition process and identify a team responsible for selecting equipment. Selecting the right equipment is the best first step in properly managing equipment. Elaine Sanchez Wilson wrote, “From the beginning planning stages to final implementation, bringing the appropriate technologies into hospitals – at the right price point – requires much preparation” (Wilson, 2011, p. 16) The team can discuss the clinical requirements and discuss options. Also this team can help standardize their inventory which helps streamline the facility by maintain an inventory of

similar equipment. Also a team can discuss each of their individual departments needs for the purchase. For biomed in particular, service manuals and service training can be negotiated in the initial purchase price. The acquisition team can also purchase equipment well suited for the hospital's individual environment or be responsible for environment preparation for new equipment. This is most important for large items such as an MRI, magnetic resonance imaging. The team will need to address and execute any training needs for the clinical staff. The biomed department will also be responsible for setting up a service strategy for the equipment, such as putting the new equipment under contract or servicing the equipment in-house.

The next MEMP topic needs to address the inventory of medical devices. The biomed department should be responsible for maintaining an accurate inventory of all medical devices. This is commonly done with use of a CMMS. This inventory will include all pieces of medical equipment that will hold records of all service and alert history. This section of the MEMP should also address how all equipment should be assessed, including hospital owned equipment, leased equipment, rented equipment, loaner equipment, and personally owned equipment, which can include clinical staff and patient owned equipment. In order to keep accurate equipment records a policy must be created to set a standard of how to properly dispose retired devices. A retired device must be marked in the database as retired in an inactive status. The retired equipment must then be properly disposed within all regulatory requirements. These requirements would include destroying any patient information stored on a medical device and environmental regulations that deal with hazardous materials.

Management strategies are explained in the MEMP. This is how the biomed department plans on servicing the equipment. The goal in this section is to ensure that all equipment is properly managed to ensure patient safety and function. In this section preventative maintenance

strategies will be given. In most cases the biomed department will rely on original equipment manufacturers' service recommendations. There are other reliable sources to gather service information such as ECRI, Emergency Care Research Institute. Requirements will be given to ensure proper function and safety of all devices.

Procedures for dealing with alerts and hazards are included in the MEMP. In some cases a hospital safety officer will be appointed to be in charge of alerts and recalls. He or she will then route the notices to the proper staff to resolve the issue. All hazards and alerts must be documented and recorded in a timely manner. A related topic is reporting patient incidents. A patient incident occurs when a patient's safety is compromised by a medical device that can include injury, illness, or death. This usually occurs when a device malfunctions. The hospital must have a set procedure to deal with such incidents as well as an investigation procedure that performs a root cause analysis. These incidents must be reported to the FDA, Food and Drug Administration, in compliance with the Safe Medical Devices Act of 1990.

The MEMP must explain how to address a situation when a piece of equipment fails. In most cases a spare device will be available. In certain situations a life support device with no available spare may fail which could have a negative effect on a patient outcome. The hospital must have a plan to deal with extreme cases such as this.

Definitions of incoming inspection procedure and maintenance intervals must be clearly defined. Joint Commission requires that certain types of equipment be addressed in this section. These particular types of equipment are: life support devices, nonlife support devices, sterilizers, dialysis water systems, nuclear medicine equipment, and medical scopes. Life support devices must have a preventative maintenance completion rate of 100%. Nonlife support equipment must have a completed monthly preventative maintenance rate of 90%. Sterilizers are required to have

proper periodic biological tests and performance verification tests performed and documented. Dialysis water systems must be cleaned and disinfected with biological and chemical tests performed and documented. Nuclear medicine equipment must be tested regularly to identify if the equipment is within tolerable operation ranges. In the event the nuclear medicine equipment is in need of calibration, the biomedical engineering department will be notified. Medical scopes, including flexible and rigid, must be inventoried and maintained with documentation. All scopes must be properly disinfected and stored. A maintenance plan must be in place to ensure proper repairs are performed, documented, and functionality is verified.

Equipment Management

In an efficient biomed department all equipment will be managed from the cradle to the grave. This means that biomed will have a connection with the acquisition, service, management, and disposal of all medical devices in a facility. Alan Gresch explains the importance of the biomed departments involvement with equipment acquisition saying, “Getting involved early can help drive standardization, plans for network integration, and indentify potential service and installation issues that could preclude a lot of unnecessary expense down the road” (Gresch, 2011, p. 196) All equipment has a life expectancy. Most manufacturers will support their equipment for an average of 7 years. Once this time passes the equipment is referred to as “out-of-support.” Most biomed technicians face this issue everyday, a piece of equipment comes in for repair and the manufacturer no longer will provide tech support, nor will it sell repair parts. This can be very challenging especially for a cash strapped hospital that can not afford spur-of-the-moment capital equipment purchases, also referred to as emergency capital. Luckily many companies offer used or refurbished repair parts that allow biomed departments to continue

servicing out-of-support equipment. These companies must be used carefully to ensure that all parts received are reliable and meet OEM specifications. Also parts purchased must have a warranty, this ensures that the seller has faith in the parts sold and will exchange them if there is a problem. Repairs can only be as good as the parts used. There are also many companies that manufacture their own repair parts. Most of these companies make consumable parts such as patient leads and probes. These companies are referred to as second source or third party vendors. Again caution must be taken when using these parts. These non-OEM parts may seem cost effective initially but may not last as long or be as accurate as OEM parts, which may cost the facility more money in the long run. Experience is the only way to truly grade these parts. These non-OEM parts should be used slowly over time so they can be analyzed on a small scale. If no problems are found and the products prove to be cost effective, it would be acceptable to continue this practice on a larger scale. Some third party vendors also allow equipment to be shipped in for repair. This is useful when the repair is too complex or if time constraints are too tight for the techs to complete the repair themselves. Warranties should be included in all vendor repairs.

Equipment life cycle is an inevitable part of healthcare technology. All equipment must be replaced at some point in time. This life cycle must be analyzed and maintained to help predict financial planning. If equipment planning is not performed, a hospital may have to spend emergency capital to replace equipment that is broken and nonrepairable due to its age. Because OEMs usually support their equipment for seven years, hospitals must plan on replacing their equipment sometime after that 7-year period. Many biomed departments can extend the equipment life cycle 2 to 3 years past the manufacture support.

There are many considerations to take into account when planning to replace equipment. First the equipment being replaced will need to be disposed of. One option is seeing if it can be traded in towards the purchase of new equipment. Secondly the equipment may be donated and perhaps be written of as a charitable donation. Some less fortunate hospitals may use the equipment or store it for parts that may no longer be available. The final option would be to dispose of the equipment. There are many recycling companies that will pick up used equipment and properly dispose it. However there are HIPAA (Health Insurance Portability and Accountability Act) regulations to consider when disposing equipment. HIPAA was created to protect patients' private information. Some medical devices store patient information, and that information must be destroyed by reformatting or shredding hard drives (HHS, 2012). Some recycling companies offer this service that takes the responsibility off of the hospital staff.

Purchasing new equipment takes research, planning, and time. Purchases should not be made in haste. Total cost of ownership, TCO, must be calculated to make the best decision. Warranty, manufacturer support, reliability, service and user training, and any kind of discounts must be analyzed and compared. One particular manufacture may have a low initial equipment purchase price but may have a short warranty period or high cost of consumables, which may result in a higher all-around cost than a piece that costs more up front but comes with a better warranty and lower cost of use.

Negotiation is a key component when purchasing new equipment. Most companies are willing to negotiate certain things such as service manuals and training. Another item to negotiate is future equipment upgrades. This would include software updates or configuration changes.

To stay as current as economically possible biomed managers and clinical engineers should perform technology assessments of the hospitals equipment periodically, every 3 to 5 years. A technology assessment will investigate emerging technologies and help identify the hospital's equipment that is out of date and needs to be upgraded or replaced. Matt Drummert, imaging specialist with Universal Hospital Services in Edina, Minnesota, writes, "Even though capital budgets are tight, or in some cases nonexistent, it is essential now more than ever that technology assessment and acquisition follow a carefully formulated process to avoid unnecessary expenditures and provide an accurate projection of the total cost of capital" (Drummert, 2011, p. 38) Performing a technology assessment will help ensure that the hospital is up to date with medical technology and trends that will help hospitals maintain competition and strive to be on the leading edge.

Standardization is also a strategy to explore. Standardization would be a hospital or hospital system using the same make and model of equipment throughout the facility. Standardization keeps training cost lower and user errors at a minimal. For example if an entire hospital system used only one type of IV pump that hospital system would only have to purchase one type of IV tubing set, and all hospital staff would be familiar with that one IV pump and how to properly use it. Also negotiating large purchases gives the buyer more power to reduce costs. Standardization also helps the biomedical department become more efficient in their work by allowing the techs to become more familiar with the equipment. Standardization can also help the biomed department by keeping stock parts. A stock part would be a part kept in storage for repair. If a hospital had only one certain patient monitor, the biomed department could easily stock commonly replaced parts that would drastically reduce downtime from not having to order parts as needed in a JIT (just in time) fashion. All Joint Commission accredited hospitals are

required to have a written policy on new equipment purchasing, which is explained in the laws and regulations section.

Risk-Based Assessments

Not all medical equipment needs periodic preventative maintenance. Risk based assessments can be used to manage these particular medical devices. If an original equipment manufacturer states in the equipment manual that no periodic maintenance is required, this is all the documentation necessary to leave this type of device on a repair only management plan. However in some cases certain preventative maintenance schedules can be overridden by thorough historic evidence that preventative maintenance is unnecessary. In order to remove a preventative maintenance schedule from a particular device a mean time before failure analysis must be performed. In most cases 1 and 2 years worth of historical data would be sufficient to perform the analysis. The potential device must be investigated to see how often it fails within a certain time period. If the device does not fail within the certain time period, it can be said in confidence that no preventative maintenance will be required. That the device will be used until it fails. At that period in time the biomedical engineering department will perform a repair and ensure that the device is working to meet manufactures specifications before it is put back into service. Binseng Wang and Brian Poplin address the issue of risk based scheduling by saying, “look beyond maintenance and work more closely with clinicians and administration to address issues related to user errors, environmental issues, and better selection of equipment in future purchases. Insisting solely on severity and ignoring user challenges would be missing the forest for the trees” (Poplin & Wang, 2011, p. 46) Of course any device considered for risk-based

assessment cannot be a life-support device. All of this must be agreed upon by the safety committee and signed off on before the maintenance schedule is altered.

Recalls

Dealing with recalls is an inevitable part of managing medical devices. Devices are recalled for various reasons, some more potentially hazardous than others. Some recalls are due to unauthorized software upgrades, while some are the result of a catastrophic event that could lead to patient injury or death. There are a few ways to receive recalls. Original equipment manufacturers are required to send notice of recall letters to hospitals with the affected device. This is sometimes not in the best interest of the hospital because it is easy to misplace mail or give the letter to the wrong person. An alternative way to deal with recalls is to use ECRI's recall alerts system. Usually there will be a super user for the hospital who will delegate who receives certain recalls. This helps ensure that the proper people are notified and that the recall will be properly handled. The ECRI system will generate periodic e-mails to alert users of new recalls. The recalls are prioritized by hazard level; the most hazardous recalls should be dealt with first. The recall will give the manufacturer, model, affected serial number range, description of the problem, and corrective action measures. Recalls may require that equipment is removed from service. Parts may be sent for techs to install that will allow the device to go back into service. Some devices may need to be destroyed. All healthcare facilities must have a policy for dealing with recalls as required by Joint Commission. Ultimately recalls are for the safety of patients and should be taken very seriously. All recalls must be documented in the CMMS.

Robert Hijazi, clinical engineering manager at Palmetto Health Hospital in Columbia, SC, explains his ideas on how to deal with recalls. He says that, "the best practice is to form a

recall committee comprised of various hospital department managers. This recall committee can assist in responding and reviewing various recalls alerts as the biomed department can endure great difficulties trying to deal with recalls without the help of the clinical departments” (Hijazi, 2011, p. 18).

Documentation

Proper documentation is necessary for a successful biomedical engineering department. A device must be entered into the database properly with all required information. Anytime the equipment is touched, which would include preventative maintenance, repair, or recalls, the information must be clearly documented. In some cases a piece of equipment history documentation may be used as a legal document in the court of law if there is a patient incident that results in injury or death. Proper documentation will help clear the biomed department from any fault involving a patient injury. If precise documents can be presented showing proper maintenance and repairs of the equipment, it can be assumed that the equipment did not fail do to improper maintenance or faulty repairs. This is another important reason that a robust CMMS be used by all biomedical engineering departments. Also technicians should accurately document their time on each work order to show reasonable time is spent managing the equipment. Time documentation is very important in a hospital setup where the biomed's time is charged to the department or customer. The customer must be billed properly. Also time can be tracked by management to analyze the technicians work load. Ted Cohen, CE manger at the UC Davis Medical Center in Sacramento California comments on technician workload by saying, “In these times of budget constraints, and with personnel costs often being the largest percent of the budget, it is very important to have metrics that quantify staffing needs based on workload”

(Cohen, 2011, p. 321). If techs are working too many hours, a new biomed position could be justified. Contrarily if techs have a low number of logged hours, some investigation may need to take place to see if the department is overstaffed. In most cases biomed departments want to see techs using their time productively managing equipment. Most biomed departments aim to see 80% of their time used productively. This may seem low, but the other 20% could be a case where a technician is caught up on work orders and is waiting for a repair call to come in. Techs may also use this time to perform rounds within the hospital. Rounds are when a technician walks to various departments of the hospital and communicates with clinical staff. This familiarizes the clinical staff with the biomed techs and helps establish a professional relationship between departments. Rounds are useful in finding broken equipment that may not have been called in to the biomed department. Rounds are a great way for biomed techs to build relationships with clinical staff and are a very important task for biomed to complete. This should be documented in the CMMS.

After Hours On-Call Coverage

Most hospital facilities will require the biomedical engineering department have a technician on-call to resolve any after-hours medical device issues. This will be formed and implemented by hospital administration and the biomedical engineering manager. This will then be managed by the biomedical engineering manager. The fairest way to deal with on-call is to put all technicians on a weekly rotation, but in most situations biomed departments should be flexible in on-call scheduling to best suit the needs of the hospital and the technicians. A policy must be made and distributed throughout the hospital so clinical staff know how to properly initiate an after-hours call. The tech should return the call of the clinical staff promptly. In some

cases the biomedical technician may be able to briefly resolve the issue over the phone. Proper authority must be given in cases where the technician is requested to come to the hospital to resolve the issue. For example a technician should never have to come to the facility after hours because a thermometer is not working. In a case such as this the biomed technician should advise the clinical staff to use another thermometer and that biomed will take care of the broken thermometer on the next business day.

Computerized Maintenance Management Systems (CMMS)

The process of tracking medical equipment has become a more efficient process due to the implementation of computerized maintenance management systems (CMMS). A CMMS is a computer program that allows the biomed department to track each piece of equipment. Upon incoming inspection each piece of equipment is entered into the database. The following information is recommended to be included in the database:

1. Hospital Equipment ID: Unique series of alphanumeric characters assigned to a piece of equipment.
2. Equipment Description: Device Type
3. Manufacturer
4. Model
5. Serial Number
6. Assigned Technician: Primary service provider (BMET or vendor)

7. Scheduled Maintenance information: interval, due date, procedure (each piece of equipment is to have a sticker showing PM information: last PM performed date, next PM due date, and tech identification)
8. Department Account: name and account code of owning department
9. Location: current location of the equipment (department or room if applicable)
10. Risk Category
11. Device Category: current status of equipment (active, inactive, storage, etc).
12. Vendor: provider of equipment and/or service if applicable
13. Purchase Order Number: Original PO# for purchase of equipment
14. Purchase Cost
15. Installation Date: date entered into service
16. Warranty Start and End Dates

The unique hospital identification is a sticker with the hospital name and an identification number. This sticker allows the equipment to be seen as a hospital asset and helps allow biomed to locate and verify equipment within the CMMS. Once the equipment is properly added to the database, biomed can track PM schedules and repairs. With each equipment work order the biomed techs can document all necessary information into the CMMS, such as parts used, performance verified that may include recorded information, and electrical safety information.

CMMS databases are very beneficial when reporting to agencies such as Joint Commission (JC). It is not uncommon for JC to request equipment history when surveying hospitals. A CMMS database allows for quick and easy access to all equipment information. Having a CMMS is also extremely helpful when dealing with recalls. Most recalls are issued by

the FDA and are easily accessed using ECRI (Emergency Care Research Institute). Usually hospital staff that serve on the safety committee are member of the ECRI alert system, which is an online database. When new alerts or recalls are issued, ECRI will send out notifications that can be tracked on their website. Upon receiving a recall notice a properly maintained CMMS will make dealing with the recall very easy. Usually when a recall is issued the manufacturer, model, and list of serial numbers are included in the notice. Most CMMS systems will have equipment search options that will allow a user to input manufacturer, model, and serial number information. This will help directly pinpoint if the facility has any equipment affected by the recall without having to go and search for the equipment piece by piece.

A great asset to any hospital is a real time location system, also known as a RTLS. A RTLS can be very useful by providing real-time location of equipment. These systems can use radio frequency, ultrasound, or WiFi. The main setup of a RTLS system requires tags attached to equipment, antennas, and computer software. There are several companies that offer a form of this technology. Some systems may only give a general area in which the equipment is located. Other systems can give accurate pinpoint locations and may also record other information such as temperatures. Temperature tracking is very useful for blanket and fluid warmers, also for laboratory freezers and refrigerators. Tracking temperatures of these devices is required for regulatory compliance, and an RTLS system with this capability simplifies the process.

The idea of RTLS is to locate assets when needed either by clinical staff for patient use or biomed looking for equipment in need of preventative maintenance. This is the component that helps biomed departments ensure regulatory compliance. RTLS can prevent hospitals from purchasing or renting unneeded equipment by preventing loss of equipment. These location systems can be very expensive but can prove to be cost effective. Many RTLS systems are for

more than just tracking equipment. They can also track patient flow and employee locations. With the addition of these features a RTLS system can be extremely effective in increasing productivity in all areas of the hospital.

Many equipment asset ID tags have barcodes on them that would allow a biomed to scan the equipment with a PDA (personal data assistant) and update various equipment profiles in real-time from any location. Some biomed departments are encompassing the technology of the Apple iPad and other wireless devices. With wifi and 3G, 4G, or LTE service, biomed can access the CMMS and even view service manuals for equipment. Randy Berlin, biomed manager at Southeast Alaska regional Health, has implemented iPads. He says, “We bought four iPads for less than the cost of two new laptops, and we have put a ton of PDF service manuals on the iPad” (Berlin, 2011, p. 38) Having access to service manuals out on the hospital floor will save time from having to return to the biomed shop and search for a manual creating a more efficient environment. Also this can possibly eliminate the need to remove the equipment from service allowing the tech to perform a simple repair on site significantly decreasing downtime. Tablet devices would also allow techs to search for phone numbers and equipment service contract information. Biomed, by nature, are usually tech savvy allowing them to use emerging technology as a very effective time and resource management tool. Wireless tablet technologies will create an overall more efficient environment. Techs will no longer have to generate PM reports from their personal computers, print them out, keep up with clipboards, then enter all the data at a later time. With a tablet the tech will be able to open and close work orders in real time on the floor that will reduce if not eliminate paperwork that will greatly improve the efficiency of the technicians.

A CMMS can also be a very effective management tool allowing reports to be generated on PM completion rates, repair history, alert and recall history, equipment uptime, equipment turnaround time, and technician time use. CMMS systems can also help track trends and mean time before failure reports that will help managers identify potential problems and create management strategies.

Budgeting: In-House vs. Contracts

There are many ways a hospital can maintain its inventory of equipment. Some hospitals will have an in-house program meaning that the biomedical engineering department is fully employed by the hospital. In an in-house program the department may have OEM (original equipment manufacturer) service contracts on certain pieces of equipment, usually medical imaging and laboratory devices. Some in-house programs may provide training to eliminate service contracts altogether. Some hospitals may elect to contract the entire biomed department. There are several companies that provide this service such as GE, Philips, TriMedx, and Aramark. These companies will take the responsibility of medical device management and create strategies to meet the needs of the facility. This type of scenario helps the hospital by allowing the service provider to be responsible for managing the equipment. Also this helps the hospital budget for medical equipment service costs. Most of these companies will negotiate service agreements with an annual cost. If an all-inclusive contract is negotiated, meaning all parts and service included, the hospital does not have to worry about surprise expenses or meeting its budget. The reverse side to this is for the equipment service provider. If an all-inclusive agreement is reached then the company must do everything it can to provide service without going over budget. Sometimes the contracted service providers will still carry OEM service

contracts and reach out for OEM service when needed. The third scenario is a combination of the first two, where usually the biomed group will be in-house but the imaging group is contracted by a service provider. Greg Thompson wrote an article about a hospital system located in northern Utah. This particular system had an in-house program that performed 85% of the work while the other 15% was done by OEMs and ISOs (Thompson, 2011, p. 13). The theory behind an in-house biomed program is to eliminate service contracts to cut costs. The reality is that not all contracts need to be removed. There are certain devices that the biomed department may not want to be responsible for due to legal issues. Some devices are actually cheaper to maintain under service contracts than to service in-house, and some OEMs simply will not sell service parts which leaves no choice but to keep service contracts. Again this goes back to selecting the right equipment for purchase.

The main goal of clinical engineering is to find a happy median between cost savings and quality of service while meeting or exceeding all regulations. Budgeting is a very important aspect for biomedical engineering directors and managers. Departments of hospitals must operate within their budget. Biomed departments are no exception. Biomed departments are not revenue generators but can help the hospital save tremendous amounts of money and should strive to show all savings and financial advantages they have to offer. There are many ways biomed departments can work well within the budget and save money for the hospital. Biomed techs can constantly search for various ways to save money such as finding used or refurbished parts. Techs using these practices should report their cost savings in the form of a stewardship win. All stewardship wins should be reported, and all techs should be recognized for their commitment to financial savings.

One of the biggest cost savings for a biomed department is through appropriate contract selection. First, all contracts must be thoroughly analyzed. Large amounts of money can be easily wasted on unnecessary contracts. Also, contracts can be negotiated to fit the exact needs of the facility. For example, if a CT (computer tomography) machine is covered under a full contract, the contract can be negotiated to a shared service agreement. A shared service agreement, also referred to as first look contract, allows in-house technicians to examine the problem first before calling in any outside help. In many cases the fix could be as simple as rebooting the system. By doing this the contract price can be significantly reduced and uptime of the equipment is greatly increased. In the scenario that a CT system only needed to be rebooted and there was no shared service agreement, the outsourced technician would have to be called in which could take hours or days just to come in and reset the unit. As a result of the shared service agreement the in-house technician was able to get the system up in running in less than an hour and money was saved on lowering the contract services. According to Elaine Sanchez Wilson shared service agreements allow facilities “to cut costs without suffering an increase in liability” (Sanchez, 2011, p. 26).

In-house vs. contract is a subject all hospitals and biomedical engineering managers must face. In large systems with multiple pieces of similar equipment, taking services in-house will usually be cost effective. By having trained staff on hand to repair and perform preventative maintenance on complex equipment, the hospital can reduce the amount of contracts they carry on particular equipment. Though the hospital is paying the salary of more advanced technicians they are saving much more money than paying for contract services. For example if a full contract on a CT machine is \$150,000.00 per year per unit, the hospital could hire a technician who could cover the same unit that would allow the hospital to drop the contract. Even if the CT

technician had an annual salary of \$75,000.00 the hospital could save \$75,000.00 annually. Add five more CTs to the equation and the hospital system could save \$825,000.00 per year.

Typically in a shared service agreement the biomed department will hire someone with CT experience who can cover first call on the units then call in the contract service provider if further assistance is needed. Again, if a full service contract is \$150,000.00, the shared service agreement may drop the contract price to \$135,000.00 saving the hospital \$15,000.00 per year per unit, and if there are several units hiring a new technician to cover the “first-calls” may prove to be cost effective. In smaller hospitals that have only one or two pieces of similar equipment, it may be cost effective to pay for contract services. This topic really varies from system to system and must be fully analyzed to make a proper decision. The goal of taking equipment service in-house is to increase response time while decreasing downtime and cost. Imagining equipment was used to explain the benefit of taking items in-house, but there are other services that are frequently contracted that could easily be taken in-house such as: ventilators, anesthesia machines, laboratory equipment, and sterilizers.

There are several different types of contracts available through many different manufacturers. A full contract would cover the unit entirely from preventative maintenance to service parts and repairs. A shared service contract, explained previously, would cover what the in-house technician could not fix. A PM only contract will cover preventative maintenance costs usually covering parts needed to complete the PM but will not cover repairs. When contracts are deemed unnecessary, the equipment is put under time and materials. Time and materials means that the in-house technicians will support the equipment to the best of their ability if further help is needed a purchase order will be used to cover the expense of parts and vendor labor.

Some equipment may be leased. Leasing equipment can have an advantage over capital purchases, such as the ability to upgrade more frequently, and not having to worry about depreciation of assets. Lease agreements may include service, parts, and consumables. Many laboratory equipment manufacturers offer a reagent lease agreements. Chemistry analyzers require certain consumables for operation. The reagent lease agreement basically allows the facility to use the manufacturer's equipment as long as the facility agrees to purchase the consumable reagents from the manufacture. Some sequential compression devices, SCDs, are given to hospital systems as long as the hospital system agrees to purchase the disposable compression leg cuffs. Most of these agreements will include maintenance in the form of an exchange. For example if a SCD fails it can be sent to the manufacturer for repair or replacement. The only problem with this is possible long downtimes for the equipment. In some cases the biomed department was able to negotiate with the SCD manufacturer to provide repair parts and the biomed department will perform the repairs. This greatly reduced downtime of the devices. Contract agreements can be negotiated with manufactures. Things to consider when negotiating contracts are: accidental damage coverage, loaner availability, response times, parts coverage, over the phone tech support, and system upgrades. Another consideration would be to spread the contracts out over a certain time frame. This will prevent all contracts from expiring at the same time creating a massive amount of work on contract renewals.

Staff Development

Having a well-trained staff is a must for any biomedical engineering department to be successful. Techs must have the knowledge and expertise required to maintain medical devices ensuring proper function and safety. Having a well-trained staff will cut costs and reduce downtime for the facility. “When identifying equipment training needs, consider high failure-rate devices and unique equipment,” says Dennis Cox, medical equipment supervisor at Eglin Hospital at Eglin Air Force Base in Florida (Cox, 2011, p.279). Training however will come at a premium. When hiring new staff, someone with an extensive background in the field will require a substantial salary to become an employee. Another option is to provide training to biomedical staff. Training is an investment. It will cost capital up front but will provide a return on investment (ROI) in the future.

The problem with training is procurement, being able to keep the trained staff from leaving. Most facilities will have techs sign a staff development form that will require the tech to agree to stay with the facility for at least 1 year after training is complete or have to pay for the training upon leaving before the contract expires. Training can come in a variety of ways. OEMs offer training, sometimes training can be negotiated in the cost of a new piece of equipment. For example if a facility is purchasing a new patient monitoring system, the facility can negotiate a reduced price on service training if purchased as a package. This training will allow the tech to have basic knowledge of the system allowing troubleshooting problems with a better understanding of how the system operates. There are also nonmodel specific classes available that teach generic principles of systems. An example would be an introductory x-ray service class. In order to gain knowledge of model specific system, a tech must know the basics of x-ray systems as they all operate under the same principles. The most widely used form of training is

hands-on training gained on the job. BMETs must have a passion to figure out problems. This passion will allow BMETs to figure out the most complex problems. A great project for any biomedical engineering department would be to implement an on-site training program where all techs can share knowledge gained from experience and formal education. For example if technicians go to school on a piece of equipment upon their arrival they should share their newly gained knowledge with the other techs. This will help the team grow as a whole. Also BMET Is should shadow BMET IIs and BMET IIIs for mentorship and training.

Another equipment negotiation can be for on-site training. On-site training is great for the department. This would be an event where an instructor from the equipment manufacturer would come to the biomed shop to give training on the new equipment. This allows all technicians to attend the training, plus no tech has to be absent from work. In the event that training is purchased with equipment, it may be best to send a tech to the training once the warranty or contract coverage has expired. If a tech is sent to training on a piece of equipment that is currently under warranty or covered under contract, the tech will not be required to service the equipment until the warranty or contract expires. This puts the tech at risk of losing the knowledge gained from training due to inactivity with the equipment.

Teamwork is crucial. Some biomedical departments divide certain areas of the hospital and assign the various locations to certain techs. This is great for those techs that specialize in particular devices, but it creates barriers for techs to progress. Cross training is a must to create an extremely productive biomed team. This allows techs to cover all areas of the hospital and become proficient in all clinical areas. This also allows the biomed department to remain fully functional when techs are out for various reasons. Again having assigned areas only holds the department back. This practice should be avoided when possible.

Process Improvement

Management should not be afraid to examine other biomed departments to contrast and compare. Some departments may do certain things wonderfully while some things need improvement. This will help biomed department learn from others mistakes and allow them to adopt better practices. Better practices can be gained by implementing ideas such as Lean. Lean practices will help biomed departments identify and eliminate wasteful practices. There are many places that can be improved by implementing lean in the biomed field. These areas would be directly related to the work environment.

Biomed shops are generally located in the basement of the hospital. This remote location could potentially cause response time issues. The closer the biomed shop is to the equipment the faster equipment can be repaired. Some biomed departments have climbed out of the depths of the hospital basement to become closer to the clinical departments, which generally increases response time and equipment uptime. Some biomed departments have placed smaller specialized shops in strategic areas to improve efficiency. For example if a hospital has an extremely large surgical department with a massive equipment inventory, a small specialized shop could be placed close to the surgical department to increase response time and reduce downtime. Surgery is an area where response time is absolutely critical. In the event that a patient is on the surgical table and a device fails, a biomed needs to be ready to take the call and assess the equipment immediately. One of the goals of a biomed department is to reduce equipment downtime. The flow of work can be analyzed, such as how a piece of equipment is received for repair and the necessary steps required to return that piece of equipment back in working order. Examining that particular workflow process may flag some wasteful practices that can be eliminated thus decreasing downtime. Simple items such as how clinical staff place service calls can be modified

to increase efficiency. Storage of tools and parts must be organized and clearly labeled to prevent wasted time from looking for items. Tool boxes should be maintained in an organized fashion where techs will know where all their tools are. Shelves should be used to store parts. All shelves should be labeled by device type and part number to create quick and easy access to parts needed. Hardware bins should be used to sort all nuts, bolts, screws, etc. by type and size. An effort of all staff members will be needed in order to create and maintain a lean atmosphere. This should be encouraged by team work.

Planning can also affect the efficiency of a biomed department. Technicians should look at their schedules and preventative maintenance work load and plan their days, weeks, and months accordingly. Preventative maintenance schedules can be analyzed in the CMMS and the workload can be distributed to maintain an even work load for all techs throughout the year. Technicians should also have a tool bag that they carry with commonly used tools. This tool bag should be taken by the tech on all calls. In the event the broken device can be fixed on the floor the tech will not have to waste time going back to the shop to retrieve a tool. Six sigma practices can reduce the amount of duplicate repairs by helping identify and eliminate common failures. A duplicate repair is when a piece of equipment is returned for repair with the same issue as recently corrected.

The image of the biomed department must be professional. Clinical staff must have faith that the biomed technicians are competent in maintaining the equipment. This can be first established with a professional relationship between clinical staff and biomed staff. Secondly biomed technicians must communicate effectively with clinical staff. Another component to biomed professionalism would be the appearance of the workplace or as commonly referred to as “the shop.” The biomed shop must be kept neat and orderly. This will give visitors and clinical

staff a professional first impression, but it is not all about appearance. A neat and orderly shop will help reduce time allowing technicians to properly locate tools, parts, and manuals in a timely manner. All biomed team members must feel a sense of pride in their shop to help maintain order. A tidy shop appearance will affect the department as a whole in a positive manner.

Motivating technicians may be a challenge for management. The best way to motivate techs is to give them credit for jobs well done. A sense of achievement and recognition can go a long way. Also management should not be afraid to initially push techs to work with more complex equipment. This will allow the techs to explore their strengths and weaknesses in their technical skills, and could possibly allow a BMET I to gain the experience required to become a BMET II. Management should effectively communicate expectations and provide a career path for the techs, but communication must always be a “two way street.” Management should always listen to the concerns, opinions, and ideas given by the techs. This also allows the techs to express their interests to management and possibly negotiate future career opportunities. Management needs to focus on growing their ambitious techs while allowing the less ambitious techs continue their everyday activities.

Customer service is another important aspect for biomed departments. Customer satisfaction can be assessed with customer satisfaction surveys. These surveys should be completed once a year and can be given electronically through e-mail. Various questions will be asked and recorded to show areas of improvement and also areas that would be better left unchanged. Opinions from outside views are always interesting and insightful. Clinical staff may have wonderful suggestions not seen from the biomed perspective. The best way to satisfy clinical staff is with proper communication and excellent service.

Biomed department schedules can be adjusted to create a more productive department and lower cost to the facility. For example full-time techs could work four 10-hour shifts as opposed to the traditional five 8-hour shifts. Certain techs could work Monday through Thursday and other techs could work Tuesday through Friday. This would cut down on after hours on-call time while giving techs a 4 day weekend. If the department is large enough a tech could be scheduled to work weekends that would not only cut down on on-call time but, also it would allow techs to get to heavily used equipment for PM. Many hospital departments, such as diagnostic imaging and surgery, either shut down or reduce their services during weekends. This makes weekends a great time for biomed techs to perform preventative maintenance in these particular departments.

Benchmarks

In the attempt to maintain and increase both quality and control benchmarks have become very common in every industry. Benchmarks are a set of operating standards that can be measured. In the biomedical engineering field there are many things that can be measured to maintain standards and increase efficiency. Measurable items include turnaround time and average age of open work orders. These two items measure how effectively a technician is performing. Turnaround time is a measurement of how long it takes a technician to receive of work order, repair the device, and put it back into service. Average age of open work orders measures how many days on average a technician allows a work order to remain open. A good CMMS can provide tools for managers to track how technicians approach work orders. A manager will look to see when the work order was first created, when the technician initiated work, how quickly he or she ordered parts if necessary, and when the work order was closed.

The longer a work order is open the greater the turnaround time for that device will be.

Turnaround time can greatly affect how the customer perceives the ability of the biomedical engineering department. The longer clinical staff has to wait for equipment to be repaired, the more dissatisfied they will become which could possibly lead to distrust in the technicians ability to complete repairs.

Customer satisfaction can also be included as a benchmark by creating customer satisfaction surveys and recording the results. Customer satisfaction surveys should be given at certain intervals. These intervals could range from every time a work order is requested, quarterly, semiannually, or annually. These surveys should ask questions that pertain to the clinical staff's feeling about the service they received. These questions should ask about the response time, the professionalism of the technician, the turnaround time of the repair, and the quality of work. Response time can also be monitored to make sure that technicians are responding in a timely manner appropriate with the situation. Standards should be put in place to control response times.

Repair work orders should be categorized into two categories, priority and nonpriority. A priority call would consist of a piece of medical equipment that is immediately necessary to improve the outcome of a patient. This would be a repair that cannot wait. For example a piece of surgical equipment stops working during the middle of a case. A technician should respond to a priority call in less than 10 minutes. A nonpriority call would be given when the operation of the device is not immediately dependant on the well being of a patient. A good example would be if an IV pump breaks. A nurse can very easily swap the broken pump for a working pump and set the broken pump to the side for biomed to repair at a later time. There are many factors that could affect the length of an open work order. These factors would include waiting for ordered

parts to be received or if a vendor or OEM is required to complete the work. These factors should be documented in the work order to justify long open work order times. Keeping track of open work orders helps keep items from being potentially forgotten. For legal requirements to be met another set of benchmarks should be measured. These benchmarks would include preventative maintenance completion rates. It is required that all life support PMs be completed on time, every time, so it is imperative that this benchmark be set at 100%.

There will always be time where preventative maintenance may not be possible to complete due to the device being in use or unable to locate. For example if a ventilator is due for preventative maintenance but is in use on a patient, it would not be wise to swap ventilators on the patient to perform the preventative maintenance. Instead the biomed technician should document in the work order that the device is in use and that they have informed the clinical staff to notify the biomedical engineering department when the device is no longer in use so the preventative maintenance can be completed. There will also be life support devices that might be difficult to find. An example device would be an external pace maker. These devices can easily fit in a drawer or simply be misplaced. It is necessary for a biomedical technician to look for the device and communicate with clinical staff in the event that the device cannot be located. The biomedical technician needs to document the dates and times spent looking for the device as well as the clinical staff notified. At the end of the month when the preventative maintenance should be completed the technician should document these work orders with the proper terms such as “could not locate” or “in use” and should explain the situation in the work order. Doing so will show that the technicians did everything they possibly could to service the device. In these events the preventative maintenance can be described as managed. Though it was not completed, all steps were taken to manage the equipment. This should satisfy all regulatory requirements. At

the time the device is not in use or is located the preventative maintenance should be performed and documented.

Networking

Information technology has become ever present in the world of biomed. Many healthcare devices are networked and as time progresses more and more devices will be networked either hardwired or wirelessly. This can prove to be a struggle at some facilities. For example the biomed department receives a work order that patient information from a patient monitor is not transferring to the patient charting program. The biomed department may investigate to find out that the monitor is working properly and the problem lies in the networking system over which biomed has no control. This scenario will involve biomed department contacting the information technology (IT) department to resolve the issue. Most hospitals seem to have biomed and IT as separate entities that makes sense, but as medical equipment evolves becoming more network dependent, the biomed and IT departments should also evolve to best suit the situation.

Combining the departments may not be the best situation. Perhaps having a networking expert work with the biomed department as needed would prove to be successful. Martin Janssen and Rick Schrenker address the topic of networking by saying, “To be effective, service strategies from the CE and IT communities, along with risk management, will have to be fully integrated” (Janssen & Schrenker, 2011, p. 299). To keep up with networking trends in the medical field biomed must be willing to learn the basics of networks. The future suggests that new biomed recruits must have some networking knowledge. Some biomed service training schools now require a network certification as a prerequisite. Networking in a hospital

environment is also heavily regulated and must contain certain integrity and security requirements.

Biomedical Engineering Associations

Joining a biomedical engineering association is very beneficial for anyone in the field. Local biomedical professionals can meet and discuss current topics, new equipment, trends, changing rules and regulations, recalls, best practices, etc. Biomed associations give biomed a chance to network, give advice, learn from others mistakes, and avoid making bad decisions. Biomed associations can host conventions where vendors can demonstrate their services or manufacturers can demonstrate their equipment.

Internships

Internships make a great option for biomed departments. Almost all healthcare careers require some sort of internship, biomed should not be any different. Biomed departments can team up with local universities or other educational venues offering a curriculum in biomedical engineering or electronics. An internship is beneficial to both the student and the department. The student gets real hands-on experience, and the biomed department gets low cost or free labor. Chris Gaerig writes, “Interns can assist with stressful workloads, and they introduce new energy and ideas into a department” (Gaerig, 2011, p. 34) A graduate with internship experience has a substantial advantage against a graduate without any experience.

Summary

The main requirement of biomedical engineering is to ensure that medical devices are functioning correctly and safely. Effectively managing preventative maintenance and repairs and having properly trained technicians will help ensure that medical devices are being properly maintained.

Managing medical devices is clearly not a simple task. It takes involvement from many people and most importantly teamwork. Not only should the biomedics work together as a team, the biomedics and clinical staff must work together as a team. The most important aspect is creating relationships with all hospital staff. These relationships will help gain and maintain confidence in the abilities in the biomed department and will help deter negative situations.

Biomedical engineering can be a very rewarding career for any individual with electronic and mechanical skills, an ambition to constantly learn, and a desire to create and maintain a safe environment for clinical staff and patients.

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