

Meeting CMS Regulatory Compliance

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Sodexo CTM, LLC.

Safety Moment - Know Your Exits



THE BEST WAY IN IS NOT ALWAYS THE BEST WAY OUT.

Sometimes safety is about quickly getting away from an unsafe situation. That's why it pays to know your exits.

Chances are you're aware of the exits from your home or your workplace. But what about the stores where you shop, the public buildings you enter, the venues you take your family to, or the hotels where you stay?

Get in the habit of always locating the emergency exit wherever you are. If you know exactly where to go, you'll get there a lot quicker.



§482.41(c)(2) - Equipment must be maintained to ensure an acceptable level of safety and quality.

- In order to ensure an acceptable level of safety and quality, the hospital must identify the equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the hospital must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the hospital (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the hospital (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

What the Joint Commission Says...

EC.02.01.01 Manage Safety and Security risks

- EP1 Implements its process to identify safety and security risks associated with environment of care that could affect patients, staff and other people coming to the hospital's facilities.
- EP3 Takes action to minimize or eliminate identified safety and security risks in the physical environment.
- EP5 The hospital maintains all grounds and equipment.
- EP11 Responds to product notices and recalls.

§482.41(c)(2) - Equipment must be maintained to ensure an acceptable level of safety and quality.

- All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.
- All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using hospital personnel, contracted services, or through a combination of hospital personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.
- *NFPA 99 2012 Edition has been adopted by CMS*
 - › *10.5.2.1.2 All patient care-related electrical equipment used in patient care rooms shall be tested in accordance with 10.3.5.4 or 10.3.6 before being put into service for the first time and after any repair or modification that might have compromised electrical safety.*

What the Joint Commission Says...

EC.02.04.03 Inspects, test and maintains medical equipment

- EP1 Before initial use and after major repairs or upgrades of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks.
- EP2 Documents, inspects, tests and maintains all high-risk equipment.
 - › **Note 1:** High-risk equipment includes medical equipment for which there is a risk of serious injury or event death to a patient or staff member should it fail, which includes life-support equipment.
 - › **Note 2:** Required activities and associated frequencies for maintaining, inspecting, and testing of medical equipment completed in accordance with manufactures' recommendations must have a 100% completion rate.
 - › **Note 3:** Scheduled maintenance activities for high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital's AEM program.
- EP3 Documents, inspects, tests and maintains all non-high-risk equipment.
 - › **Note:** Scheduled maintenance activities for non-high-risk medical equipment in an alternative maintenance (AEM) program inventory must have 100% completion rate. AEM frequency is determined by the hospital's AEM program.

What the Joint Commission Says...

EC.02.04.03 Inspects, test and maintains medical equipment

- EP4 Documents, conducts performance testing, and maintains all sterilizers.
- EP5 Documents and performs equipment maintenance, chemical and biological testing of water used in hemodialysis.
- EP8 Equipment listed for use in oxygen-enriched atmospheres is clearly labeled as follows:
 - › Oxygen-metering equipment, pressure-reducing regulators, humidifiers, and nebulizers are labeled with name of manufacture or supplier
 - › Oxygen-metering equipment and pressure reducing regulators are labeled “OXYGEN-USE NO OIL.”
 - › Labels on flowmeters, pressure-reducing regulators, and oxygen-dispensing apparatuses designate the gases for which they are intended.
 - › Cylinders and containers are labeled in accordance with Compressed Gas Association C-7 Applicable Healthcare Organization Policy

What the Joint Commission Says...

EC.02.04.03 Inspects, test and maintains medical equipment

- EP10 Documents and performs equipment maintenance on hyperbaric equipment.
- EP16 Document, inspect, test, and calibrate nuclear medicine equipment annually.
- EP18 Maintains the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced.
- EP26 Anesthesia delivery systems must be checked at the final path to patient after any adjustment, modification, or repair. BEFORE the device is returned to service, each connection is checked to verify proper gas flow and an O2 analyzer is used to verify oxygen concentration. Areas where oxygen equipment are service are clean and free of oil, grease, or other flammables.
- EP27 Meets NFPA 99-2012: Health Care Facilities Code requirements related to electrical equipment in the patient care vicinity.

§482.41(c)(2) - Equipment must be maintained to ensure an acceptable level of safety and quality.

- Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified.
- The hospital maintains records of hospital personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.
- All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules, fall under the purview of the hospital's clinical maintenance personnel, safety department personnel or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.

What the Joint Commission Says...

EC.01.01.01 Minimize risks in the Environment of Care

- EP1 Leaders identify an individual(s) to manage risk, coordinate risk reduction activities in the physical environment, collect deficiency information and disseminate summaries of actions and results.
- EP3 Has a library of information regarding inspection, testing, and maintenance of its equipment and systems.
- EP8 The hospital has a written plan for managing medical equipment.



Medical Equipment Management Plan (MEMP)

The MEMP should be a high level overview of your program with references to the departments policies.

- What should be included in a robust MEMP?
 - › Objectives – Outline how the department will support a safe patient care and treatment environment by managing risks associated with the use of clinical equipment.
 - › Scope – Define the scope your program, who supports and represents the program (influencers/committee members), and a crosswalk from the elements of performance to the department's policies.
 - › Performance – List and define quality monitors and goals associated with a continual improvement process in mind.

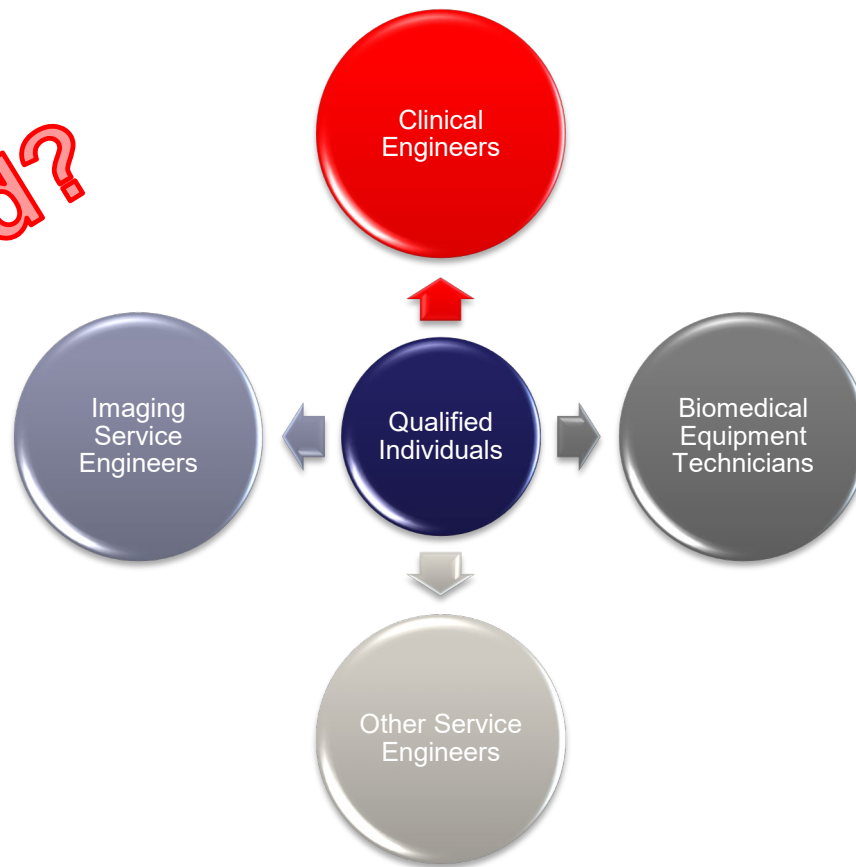
What the Joint Commission Says...

EC.03.01.01 Staff are familiar with their roles and responsibilities

- EP1 Staff responsible for maintenance, inspection, and testing of medical equipment is competent and receive continuing education and training

§482.41(c)(2) – Who is Qualified?

Who's Qualified?



Recommended Qualification Record Keeping

A copy the following items should be maintained for each employee:

- Current resume
- College transcripts, degree, or certificate
- Certificate of Training from all OEM/3rd Party classes attended
- Internal hospital/department specific training
- Current competency assessment

§482.41(c)(2) – Qualification Record Keeping



Sodexo CTM, Inc.

Competency Assessment

Internal Use Only

Name:		Position:												
Account:		Person Conducting Assessment:												
Date:														
Instructions: For all Sodexo CTM technical personnel, within at least six months of initial assignment to the healthcare organization, and at least annually thereafter, the employee will complete the Self-Assessment portion and the Supervisor will complete the Manager Assessment portion by marking the appropriate level of proficient and indicating the assessment method. Add comments or action plans as necessary.														
LEVEL OF PROFICIENCY C. Competency Validated N. Novice Level, Opportunity for Development NA. Not Applicable					ASSESSMENT METHOD A. Demonstration (i.e. receiving consistent feedback from customers/peers, etc.) B. Measurement (i.e. CMMS Documentation, etc.) C. Interview (one-on-one)									
SECTION 1 - CORE COMPETENCIES					Self-Assessment		Manager Assessment							
					Level of Proficiency			Level of Proficiency			Assessment Method			Comments / Action Plan
A. Documentation					C	N	NA	C	N	NA	A	B	C	
1 Accurate documentation of hours work (both work order and non-work order hours)														
2 Complete corrective and special requests with proper fields completed														
3 Complete incoming inspections and equipment record data entry														
4 Initiate purchase order requests and follow-up paperwork														
5 Proper use of the computerized management maintenance system														

§482.41(c)(2) – Qualification Record Keeping



Sodexo CTM, Inc.

Competency Assessment

Internal Use Only

Name: Enter Employee Name on First Tab	Position: Enter Position on First Tab
Account: Enter Account Name on First Tab	Person Conducting Assessment: Enter Manager Name on First Tab
Date: Enter Date on First Tab	

Instructions: For all Sodexo CTM technical personnel, within at least six months of initial assignment to the healthcare organization, and at least annually thereafter, the employee will complete the Self-Assessment portion and the Supervisor will complete the Manager Assessment portion by marking the appropriate level of proficient for performing Corrective Maintenance (CM) and Planned Maintenance (PM), and assessment method. Add comments or action plans as necessary. For each Equipment Skill category, specific device types can be add as appropriate for the personnel undergoing the assessment, based on their educational and training background. Certain cells are blacked out due to PMs not being performed on certain equipment.

LEVEL OF PROFICIENCY:
 1. Received Training (OJT or Other Training)
 2. Some experience (may require practice and/or assistance)
 3. Competent and can perform independently
 4. Competent, performs independently, and develops staff by teaching and mentoring others
 NA. Not Applicable

ASSESSMENT METHOD
 A. Demonstration (i.e. receiving consistent feedback from customers/peers, etc.)
 B. Measurement (i.e. CMMS Documentation, etc.)
 C. Interview (one-on-one)
 D. Post-test (Internal or external technical testing)

SECTION 2 - EQUIPMENT COMPETENCIES	Self-Assessment																Manager Assessment										Comments
	Planned Maintenance (PM) Level of Proficiency				Corrective Maintenance (CM) Level of Proficiency				Planned Maintenance (PM) Level of Proficiency				Corrective Maintenance (CM) Level of Proficiency				Assessment Method			Select Yes to Add to Training Plan							
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	A	B	C	D			
A. Anesthesia (AN) Equipment Skills																									Anesthesia (AN)		
1 Anesthesia Delivery Units																											
2 Anesthesia Monitoring Systems																											
3 Anesthesia Vaporizers																											
4																											
5																											
6																											
B. Diagnostic Imaging and Radiation Therapy (DI) Equipment Skills																									Diagnostic Imaging and Radiation Therapy (DI)		
1 Angiographic Laboratory and Associated Equipment																											
2 Catheterization Laboratory and Associated Equipment																											
3 Contrast Injectors																											
4 CT Scanners																											
5 Densitometers																											
6 Laser Imagers																											
7 Mammography Systems																											
8 MRI Systems																											
9 Nuclear Medicine Systems																											
10 PACS or Image Archiving Systems																											
11 PET Scanners																											
12 Portable C-arm Systems																											
13 Portable Radiological Systems																											
14 Radiation Therapy Systems																											
15 Radiographic Systems																											
16 Radiological and Fluoroscopy Systems																											
17 Specials Units																											
18 SPECT Scanners																											
19 Ultrasound Systems																											
20																											



§482.41(c)(2) – Qualification Record Keeping



Sodexo CTM, Inc.

Training Plan
Internal Use Only

Name:	Enter Employee Name on First Tab	Position:	Enter Position on First Tab		
Account:	Enter Account Name on First Tab	Person Conducting Assessment:	Enter Manager Name on First Tab		
Date:	Enter Date on First Tab				
Instructions: The immediate supervisor shall develop a technical training plan for all Sodexo CTM technical personnel based on the comparison of the CTM personnel's competency assessment with their job description and on the equipment and service delivery strategy needs of the account. Before training can be provided, the Sodexo CTM Staff Development Form must be filled out for all training requests and submitted to the District Manager (DM) for approval.					
Equipment Classification / Description	List the Manufacturer(s) / Model(s) (If Manufacturer / Model specific training is needed)	Reason for Training Need (e.g. professional development, contract/warranty expiring, etc.)	Type of Training Needed (e.g. OEM, Third-Party, On-the-Job, etc.)	Target Training Month	Date Completed
Error					
1	Error. No items on the second tab were selected to be included in the training plan.				
2					
3					
4					
5					

§482.41(c)(2) - OEM Required Maintenance Program

- Hospitals comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. Hospitals may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the hospital must maintain documentation of those recommendations and the hospital's associated maintenance activity for the affected equipment.
- Other Federal law or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements.
- Imaging/radiologic equipment.
- The equipment is a medical laser device.
- New equipment for which sufficient maintenance history, either based on the hospital's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination.

What the Joint Commission Says...

EC.02.04.01 Manages Medical Equipment Risks

- EP5 Activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:
 - › Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements
 - › Medical laser devices
 - › Imaging and radiologic equipment (whether used for diagnostic or therapeutic processes)
 - › New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies



§482.41(c)(2) - Alternate Equipment Management (AEM) Program

- A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the hospital associated with the use of facility or medical equipment.
- The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance.
- The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors.
- The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

What the Joint Commission Says...

EC.02.04.01 Manages Medical Equipment Risks

- EP4 Identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.
 - › **Note 1:** The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice, such as the American National Standards Institute/Association for the Advancement of Medical Instrumentation handbook ANSI/AAMI EQ56:2013, Recommended Practice for a Medical Equipment Management Program.
 - › **Note 2:** Medical equipment with activities and associated frequencies in accordance with Manufacturers' recommendations must have a 100% completion rate.
 - › **Note 3:** Scheduled maintenance activities for both high-risk and non-high-risk medical equipment in an alternative equipment maintenance (AEM) program inventory must have a 100% completion rate. AEM frequency is determined by the hospital's AEM program.

What the Joint Commission Says...

EC.02.04.01 Manages Medical Equipment Risks

- EP6 A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternative manner that includes the following:
 - › How the equipment is used, including the seriousness and prevalence of harm during normal use
 - › Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm
 - › Availability of alternative or backup equipment in the event the equipment fails or malfunctions
 - › Incident history of identical or similar equipment
 - › Maintenance requirements of the equipment
- EP7 Identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.
- EP9 Written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.

§482.41(c)(2) - Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is “interval-based maintenance” performed at fixed time intervals (e.g., annual or semi-annual), but may also be “metered maintenance” performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.
- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer’s recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.

Maintenance Strategies (continued)

- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a “run it until it breaks” philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.
- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.



§482.41(c)(2) - Equipment Inventory

- All hospital medical equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities.
- If the hospital is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.
- To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.
 - › Unique identification number
 - › Equipment manufacturer
 - › Model number
 - › Serial number
 - › Description
 - › Location
 - › Service provider
 - › Acceptance date
 - › Any additional information the hospital believes may be useful for proper management of the equipment

What the Joint Commission Says...

EC.02.04.01 Manages Medical Equipment Risks

- EP2 Maintains a written inventory of all medical equipment or a written inventory of selected equipment categorized by physical risk associated with use (including all life-support equipment) and equipment incident history. The hospital evaluates new types of equipment before initial use to determine whether they should be included in the inventory.
- EP3 Identifies high-risk medical equipment on the inventory for which there is a risk of serious injury or death to a patient or staff member should the equipment fail.

What the Joint Commission Says...

EC.04.01.01 Collects information to monitor conditions in the environment.

- EP1 Establishes a process for continually monitoring, internally reporting and investigating for medical/ laboratory equipment management problems, failures and use errors.
- EP10 Based on the established process, reports and investigates medical/laboratory equipment problems, failures and use errors.
- EP15 Every 12 months, evaluates the environment of care management plan including a review of the plan's objectives, scope, performance, and effectiveness.

References

“Chapter 10.5.2.1.2.” Health Care Facilities Code: Including All Gas & Vacuum System Requirements, National Fire Protection Association, 2011, p. 96.

“Environment of Care.” Comprehensive Accreditation Manual: CAMH for Hospitals, 1/2019 ed., Joint Commission Resources, 2019, pp. EC-1-EC-44.

United States, Congress, “State Operations Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals.” *State Operations Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*, 12 Oct. 2018. www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.