INDICATOR	Met	Not Met	Comments
POLICY			
The organization has a medical equipment maintenance program in place that ensures that equipment is safe to use during patient care.			
For deemed status organizations: All Medical equipment is included in a written inventory. The inventory identifies high-risk/critical equipment that includes all life support equipment and any other device where there is a risk of serious injury or death to a patient or staff member should it fail.			
For non-deemed status organizations: The organization maintains a written inventory of either all medical equipment or an inventory of select medical equipment categorized by physical risk that includes life-support equipment. New equipment is evaluated prior to initial use to determine if it will be included in the organization's inventory.			
Equipment is inspected and tested according to the manufacturer's Instructions for Use (IFU) prior to use on patients.			
Manufacturer IFUs are current and available for users and biomedical engineering staff.			
MAINTENANCE ACTIVITIES			
Medical equipment and devices are maintained and in functional order. There is no damage to the equipment items inspected.			
Medical equipment maintenance activities are conducted following the manufacturer's IFU. This includes inspection, testing, and calibration. These activities are documented. (Select several equipment items and review documented maintenance activities for compliance)			
Maintenance activities are conducted at a frequency defined by the IFU.			
(Determine if the organization performs Alternative Equipment Maintenance (AEM) activities.) If AEM activities are performed, they do not impact equipment safety and are 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. This may include reduced or altered maintenance tasks, relaxed frequencies of maintenance, and run-to-fail strategies. AEM maintenance activities and frequencies follow manufacturers' recommendations. AEM is not allowed for: • Equipment subject to federal or state law or Medicare Conditions of Participation.			

INDICATOR	Met	Not Met	Comments
• Imaging and radiologic equipment (diagnostic or therapeutic). • Medical LASER devices. • New medical equipment with insufficient maintenance history to support the AEM strategy.			
Devices used to maintain medical equipment are inspected, tested, and calibrated according to their respective IFU. These activities are documented per the organization's policy.			
Periodic functionality tests are conducted according to the IFU. These activities are documented per the organization's policies. This includes any quality control checks. *(These activities are typically performed by the user in the patient care setting).*			
Medical devices connected to the organization's network and/or intranet have been inspected to identify risks and hazards associated with cybersecurity vulnerabilities. This includes wireless devices. Medical equipment is included in the organization's Cybersecurity Plan.			
EQUIPMENT POWER			
If medical equipment is plugged into an electrical outlet and used in a patient care room/area, inside the patient care vicinity *(The "patient care vicinity" is defined as a space, within a location intended for the examination and treatment of patients, extending 6 feet beyond the normal location of the bed, chair, table, treadmill, or other device that supports the patient during examination and treatment and extending vertically to 7-foot 6-inches above the floor.)*: • UL power strips must be permanently attached to a rack-, table-, pedestal-, or cart-mounted & tested medical equipment assembly. • Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1. • Power strips cannot be used for non-medical equipment.			
If medical equipment is plugged into an electrical outlet and used in a patient care room/area, outside the patient care vicinity: • UL power strips could be used for medical & non-medical equipment with precautions. • Power strips providing power to medical equipment in a patient care room/area must be UL 1363A or UL 60601-1. • Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363.			

Applicable to the following Accreditation Programs: (X) Hospital (X) Critical Access Hospital (X) Behavioral Health (X) Ambulatory Care (X) Office Based Surgery ( ) Disease Specific Certification ( ) Staffing Certification

Regulatory Information may change over time as healthcare expectations change. This document is current as of the date noted within this footer

INDICATOR	Met	Not Met	Comments
If medical equipment is plugged into an electrical outlet and not used in a patient care room/area, inside and outside the patient care vicinity: • UL power strips could be used with precautions • Power strips providing power to non-medical equipment in a patient care room/area must be UL 1363.			
In non-patient care areas/rooms, other UL strips could be used with the general precautions.			
Critical equipment with/without battery power backup must be plugged into emergency power outlets to maintain function during power outages and maintain battery charge.			
TRAINING			
Staff are trained on the use of the medical equipment they use during the provision of medical care. This includes inspection, safe operation, periodic functionality checks, troubleshooting procedures, and the procedures to follow with equipment malfunction/damage.			
Biomedical staff who conduct maintenance activities are qualified to do so. This includes contracted services staff.			

Applicable to the following Accreditation Programs: (X) Hospital (X) Critical Access Hospital (X) Behavioral Health (X) Ambulatory Care (X) Office Based Surgery ( ) Disease Specific Certification ( ) Staffing Certification