HEADS UP...

TOPIC: Performance testing and maintenance of sterilizers
***SETTING:* Office-Based Surgery (OBS)**

Why is this important?

The testing and proper performance of sterilizers is essential to maintaining quality care and patient safety. Office-based surgery centers are frequently cited for non-compliance for issues related to performance testing and maintenance of sterilizers (EC.02.04.03 EP 4). This standard and EP is also often scored as a higher-risk finding for this setting.

Scope of the Problem:

Time period: **January 1, 2019 – March 31, 2020**
Number of full surveys performed: **95**
Number of surveys which had moderate and high-risk findings related to performance testing and maintenance of all sterilizers (EC.02.04.03 EP 4): **10 (11%)**

Observations identified within a specific topic may reveal systemic areas for improvement across the organization. These deficits might be reflected in additional standards/EPs within the human resources chapter and/or other chapters/standards/EPs: IC.02.02.01 EP 2.

Sample survey observations [from surveyor notes] (and contributing factors)

- There was no evidence that the sterilizers/autoclaves had received the daily, weekly, and/or monthly maintenance activity per manufacturer's recommendation.
    - The practice had not implemented testing to assure proper air removal from their pre-vacuum autoclave chamber.

Potential contributing factors:

- Lack of staff understanding and education regarding the requirements needed to perform maintenance activities on all sterilizers (e.g., staff did not understand that the autoclave only used for dental hand pieces needed the same treatment as the other autoclaves).
- Leadership failed to ensure that the assigned staff performed the recommended tests and maintenance activities for autoclaves.
- Lack of a process to confirm compliance with organization policy or chosen evidence-based guideline for routine (e.g., daily, weekly, monthly) maintenance (e.g., supervisor, IC or other staff could not confirm maintenance was performed).
- Lack of compliance with organization policy for monitoring and\or documentation regarding testing and maintenance.
- Not following manufacturers' instructions and recommendations for the testing and maintenance of sterilizer equipment.
- Policies and procedures were not in compliance with the manufacturer's instructions.

How to identify potential problems in your organization

Review your policies and procedures

☐ Does the organization have policies and procedures for ensuring the testing and maintenance of all sterilizers?

- Is this process periodically reviewed?
- Is this process in alignment with manufacturers' instructions for all sterilizers?
- Does the policy indicate the frequency of inspections and testing for sterilizing equipment or refer to IFU for sterilizer?
- Does the policy indicate how to respond when the equipment fails an inspection or test?
- Does the policy and procedure address staff responsibilities (e.g., who is responsible for the testing and maintenance of the equipment? Who has oversight and is responsible for reviewing that corrective actions are being completed?)

Interview staff

☐ Relevant staff demonstrates knowledge of requirements for testing and maintenance activities for sterilizing equipment.

- Are staff knowledgeable regarding the frequency in which testing, quality control, and maintenance activities need to occur (e.g., daily, weekly and monthly activities recommended by the manufacturer)?
- Can staff identify when there has been a real or potential process failure (e.g., positive biological, no change in peel pack color indicator, or failed indicator strip)?
- Are staff aware of the steps/process to take when sterilizer equipment may have failed (e.g., notify supervisor, quarantine load until resolved)?
- Does the staff know how to recall instruments if distributed?

Review employee education and competency records

☐ Is there actual evidence of demonstrated competency (e.g., able to identify a failed Bowie Dick versus pass and provide next steps if failed)?

☐ Are there specific competencies staff must complete based on their assigned duties?

☐ Is the frequency of competency assessment appropriate to ensure compliance with requirements (e.g., state, IFUs, policy)?

Assess your environment

☐ Is there a way for your staff to know the requirements (e.g., sterilizer equipment checklist, poster or other document that outlines the schedule and type of testing and maintenance that needs to be completed)?

☐ Are the sterilizer equipment manufacturers' instructions readily available? Are tests and maintenance performed according to the manufacturers' instructions?

Evaluate implementation

☐ Are the testing and maintenance activities documented as required?

☐ Does someone review and monitor maintenance of equipment on a regular basis?

What are some resources that can assist in mitigating risks in these areas?

- The Joint Commission Resources, IC Made Easy: Your Key to Understanding Infection Prevention and Control, 2019.
- The APIC/JCR Infection Prevention and Control Workbook, Third Edition, 2017.
- Consult manufacturers' instructions for use (IFU) and user guides for guidance regarding inspection, testing and maintenance.