ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

2022-2023 Educational Webinar Series

The Joint Commission - 2023

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Speaker:

Herman McKenzie, MBA, CHSP

The Joint Commission

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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. They will be addressed at the Q&A portion.

❖If there is any urgent issue, please use the "chat" feature to communicate with the host/moderator.

❖Please remember to complete the webinar evaluation after attending. A link will be provided at the end.

About the speaker

Herman A. McKenzie, MBA, CHSP

- 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).

The Joint Commission

Topics / Learning Objectives

- TJC Expectations
- New/Revised Standards, Elements of Performance
- Clarity on Alternate Equipment Maintenance Programs
- Cybersecurity

TJC Expectations

What we are and what we aren't

ACCE – 2022-2023 Educational Webinar series

TJC Expectations

- TJC is not a regulatory agency

- TJC does not provide technical training
  - We do provide seminars, webinars, speaking engagements focused on compliance

- TJC cannot consult or endorse a product or service
  - Policy review outside a survey event
  - Recommend a medical device

TJC Expectations

- Ensure medical equipment management processes are developed
- Evaluate these processes
- Validate that inspection, testing and maintenance activities are conducted
- Ensure compliance with the Conditions of Participation

Revised Element of Performance

What's New

EC 02.05.01 EP 23

- Power strips in a patient care vicinity are only used for components of movable electrical equipment assemblies used for patient care. These power strips meet UL 1363A or UL 60601-1. Power strips used outside of a patient care vicinity, but within the patient care room, meet UL 1363. In non–patient care rooms, power strips meet other UL standards. (For full text, refer to NFPA 99-2012: 10.2.3.6; 10.2.4; NFPA 70-2011: 400-8; 590.3(D); Tentative Interim Amendment [TIA] 12-5)
- Note 1: The mounting of power strips to medical equipment assemblies or the reconfiguration of equipment powered by power strips in a medical equipment assembly must be performed by personnel who are qualified to make certain that this is done in accordance with NFPA 99-2012: 10.2.3.6.

EC 02.05.01 EP 23

- Note 2: Per NFPA 99-2012: 3.3.138, patient care room is defined as any room of a health care facility wherein patients are intended to be examined or treated. Per NFPA 99-2012: 3.3.139, patient care vicinity is defined as a space, within a location intended for the examination and treatment of patients, extending 1.8 meters (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 2.3 meters (7 feet, 6 inches) above the floor.
- Note 3: In new facilities, the number of receptacles shall be in accordance with NFPA 99-2012: 6.3.2.2.6.2. If patient bed locations in existing health care facilities undergo renovation or a change in occupancy, the number of receptacles must be increased to meet the requirements of NFPA 99-2012: 6.3.2.2.6.2 to eliminate the need for power strips.

EC 02.05.01 EP 23

- Needed to emphasize that RPT's should only be managed by those familiar with the code requirements (Note 1)
- Additional language to identify where patient care (Note 2)
- RPTs should not be used as a substitute for fixed wiring (Note 3)

EC 02.05.01 EP 23

Observations

- The 2 IV pole mounted power strips, located in OR 3, were being used to power other devices not attached to the IV pole. This was confirmed by the Chief of Plant and Engineering.
- In 1 of 6 areas checked, it was observed on the 3rd floor of the Blank building inside the nurse's station a relocatable power strip was plugged in to another relocatable power strip and in use.
- Observed in Building Tour. There was a power strip in the Horizon Exam Room that did not meet UL 1363A or UL 60601-1. Medical equipment was plugged into the power strip.

RPT On a Pole -versus-Installed As Part of An Equipment Assembly

Clarity on Alternate Equipment Maintenance (AEM) Programs

Ensuring compliance

Requirements to set up an AEM program?

- An alternate equipment maintenance (AEM) program describes deviation from manufacturer recommendations for one or more biomedical devices, each of which must be identified on the inventory.
- The deviation may involve inspection and maintenance intervals, the details of required maintenance activities, or both.
- Setting up an AEM program requires an inclusion risk assessment for each piece of medical equipment under consideration and a thorough review of each device's maintenance history. These processes must be documented.

AEM, continued

- Per Environment of Care (EC) Standard EC.02.04.01 and Standard EC.02.04.03, The Joint Commission requires organizations to follow manufacturers' recommendations or—if specific criteria are met—an alternative equipment maintenance (AEM) program, unless federal or state laws or regulations mandate stricter or more specific requirements.

AEM Standards and EPs

- **Administrative Requirements**
- EC 02.04.01 EP 4
- EC 02.04.01 EP 5
- EC 02.04.01 EP 6
- EC 02.04.01 EP 7
- **Operational Requirements**
- EC 02.04.03 EP 2
- EC 02.04.03 EP 3

Top Tips for AEM Program Development

- Organizations should do the following when developing an AEM program:
  - Make sure that the equipment you are considering for the AEM program, including critical equipment, is readily identifiable in the inventory.
  - Document the qualifications of personnel responsible for developing and implementing the AEM program.
  - Document the qualifications of personnel maintaining equipment in the AEM program, including staff and outside contractors/vendors

Top Tips for AEM Program Development

- Document all maintenance activities and frequencies for all equipment in the AEM program
- Ensure that staff responsible for the AEM program can explain how the decision was made to place specific devices in the program
- Make sure that your AEM methodology considers risk factors and uses available evidence.
- Be able to demonstrate that maintenance is being performed following the maintenance activities and frequencies defined in the AEM program.

Top Tips for AEM Program Development

- Routinely evaluate the safety and effectiveness of AEM program maintenance activities and take corrective action as needed.

Cybersecurity

Where does TJC stand?

Cybersecurity – Questions from the field

1.What is the status of the new Cybersecurity of Connective medical devices surveys?

- In June 2022 TJC convened a technical advisory panel
- Currently reviewing literature regarding the issue
- CEO’s focus is on standards reduction

Cybersecurity – Questions from the field

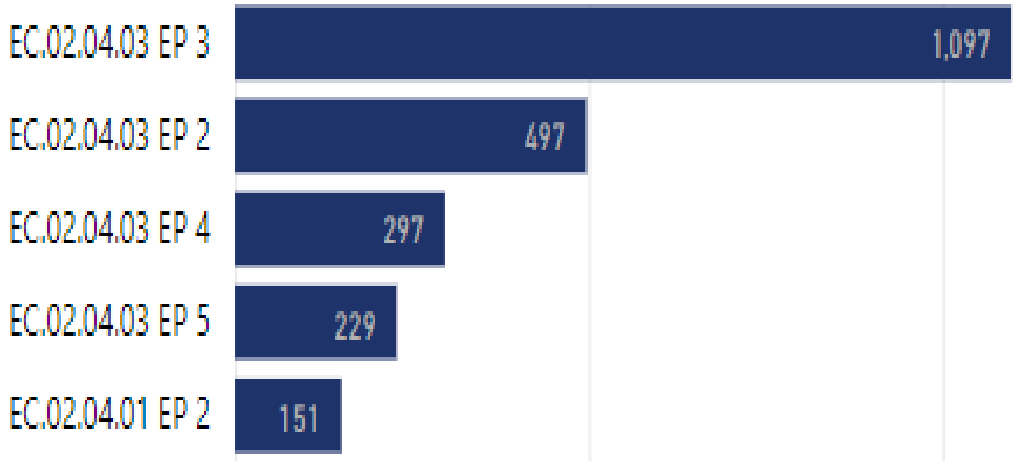
2. Do you know any of the basic requirements that will be included in the Cybersecurity for Medical device ‘s survey? Like an accurate inventory?

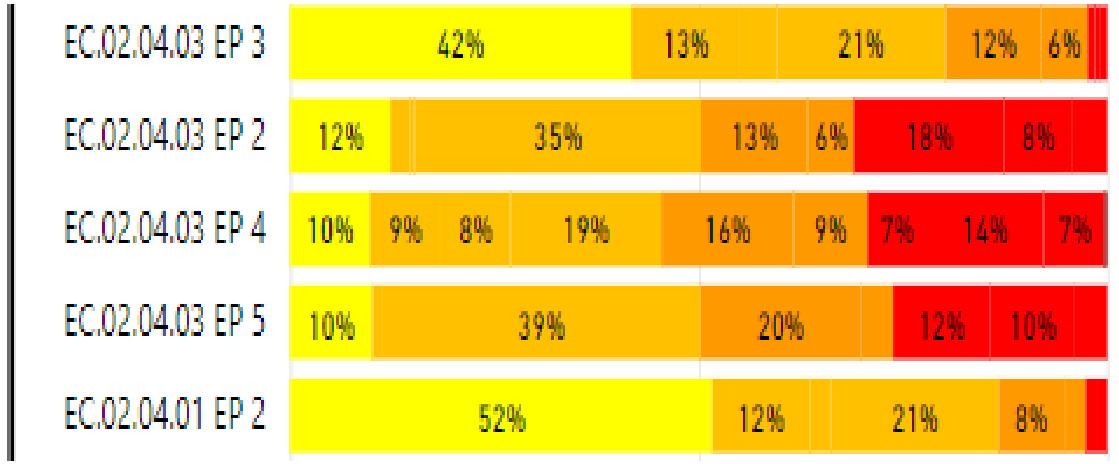
- No new standards have been introduced
- Information Management (IM) IM 02.01.03 chapter addresses protected health information but not focused on medical equipment.
- The medical equipment standards already require an inventory

Medical Equipment Observations

What's being scored on survey

Top Scored Medical Equipment Observations





EC 02.04.01 EP 2

- 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.

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

EC 02.04.01 EP 2

Observations

- Sequential compression device found not on inventory
- Noninvasive Blood Pressure machine not on inventory
- Centrifuge not on inventory

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.

EC 02.04.03 EP 5

Observation

- During tracer activities in the Dialysis Clinical area, it was identified that there were gaps on the water testing logs, missing water ranges and entries scratched over by the staff. This was confirmed by the Nurse Manager.

- Observed in Tracer Activities. During tracer activity in Dialysis the dialysis conductivity and other water quality testing was not performed in 2 of the past 4 quarters. Department coordinator aware of this observation and has been corrected in the past 6 months.

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)

EC 02.04.03 EP 4

Observations

- Observed in Infection Control System Tracer. There was no evidence that the Steris AMSCO sterilizers had received the daily or weekly maintenance activity per manufacturer's recommendations.
- Observed in Infection Control System Tracer. During the sterile processing system tracer, observed there was no evidence that a leak test was performed on 4 of 4 steam sterilizers on a weekly basis as required by the manufacturer's instructions for use or organization policy as stated by the sterile processing technician. This was confirmed by the sterile processing technician and infection control officer.

EC 02.04.03 EP 2

The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented.

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.

EC 02.04.03 EP 2, continued

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. (See also PC.02.01.11, EP 2)

EC 02.04.03 EP 2

Observations

- During an individual tracer in the Diabetes Clinic, it was observed the AED was past due for periodic maintenance review. The maintenance was due on 4/17/2020 . This was confirmed with the interim CEO.

- While reviewing the filter changes for the automated endoscope high level disinfection machine, it was noted that BIOMED is changing the main water filters but has not been changing the filters in the machine itself as required by the manufacture's instructions for use. Confirmed with BIOMED and GI managers.

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.

EC 02.04.03 EP 3

Observations

- Discussion with the hospital perfusionist revealed that the heater/coolers were not receiving the quarterly and monthly preventive maintenance that were recommended by the manufacturer for the Hemotherm 400CE machine.

- The periodic maintenance of the CT scan machine was performed later than scheduled, while the surveyor was on site. The organization was also unsure as to when it was last performed due to recent change in leadership.

Concluding Tips for Success

- Get Organized (where are your records?/ who has access)
- Complete Documentation (dates / measurements / values)
- Understand the Standards and Elements of Performance (EPs) (do not rely on word of mouth)
- TJC education sessions provide standard interpretation and compliance guidance. They do not replace the manual

Questions & Discussions

Enter your questions to the Q&A window

Thank You

Please complete the online evaluation/attendance form https://www.surveymonkey.com/r/ACCE_2022-2023_series_session6-webinar or scan the QR code