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The Joint Commission - 2021

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Speaker:
Herman A. McKenzie, MBA, CSHP
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QUALITY OF LIFE SERVICES
About the Moderator

Binseng Wang ScD, CCE

- Binseng Wang is Vice President, Program Management with Sodexo CTM, an independent service organization
- Previously, Dr. Wang was Director, Quality & Regulatory Affairs for Greenwood Marketing, LLC, as well as Vice President, Quality & Regulatory Affairs, for Sundance Enterprises, Aramark Healthcare Technologies, and MEDIQ/PRN.
- He also worked as a Visiting Scientist at NIH and an Adjunct Professor at the Milwaukee School of Engineering.
- He is a fellow of ACCE and AIMBE. He received the 2010 AAMI CE Achievement Award, the 2015 ACCE Lifetime Achievement Award, and the 2019 AAMI-TRIMEDX Iconoclast Award, and was inducted into the Clinical Engineering Hall of Fame by ACCE in 2017.
- He earned a Doctor of Science degree from MIT and is a Certified Clinical Engineer (CCE).
Logistics

- All attendees have their microphones muted during the presentation.
- Questions to the panelists must be submitted via the “Q&A” feature in Zoom at any time.
- If there is any urgent issue, please use the “chat” feature to communicate with the panelists.
- Please remember to complete the webinar evaluation after attending. A link will be provided at the end.
About the speaker

• Herman McKenzie is currently the Director, Department of Engineering in the Standards Interpretation Group at The Joint Commission. In this role, he leads the standards interpretation and customer support activities relative to the Life Safety and Environment of Care standards. Mr. McKenzie also manages all activities associated with the daily operations of the Engineering department, provides standards interpretation and education to The Joint Commission’s Surveyors and accredited organizations, reviews equivalency requests and survey reports, conducts surveys and Intracycle Monitoring conference calls, serves as faculty for educational programs, and is a speaker for national, regional, state, and local audiences.

• Mr. McKenzie has more than 30 years of experience in health care having held managerial and directorial roles in clinical engineering, plant operations and facilities services in the Chicago area. He was part of the team that opened the first new hospital in Illinois in over 25 years.

• Mr. McKenzie is the past President of the Healthcare Engineers Society of Northern Illinois (HESNI) and is a member of the American Society for Healthcare Engineering (ASHE).

• Mr. McKenzie earned his Master of Business Administration from Governors State University, University Park, Illinois, and his Bachelor of Science degree in Electronics Management from Southern Illinois University, Carbondale, Illinois. He is also a Certified Healthcare Safety Professional (CHSP).
Session Description

**Today’s Panel Discuss Objectives**

1. Overview of standards for medical equipment
2. Leading the way to Zero
3. Frequently asked (public health emergency) questions from healthcare technology managers
STANDARDS: MEDICAL EQUIPMENT

The 2 standards for medical equipment:

EC.02.04.01:
The hospital manages medical equipment risks.
- This is the “administrative” standard; rules regulations and codes

EC.02.04.03:
The hospital inspects, tests, and maintains medical equipment.
- This is the maintenance or operational set of requirements
EC.02.04.01 EP 2

For Hospitals that use Joint Commission accreditation for deemed status purposes:
The hospital maintains a written inventory of all medical equipment.

For Hospitals that do not use Joint Commission accreditation for deemed status purposes:
The hospital maintains either 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.

- Key Success Point:
  - Know if your organization uses the Joint Commission accreditation for deemed status
EC.02.04.01 EP 3

The hospital 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.

Note: High-risk medical equipment includes life-support equipment.

- Key Success Point:
  - Your medical equipment inventory must readily identify high-risk
EC.02.04.01 EP 4

The hospital 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.
The hospital 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 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.
EC.02.04.01 EP 5

For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital’s 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 must 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 purposes)
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies

**Note:** Maintenance history includes any of the following documented evidence: Records provided by the hospital’s contractors. Information made public by nationally recognized sources. Records of the hospital’s experience over time

- **Key Success Point:**
  - your PM program aligns with manufacturer instructions
EC.02.04.01 EP 6

For hospitals that use Joint Commission accreditation for deemed status purposes: A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate 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 (For more information on defining staff qualifications, refer to Standard HR.01.02.01)

• Key Success Point:
  • use job descriptions, not individual's names
  • your PM program aligns with manufacturer instructions
  • written criteria used to support the determination of an AEM strategy
**EC.02.04.01 EP 7**

For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

- **Key Success Point:**
  - If you implement an AEM strategy, be sure your medical equipment inventory readily identifies these devices as such
The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.

- **Key Success Point:**
  - Written process or policy to manage broken equipment
  - Equipment users know what to do with defective devices
The hospital identifies quality control and maintenance activities to maintain the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced. The hospital identifies how often these activities should be conducted.

- Key Success Point:
  - Your written plan, process or policy identifies each modality
The hospital inspects, tests, and maintains medical equipment. These are the maintenance activities set of requirements.
For hospitals that do not use Joint Commission accreditation for deemed status purposes: Before initial use of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks.

For hospitals that use Joint Commission accreditation for deemed status purposes: 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.

- Key Success Point:
  - New devices tested prior to being put into use
  - Process in place for loaner, rental and patient owned equipment
EC.02.04.03 EP 2

The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented. (See also PC.02.01.11, EP 2)

Note 1: High-risk equipment includes medical equipment for which there is a risk of serious injury or even 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 manufacturers’ 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.

Key Success Point:
- This EP includes equipment user's maintenance activities, confirm with users they are following manufacturers instructions and are documenting actions
EC.02.04.03 EP 3

The hospital inspects, tests, and maintains non-high-risk equipment identified on the medical equipment inventory. These activities are documented.

Note: Scheduled maintenance activities for 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.

- Key Success Point:
  - This EP includes equipment user's maintenance activities, confirm with users they are following manufacturers instructions and are documenting actions
EC.02.04.03 EP 4

The hospital conducts performance testing of and maintains all sterilizers. These activities are documented.
(See also IC.02.02.01, EP 2)

- Key Success Point:
  - This EP includes equipment user's maintenance activities, confirm with users they are following manufacturers instructions and are documenting their actions
The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.

- **Key Success Point:**
  - Dialysis equipment testing log maintained and complete
  - Process in place for quality control testing dialysis test strips
  - Conductivity and other water quality testing not being performed consistently
  - Cultures of the water treatment are performed as required
  - Documentation of action taken when the cultures and colony counts are out of range and above the recommended limits
The hospital maintains the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced.

- **Key Success Point:**
  - Documentation of repairs and calibrations
  - Corrective actions taken are documented for any noted degradation in device performance
These are the requirements for the diagnostic medical physicist to at least annually conduct a performance evaluation of all; CT, MRI, Nuclear Medicine, positron emission tomography, fluoroscopic imaging equipment.

**Note:** Medical physicists or MRI scientists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist or MRI scientist.
The hospital meets NFPA 99-2012: Health Care Facilities Code requirements related to electrical equipment in the patient care vicinity. (For full text, refer to NFPA 99-2012: Chapter 10)

Note: For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital meets the applicable provisions of the Health Care Facilities Code Tentative Interim Amendment (TIA) 12-5.

- Key Success Point:
  - Review NFPA 99-2012: 10.5.6 Record Keeping – Patient Care Appliances
  - 10.5.6.1.1 permanent file of instruction and maintenance manuals
  - 10.5.6.2 Documentation
  - 10.5.8 Qualifications and Training of Personnel
ZERO HARM

What are the top 3 anticipated challenges that hospitals can achieve Zero Harm?
Patient Safety Risks

- High-Level Disinfection & Sterilization
- Suicide Prevention
- Sterile Compounding
- Hemodialysis
High-Level Disinfection (HLD) & Sterilization

- Failure to comply with HLD and sterilization guidelines have led to numerous outbreaks across the country

- Organizations should have adequate facilities and implement consistent processes regardless of the setting where instruments or equipment are being used or reprocessed

- Surveyors will evaluate these processes at remote ambulatory settings
EC 02.04.03 EP 4 Sterilizers

The hospital conducts performance testing of and maintains all sterilizers. These activities are documented. (See also IC.02.02.01, EP 2)

- Key Success Point
  - Includes “equipment user” maintenance activities
  - Maintenance activities are complete and timely
Sterile Compounding

- As seen in recent media reports, despite increased regulations, incidents of contamination continue to occur.

- Expect the survey team to spend additional time in evaluating compounding services within your organization, including in remote ambulatory settings.

- For home care organizations, the new “Medication Compounding” standards chapter will be utilized to evaluate compliance.

  - Key Success Point:
    - Includes all maintenance activities for hoods and isolators
Hemodialysis

- A very technical, high-risk area, care teams must be capable and competent to protect themselves from the risk of needle sticks, blood exposure and other complications of treatment while caring for hemodialysis patients.
Hemodialysis: EC 02.04.03 EP 5

The hospital performs equipment maintenance and chemical and biological testing of water used in hemodialysis. These activities are documented.

- **Key Success Points:**
  - Includes “equipment user” maintenance activities
  - Dialysis equipment testing log maintained and complete
  - Process in place for quality control testing dialysis test strips
  - Documentation of testing dialysis strips
  - Check for expired dialysis / chlorine / pH test strips
  - Conductivity and other water quality testing performed consistently
Common Compliance Questions
Healthcare Technology Management
Q: Preventive Maintenance

I have not been able to keep up with my preventive maintenance inspections during the pandemic. Will TJC penalize me for being below 100%
A: Preventive Maintenance

TJC cannot waive Condition of Participation requirements however:

- Waivers were issued for inspection, testing and maintenance (ITM) activities by CMS (blanket 1135)
- Organizations should complete ITM tasks as much as can be accomplished safely
- Once we establish your survey ready date, we expect you to become compliant
Q: Equipment modifications

We have run IV lines outside patient rooms so that staff can maintain distance from exposed patients. What does TJC feel about this?
A: Equipment Modifications

TJC would expect that you have verified that the extended tubing will not compromise the operation of the infusion pump.
Q: PM Documentation

Can I document that I am not 100% compliant due to the pandemic with the entry “Covid19”
A: PM Documentation

TJC does not dictate how organizations document their records outside of verification of operational parameters when required by the manufacturer. The waiver will allow organizations to come below ITM requirements.
Q: Waiver Documentation

Do I need to document and justify that I am taking a waiver?
A: Waiver Documentation

Organizations do not have to justify or document the reasons for taking the waiver as long as they have activated their Emergency Operations Plan.
Please complete the online evaluation/attendance form at
https://www.surveymonkey.com/r/ACCEwebinar_03-30-21