

# Medical Equipment Management: Regulatory & Standards Compliance

Course Length: 1 Day

CEU's Awarded: 0.8

Tuition: \$895

Call 440-519-1555 for Additional Information

## Course Introduction

Managing multivendor medical equipment maintenance in today's environment of regulatory and standards constraints can be a daunting task. Unscheduled inspections, incident reporting, and other compliance and accreditation issues can be intimidating unless you are fully prepared at all times.

This course will introduce, review and provide examples of compliance for the regulatory and standards organizations for hospital based medical equipment management programs. We will define the requirements and detail specific compliance examples for each standard or regulation.

Major attention will be directed to the Joint Commission requirements for medical equipment management, to prepare attendees to meet the requirements and prepare for an accreditation site visit.

## Course Objectives

At the conclusion of this course, attendees will be able to:

- Identify **Regulatory** organizations and their medical equipment management compliance program requirements
- Identify **Standards** organizations and their medical equipment management compliance program requirements
- Write an effective plan for medical equipment management
- Understand and write the required medical equipment management program policies and procedures for standards and regulatory compliance
- Understand and have examples for being in compliance with the Joint Commission medical equipment management standards
- Understand the Joint Commission accreditation process and the proactive measures that should be in place for an on-site accreditation visit

## Who Should Attend:

- All levels of personnel in a clinical engineering department: team leaders, supervisors, managers and directors of medical management programs
- Facilities, materials management or other department managers who are responsible for the medical management functions
- Administrators responsible for the medical equipment management function
- Biomedical equipment technicians
- Service and management personnel of independent service organizations (ISO)
- Service and management personnel of manufacturers

- I. Overview
  - A. Codes & regulations - OSHA, FDA, SMDA, CDRH, EPA, MQSA, HIPPA, FCC, NRC
  - B. Standards organizations - Joint Commission, NFPA, ECRI, UL, CFA, ISO, AAMI, ASHE
- II. Joint Commission visit
  - A. Survey process
  - B. Interviews
  - C. Building tours
  - D. EC document review
  - E. Three evaluation methods
- III. Management plan preparation
  - A. Medical equipment
  - B. Plan coordination for EC
  - C. Annual assessment
  - D. Committees involvement
- IV. Selection process of medical devices
  - A. Decision making
  - B. Capital budget
  - C. Planning
  - D. Installation
- V. Acceptance testing
  - A. Notification of delivery
  - B. Delivery of medical device
  - C. Involvement in installation
  - D. Testing procedures
  - E. Risk assessment
  - F. Patient owned equipment
  - G. Rented & leased equipment

- VI. Risk criteria
  - A. Medical/non-medical devices
  - B. On and off PM scheduling
  - C. Life support and non-life support equipment
  - D. PM completion requirements
  - E. Risk assessment examples
- VII. Inventory
  - A. Software management
  - B. Comprehensive of all departments and devices
- VIII. PM tasks
  - A. Creation method – sources
  - B. Inspection interval
  - C. Review & approval
  - D. Alarm testing
  - E. Annual review process
  - F. Laboratory equipment
- IX. Hazard notices and recalls
  - A. Process and sources used
  - B. Material mgnt interaction
  - C. Procedure for site visit of FDA or OSHA officer
- X. SMDA program
  - A. Process & involvement
  - B. Incident investigation
  - C. Discoverable information of documentation methods
- XI. Repair program
  - A. Processes
    - 1. Daylight and off hours
    - 2. User errors

- 3. Incident reporting
- 4. Trending & assessment
- B. Contracted suppliers – methods & documentation
- XII. Emergency procedures
  - A. Clinical staff procedures
    - 1. Clinical intervention for failed equipment
    - 2. Spare equipment
    - 3. Repair services
  - B. Clinical engineering procedures
    - 1. Repair services
    - 2. Emergencies - fire, disasters, chemical spills
- XIII. Performance indicators
  - A. Method for development and identification
  - B. Review current & past PIs
  - C. Reporting PIs
  - D. Annual assessment
- XIV. Employees
  - A. New employee orientation
  - B. Job descriptions
  - C. Employee competence
  - D. CE employee training
    - 1. Working in clinical areas
    - 2. Working with patients
    - 3. Infection control
    - 4. Continuing education
- XV. Sterilizer testing
  - A. Responsible departments
  - B. Procedures & documentation
  - C. Hazardous gas monitoring
- XVI. Dialysis water testing
  - A. Involvement with dialysis
  - B. Procedures & documentation
  - C. PM program of equipment
- XVII. Recommended operational Policies and procedures
- XVIII. Course review and critique