Medical Equipment Management (The Joint Commission, 2018)

What We Know

› The Joint Commission (TJC) is a national, non-profit organization that accredits and certifies more than 21,000 United States healthcare organizations. TJC develops scoring requirements to guide healthcare organizations in achieving accreditation and improving the quality of healthcare. Each standard is supported by a rationale and includes several elements of performance (EPs; i.e., specific actions, structures, or activities that are designed to help meet the standard)(2)

› TJC has developed a variety of accreditation standards that are specifically intended to promote patient safety and quality of care by reducing the risks associated with the use of medical equipment(3,8,10,14)

• Between 2014 through the second quarter of June 2017, there were a total of 37 medical equipment-related sentinel events(6)

• Two Environment of Care (EC) standards (i.e., standards that are designed to promote a safe, supportive, and functional hospital environment) specifically address medical equipment management(8)

– EC.02.04.01 requires hospitals to manage risks that are associated with medical equipment(3,4)
  - The EPs for this standard state that for hospitals that do not use TJC accreditation for deemed status purposes (e.g., an organization receiving U.S. Centers for Medicare & Medicaid [CMS] certification based on TJC accreditation), the hospital is required to
    - maintain a written inventory of all equipment or of only equipment that has been determined by the hospital to potentially cause physical harm, including all life-support equipment; the equipment that is inventoried should be categorized according to the type of physical harm that could be caused and by the history of incidents involving the equipment
    - follow manufacturer recommendations or the strategies of an alternative equipment maintenance program (e.g., American National Standards Institute’s Recommended Practice for a Medical Equipment Management Program) for equipment inspection, maintenance, and testing activities and frequencies; identify these activities and frequencies in writing
    - maintain written procedures to be followed in case of equipment failure
    - identify quality control and maintenance activities to maintain the quality of diagnostic CT scan, PET scan, MRI, and nuclear medicine (NM) imaging
  - The EPs for this standard state that for hospitals that use TJC accreditation for deemed status purposes, the hospital is required to
    - maintain a written inventory of all medical equipment
    - follow manufacturer recommendations for inspection, maintenance, and testing activities and frequencies for
    - equipment that is subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining is in accordance with manufacturer recommendations, or otherwise establishes more stringent maintenance requirements
- medical laser devices
- imaging and radiologic equipment
- new medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies
- identify the equipment inspection, maintenance, and testing activities and frequencies in writing
- use a qualified individual as defined by TJC Standard HR.01.02.01 to identify written criteria needed to support the determination of whether or not it is safe to permit medical equipment to be maintained in an alternate manner (e.g., for equipment items that are not included in the list above)
- identify in writing all medical equipment on its inventory that is included in an alternative equipment maintenance program
- maintain written procedures to be followed in case of equipment failure

EC.02.04.03 requires hospitals to test, inspect, and safely maintain medical equipment\(^{(3)}\)

- The EPs for this standard state that the hospital is required to
- perform operational, safety, and functional tests prior to the initial use of the equipment; hospitals using TJC accreditation for deemed status purposes must also perform operational, safety, and functional tests after major repairs or upgrades of medical equipment that is listed on the facility medical equipment inventory
- inspect, test, maintain, and document the inspection, testing, and maintenance of high-risk equipment (e.g., defibrillators), including equipment used for life support
- inspect, test, maintain, and document the inspection, testing, and maintenance of non-high-risk equipment that is listed on the equipment inventory in EP.02.04.01
- test, maintain, and document testing and maintenance of all sterilizers
- perform chemical and biologic testing of the water used in hemodialysis, perform maintenance on hemodialysis equipment, and document the performance of these activities
- clearly label equipment for oxygen-enriched atmospheres (e.g., flow meters, humidifiers, cylinders and containers)
- comply with construction, equipment, administration, and maintenance requirements for hyperbaric equipment
- annually inspect, test, calibrate, and document inspection, testing, and calibration of nuclear medicine equipment (if the hospital uses TJC accreditation for deemed status)
- annually measure the actual radiation dose provided by each CT imaging system; the testing must be documented and a qualified medical physicist must verify that the radiation dose displayed during the performance of CT imaging of the brain of an adult, abdomen of an adult, and the brain of a pediatric patient is within 20% of the actual dose delivered
- evaluate performance of CT, MRI, PET, and NM imaging equipment
- test image acquisition of display monitors
- maintain the quality of diagnostic CT, PET, MRI, and NM images produced
- perform equipment testing and maintenance on anesthesia apparatus
- meet the National Fire Protection Association (NFPA) 99-2012 Health Care Facilities Code requirements for electrical equipment in patient care areas

• Medical equipment management is specifically addressed in two infection control (IC) accreditation standards\(^{(9,14)}\)

– IC.01.04.01 requires hospitals to set a goal for limiting disease transmission based on identified risks in the hospital
  - An EP for this standard requires the hospital to have written procedures in place to limit disease transmission occurring as a result of the use of medical equipment, devices, or supplies
– IC.02.02.01 requires hospitals to reduce the risk for disease transmission occurring as a result of the use of medical equipment, devices, or supplies
- EPs for this standard require the hospital to
  - properly store and dispose medical equipment, devices, and supplies
  - follow regulatory and professional standards when reprocessing single-use devices
  - implement procedures to prevent disease transmission when cleaning medical equipment, devices, or supplies or when performing low-level disinfection
  - implement procedures to prevent disease transmission when performing high-level disinfection (HLD) of medical equipment, devices, or supplies

- In 2014, the U.S. CDC reported an outbreak of New Delhi metalo-β-lactamase (NDM)-producing *Escherichia coli* among patients in Illinois who underwent endoscopic retrograde cholangiopancreatography (ERCP). The CDC and experts were concerned that HLD using an automated endoscope reprocessor (AER) could be insufficient in preventing transmission of multidrug-resistant bacteria.\(^{(1)}\) In 2015, the CDC endorsed the Healthcare Infection
Control Practices Advisory Committee (HICPAC) recommendations for the flexible endoscopy reprocessing program, including pre-cleaning, leak-testing, manual cleaning, visual inspection, disinfection or sterilization, storage, and documentation. 

- Failure to properly sterilize medical equipment contributes to patient risk for contamination and potential outbreaks. TJC reported that in 2016, 74% percent of all immediate threat to life (ITL) events were related to improperly sterilized or HLD equipment. IC.02.02.01 is the most commonly cited standard for noncompliance during TJC surveys. Citations for noncompliance typically arise from

- lack of leadership
- inadequate sterilization and HLD equipment training
- disregard for following evidence-based protocols
- lack of designated and competent staff assigned to sterilization and HLD
- poor facility design

• TJC has continued to identify the National Patient Safety Goal (NPSG) for 2018 that addresses medical equipment management.

– NPSG.06.01.01 requires hospitals to reduce the harm associated with clinical alarm systems
- Clinical alarm systems are alarms at the patient’s bedside that are intended to alert healthcare personnel of potential patient problems, but can place the patient at risk for adverse healthcare events if the alarms are difficult to detect, set inappropriately, or alarm so frequently that healthcare personnel become desensitized and stop responding to alarms or disable the alarms
- TJC reports 98 alarm-related sentinel events between January 2009–June 2012; of those, 80 resulted in patient death

- EPs for this standard require hospitals to
- prioritize alarm system safety (already effective as of July 1, 2014 under a prior NPSG)
- identify those alarm signals that are considered most important to manage based on staff input, likelihood of risk to patients if the alarm is ignored or malfunctions, potential risk to patients based on internal incident history, the necessity of the alarm, and published guidelines or best practices (already effective as of July 1, 2014 under a prior NPSG)
- establish policies and procedures to manage the alarms that are determined to be most important to manage; policies and procedures should address clinically appropriate alarm settings, indications for disabling alarms or changing alarm parameters, monitoring and responding to alarms, checking accuracy of alarm systems, and determining those persons with the authority to set or change alarm parameters or disable alarms
- educate staff members regarding their responsibilities related to clinical alarm system

• TJC standards regarding medical equipment maintenance do not require hospitals to follow manufacturer recommendations regarding equipment maintenance frequency, but rather allow hospitals to develop their own maintenance practices if they can demonstrate that a different maintenance practice is safe and effective.

• An analysis of sentinel events that were reported to TJC in 2011 did not show a significant number of adverse patient events occurring as a result of maintenance omissions; the investigators concluded that there is no indication that current standards should be changed to enforce hospital compliance with manufacturer recommendations regarding equipment maintenance.

What We Can Do

› Learn about medical equipment management and best practices so you can accurately assess your facility’s ability to promote patient safety through effective medical equipment management and compliance with TJC standards and the NPSG; share this information with your colleagues
› Collaborate with your colleagues and members of your facility TJC accreditation team to design and implement policies and procedures to promote compliance with TJC standards and the NPSG regarding medical equipment management
References


