

Equipment Technology Malfunctions

Course

Principles of Health Science

Unit X

Vital Signs

Essential Question

Why is it important to have a Medical Equipment Management Plan in place?

TEKS

130.202 11(B)

Prior Student Learning

None

Estimated time

1-2 hours

Rationale

Healthcare technology management is a fundamental part of managing and maintaining medical devices used in various healthcare settings such as the home, the field, the doctor's office, and the hospital. Its purpose is to ensure that equipment used in patient care is operational, safe, and properly configured.

Objectives

Upon completion of this lesson, the learner should be able to:

- describe the importance of having an Equipment Technology Management Plan;
- evaluate the implications for using, performing, or relying on medical equipment that is not functioning properly; and
- identify careers associated with equipment malfunctions.

Engage

An equipment malfunction occurred with the oxygen delivery system at a long term care facility. Every patient who was hooked up to a ventilator had to be taken to nearby hospitals. The problem was resolved within two hours.

How could an equipment malfunction occur?

Could this have occurred because of poor maintenance of the system?

Who is accountable for this issue?

Who would investigate this issue?

Why is it important to inform someone of an equipment malfunction?

OR

Have 5 broken pieces of equipment and have volunteers try to figure out the problem.

Key Points

- I. Healthcare Technology Management
 - A. Includes the business processes used in interaction and oversight of the medical equipment involved in the diagnosis, treatment, and monitoring of patients
 - B. The related policies and procedures govern activities such as the selection, planning, and acquisition of medical devices
 - C. It is a recognized profession
 1. that ensures that equipment and systems used in patient care are operational, safe, and properly configured to meet the mission of the healthcare industry

2. that the equipment is used in an effective way consistent with the highest standards of care by educating the healthcare provider, equipment user, and patient
 3. that the equipment is designed to limit the potential for loss, harm, or damage to the patient, provider, visitor, and facility through various means of analysis prior to and during acquisition, monitoring and foreseeing problems during the lifecycle of the equipment
- D. Categories of a Medical Equipment Management Plan
1. Equipment Control
 - a. Every medical treatment facility should have policies and processes on equipment control
 - b. Equipment control involves the management of medical devices and begins with the receipt of a newly-acquired equipment item and continues through the item's entire life-cycle
 - c. Newly acquired devices should be inspected by in-house or contracted biomedical equipment technicians (BMETs) who will establish an equipment control/asset number against which maintenance actions are recorded. This is similar to creating a new medical chart for a new patient
 - d. Once an equipment control number is established, the device is safety inspected and readied for delivery to clinical and treatment areas in the medical office, treatment facility, hospital, etc.
 - e. Equipment Managers
 - i. Responsible for continuous oversight and responsibility for ensuring safe and effective equipment performance through full service maintenance
 - ii. Responsible for developing policies and procedures for the medical equipment management plan and resolution of defective biomedical equipment issues
 2. Equipment Inventories
 3. Work Order Management
 - a. Involves systematic, measureable, and traceable methods to all acceptance/initial inspections, preventive maintenance, and calibrations, or repairs by generating scheduled and unscheduled work orders
 - b. Includes all safety, preventive, calibration, test, and repair services performed on all such medical devices
 - c. A work order management system can manage personnel time, total number of hour's technician spent working on equipment, maximum repair dollar for one time repair, or total dollar allowed to spend repairing equipment

4. Data Quality Management
 - a. The data needed to establish basic, accurate, maintainable automated records for medical equipment management includes:
 - i. Nomenclature: defines what the device is and the type of maintenance is to be performed
 - ii. Manufacturer: this is the name of the company that received approval from the FDA to sell the device
 - iii. Nameplate model: the model number is typically located on the front/behind of the equipment
 - iv. Serial number: this is usually found on the data plate as well. Often shown as S/N.
 - v. Acquisition cost: the total purchase price for an individual item or system
 - vi. Condition code: this code is mainly used when an item is turned in and should be changed when there are major changes to the device that could affect whether or not an item should be salvaged, destroyed, or used by another
 - vii. Maintenance assessment: this assessment must be validated every time a BMET performs any kind of maintenance on a device
5. Equipment Maintenance
6. Quality Assurance
 - a. Is a way of identifying an item of supply or equipment as being defective
 - b. A good quality control/engineering program improves quality of work and lessens the risk of staff/patient injuries/death
7. Patient Safety
 - a. Patient safety is among the most important goals of every healthcare provider
8. Risk Management
 - a. Helps the medical treatment facility avoid the likelihood of equipment-related risks, minimize liability of mishaps and incidents, and stay compliant with regulatory reporting requirements
 - b. A risk-rating system is often to used for every equipment type
 - i. High risk – example, defibrillators
 - ii. Medium Risk – general purpose infusion pump
 - iii. Low Risk – electronic thermometers
9. Hospital Safety Programs

- 10. Accident Investigation
- 11. Analysis of Failures, Root Causes, and Human Factors
- 12. Safe Medical Devices Act of 1990 (SMDA)

II. Biomedical Engineers

- A. Use engineering principles to solve health related and medical problems
- B. Do a lot of research to design medical devices like artificial hearts, pacemakers, dialysis machines, and surgical lasers
- C. Supervise biomedical equipment maintenance technicians
- D. Investigate medical equipment failure
- E. Advise hospitals about purchasing and installing new equipment
- F. Working Conditions
 - 1. Hospitals, universities, industry, and research laboratories
 - 2. Some local travel may be required if medical equipment is located in various clinics or hospitals
- G. Duties
 - 1. Vary from one position to another
 - 2. Design and develop medical devices such as artificial hearts and kidneys, pacemakers, artificial hips, surgical lasers, automated patient monitors and blood chemistry sensors
 - 3. Design and develop engineered therapies
 - 4. Adapt computer hardware or software for medical science or health care applications; develop expert systems that assist in diagnosing diseases, medical imaging systems, models of different aspects of human physiology
 - 5. Conduct research to test and modify known theories and develop new theories
 - 6. Ensure the safety of equipment used for diagnosis, treatment and monitoring
 - 7. Investigate medical equipment failures and provide advice about the purchase and installation of new equipment
 - 8. Develop and evaluate quantitative models of biological processes and systems
 - 9. Apply engineering methods to answer basic questions about how the body works
 - 10. Contribute to patient assessments
 - 11. Prepare and present reports for health professionals and the public
 - 12. Supervise and train technologists and technicians
- H. Fields of Study for Biomedical Engineers
 - 1. Bioinformatics: developing and using computer tools to collect and analyze data
 - 2. Bioinstrumentation: applying electronic and measurement techniques
 - 3. Biomaterials: developing durable materials that are compatible with a biological environment
 - 4. Biomechanics: applying knowledge of mechanics to

- biological or medical problems
5. Bio-nano Engineering: developing novel structures of nanometer dimensions for application to biology, drug delivery, molecular diagnostics, Microsystems and nanosystems
 6. Biophotonics: applying and manipulating light, usually laser light, for sensing or imaging properties of biological tissue
 7. Cellular and Tissue Engineering: studying the anatomy, biochemistry and mechanics of cellular and sub-cellular structures; developing technology to repair, replace or regenerate living tissues; and developing methods for controlling cell and tissue growth in the laboratory
 8. Clinical Engineering: applying the latest technology to health care and health care systems in hospitals
 9. Genomics and Genetic Engineering: mapping, sequencing and analyzing genomes (DNA), and applying molecular biology methods to manipulate the genetic material of cells, viruses and organisms
 10. Medical or Biological Imaging: combining knowledge of a physical phenomenon (sound, radiation, and magnetism) with electronic processing, analysis and display
 11. Systems Physiology: studying how systems function in living organisms
 12. Therapeutic Engineering: developing and discovering drugs and advanced materials and techniques for delivering drugs to local tissues with minimized side effects

Activity

- I. Read and discuss the following article.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5706a6.htm>
- II. Complete the Data Control Activity

Assessment

Successful completion of Medical Equipment Malfunction article discussion
Successful completion of the Equipment Control Activity

Materials

Equipment Control Activity
Equipment Control Activity Key

Medical Equipment Malfunctions Associated with Inappropriate Use of Cleaning and Disinfecting Liquids --- United States, 2007

Available at <http://www.fda.gov/cdrh/safety/103107-cleaners.html>

Accommodations for Learning Differences

For enrichment, the student will review and analyze a Medical Equipment Management Plan. You can access a sample from Texas Tech University Health Science Center

<http://www.ttuhschool.edu/som/clinic/policies/CPolicy10.50.pdf>

For reinforcement, the student will research any of the listed careers in the Notes section of this lesson.

National and State Education Standards

National Health Science Standards

Health care workers will apply technical skills required for all career specialties. They will demonstrate skills and knowledge as appropriate.

TEKS

130.202 (c) 11(B) recognize and relate the process for reporting equipment or technology malfunctions

Texas College and Career Readiness Standards

English Language Arts

II. B. Understand new vocabulary and concepts and use them accurately in reading, writing and speaking.

III. B. Develop effective speaking styles for both group and one-on-one situations.

IV. A. Apply listening skills as an individual and as a member of a group in a variety of settings.

Science

1.E.1. Use several modes of expression to describe or characterize natural patterns and phenomena. These modes of expression include narrative, numerical, graphical, pictorial, symbolic, and kinesthetic.

1.E.2. Use essential vocabulary of the discipline being studied.

Notice to Readers: Medical Equipment Malfunctions Associated with Inappropriate Use of Cleaning and Disinfecting Liquids --- United States, 2007

On October 31, 2007, the Food and Drug Administration (FDA), in collaboration with CDC, the Environmental Protection Agency, and the Occupational Safety and Health Administration, issued a public health notification alerting health-care providers and the public about medical device malfunctions caused by improper use of cleaning and disinfecting liquids.* Inappropriate use of cleaning and disinfecting liquids on certain electronic medical equipment can cause equipment damage and malfunctions, which might have serious, even life-threatening consequences. Under the Safe Medical Device Act, health-care facilities are required to report to FDA any medical device malfunctions that cause or could cause death or serious injury. This notice provides recommendations to help prevent medical device malfunctions attributed to improper cleaning and disinfection.

Cleaning and disinfection are important practices to ensure that medical equipment surfaces do not serve as reservoirs for infectious pathogens. Cleaning is designed to remove infectious pathogens from inanimate objects, whereas disinfection is the process by which remaining pathogens are inactivated. Each of these two distinct processes usually involves the use of liquids (i.e., water and detergents for cleaning and chemical disinfectants for microbial inactivation). Because many types of equipment used in health-care settings have matted surfaces, moving parts, gaps, joints, and unsealed housings, improper cleaning and disinfection can create opportunities for fluids to enter the internal surface of medical equipment, resulting in damage that can cause or contribute to equipment malfunctions.

Health-care facilities, public health officials, and device manufacturers can take several measures to help improve device cleaning and disinfection and to prevent equipment malfunctions in the future. Facility staff should review equipment currently in use to determine which pieces of equipment have manufacturer instructions for cleaning but not for disinfection. Equipment that cannot be disinfected should be used in a way that minimizes the risk for contamination, for example, by positioning it far from contaminated areas or by covering it with a barrier that can be easily cleaned or replaced. If this is not possible, the facility should contact the manufacturer to discuss options for safe and effective disinfection. If the equipment is fluid-tight, and both cleaning and disinfection instructions are provided by the equipment manufacturer, the recommended cleaning agents and chemical disinfectants should be used and the conditions for their use followed. Finally, personnel responsible for cleaning and disinfection must be given appropriate training.

Reports of medical equipment malfunctions that cause or could cause death or serious injury should be made by using FDA's MedWatch 3500A form, available at <https://www.fda.gov/medwatch/getforms.htm>. Health-care facilities also are encouraged to report medical devices malfunctions that do not meet the mandatory reporting to MedWatch by telephone (1-800-332-1088); by fax (1-800-332-0178); by mail (MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787); or online (<https://www.fda.gov/medwatch/report.htm>).

* Available at <http://www.fda.gov/cdrh/safety/103107-cleaners.html>.

EQUIPMENT CONTROL

RATIONALE

Equipment control begins with the receipt of a newly-acquired item and should be inspected by a Biomedical Equipment Technologist (BET) to ensure they are operational, safe, and properly configured.

OBJECTIVE

You will be the BET in this assignment and do a safety inspection of these items prior to their release to the various medical departments. You will complete the Data Quality Management spreadsheet so that your hospital will have an accurate record of what was received and inspected. Be careful because there were three recalls issued, one in each of the last three years, and therefore they should not be released!

You can find recalls listed with the Food and Drug Administration website.

<http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm>

INSTRUCTIONS

Complete the Data Quality Management spreadsheet by placing the information below into the spreadsheet and then answer the following questions.

Welch Allyn AED 10
Quantity Purchased: 1
Sales Price: \$749.95
Serial Number: WA730201
Model Number: 4320-0010
Date Purchased: 9/22/2007

Littman Blood Pressure Cuffs
Quantity Purchased: 50
Sales Price: \$32.95
Serial Number: LB2041
Model Number: 2041
Date Purchased: 12/12/2009

Stryker Cast Cutter
Quantity Purchased: 2
Sales Price: \$249.95
Serial Number: YS41
Model Number: 01920-3344
Date Purchased: 3/31/2009

GE CT Scanner
Quantity Purchased: 1
Sales Price: \$104,000
Serial Number: GE64109
Model Number: 0020-4311-062
Date Purchased: 3/20/2010

Olympus Endoscopic Ultrasound
Quantity Purchased: 15
Sales Price: \$12,499
Serial Number: OLY241012
Model Number: 2022-1020
Date Purchased: 9/20.2011

CareFusion AVEA Ventilator
Quantity Purchased: 1
Sales Price: \$10,999
Serial Number: CF2000
Model Number: 2000-9292
Purchased: 4/1/2011

Schiller EKG Machine
Quantity Purchased: 1
Sales Price: \$6,250
Serial Number: SR100001
Model Number: 4A3GGA
Date Purchased: 2/19/2008

Merit Diagnostic Cardiac Catheter
Quantity Purchased: 24
Sales Price: \$539.00
Serial Number: MERIT1176
Model Number: 1176
Date Purchased: 1/3/2008

Johnson & Johnson Oral Thermometer
Quantity Purchased: 100
Sales Price: \$4.99
Serial Number: JJ998012
Model Number: 64A2U
Date Purchased: 6/9/2011

GE Healthcare Aisys and Advance Anesthesia System
Quantity Purchased: 1
Sales Price: \$9,575
Serial Number: GE44
Model Number: 99112-2314-44
Date Purchased: 5/1/2010

Answer the following questions.

1. What three items purchased had an equipment manufacturer recall?
2. What is the use of these recalled items?
3. By using the FDA's website, what was the reason for the recall for each of the three pieces of equipment?
4. By using the FDA's website provided on the first page, what is a Class I recall?
5. When was each manufacturer recall initiated?
6. Why do you think it is important to have a Data Quality Management plan for hospital equipment inventory?

Data Quality Management Plan

| MANUFACTURER | ITEM DESCRIPTION | D.O.P | QTY | COST | S/N | MODEL # | DATE INSPECTED | RECALL |
|--------------|------------------|-------|-----|------|-----|---------|----------------|--------|
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Biomedical Equipment Technologist Signature: _____
Date Entered: _____

EQUIPMENT CONTROL

Answer the following questions

KEY

1. What three items purchased had an equipment manufacturer recall?
 - Welch Allyn AED 10
 - CareFusion AVEA Ventilator
 - GE Healthcare Aisys and Advance Anesthesia System
2. What is the use of these recalled items?
 - These devices are intended to treat adults in cardiopulmonary arrest (heart attack). They analyze an unconscious patient's heart rhythm and automatically deliver an electrical shock to the heart if needed.
 - The AVEA ventilator is intended for continuous breathing support for the care of neonatal through adult patients who require mechanical ventilation. These ventilators are used in hospitals and other health care institutions.
 - It is a prescription device to provide general inhalation anesthesia and ventilation support to a wide range of patients. These devices are intended for volume or pressure control ventilation.
3. By using the FDA's website, what was the reason for each recall for the three pieces of equipment?
 - There is a possibility that these recalled devices may experience failure or unacceptable delay in analyzing a patient's EKG resulting in possible failure to deliver the appropriate therapy.
 - The AVEA ventilator can develop a failure where the ventilator activates a false extended high peak alarm, opens the safety valve and stops ventilating.
 - Some of these machines' control board wiring harnesses has a defect, which could cause the machine to unexpectedly shut down, terminating ventilation, anesthetic delivery, and potentially patient monitoring.
4. By using the FDA's website provided on the first page, what is a Class I recall?
 - Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that the use of these products will cause serious adverse health consequences or death.
5. When was each manufacturer recall initiated?
 - October 27, 2007
 - September 8, 2011
 - May 10, 2010
6. Why do you think it is important to have a Data Quality Management plan for hospital equipment inventory?
 - Answers will vary from student to student.