HEADS UP…

TOPIC: Maintenance and Inspection of Laboratory Equipment
SETTING: Laboratory Accreditation Program (LAB)

Why is this important?

Properly functioning laboratory equipment is a critical component in health care as it enables the detection of disease and other healthcare-related issues. Responsibility for the maintenance and inspection of laboratory equipment falls on the laboratory staff. Comprehensive policies and procedures related to the preventative maintenance, testing, and inspection of laboratory equipment should include maintenance strategies which specify how and when to test, document, report, and/or repair equipment. Compliance to these protocols ensures that laboratory equipment has undergone the appropriate testing and quality control to protect the safety and health of the patients served and to guide appropriate health care diagnoses, treatments or interventions.

Scope of the Problem:

Time period of inquiries: **January 1, 2020 – December 31, 2020**
Number of full surveys performed: **386**
Number of high and moderate risk findings: **34 (9%)**
Relevant Standard/EP: **EC.02.04.03** The laboratory inspects, tests, and maintains laboratory equipment. **EP 7** - The laboratory performs preventive maintenance, periodic inspection, and performance testing of each instrument or piece. Observations identified within a specific topic area may reveal systemic areas for improvement across the organization. These improvement opportunities might be reflected in other chapters, standards or EPs. *See also CLIA §493.1254(b)(1)(ii), §493.1254(b)(2)(ii), §493.1254(a)(1), §493.1254(a)(2), §493.1271(c) §493.1271(c) (2), §493.1495(b)(3).*

Sample survey observations [from surveyor notes] and contributing factors

- The laboratory did not have a system in place to periodically clean, service, and inspect its microscopes.
- There was no documentation to show that preventive maintenance was performed on the chemistry or hematology analyzers.
- Cleaning the blood cell washer had not been documented, written policy required cleaning at least monthly.
- Monthly checks of CO2 levels in microbiology incubators was not documented.
- The laboratory did not document performance testing and function checks for blood bank refrigerator alarm systems.

Potential contributing factors:

- Written policies and procedures related to inspection and maintenance of laboratory equipment unclear
- Lack of oversight by leadership and/or of the laboratory manager to conduct and document annual staff competencies.
- Job duties and responsibilities involving laboratory maintenance are not clearly defined

How to identify potential problems in your organization

Review policies, procedures, and protocols

☐ Does the laboratory have clearly written policies and procedures related to preventative maintenance, inspection, and testing of laboratory equipment? Do the policies outline:

- What specifications are followed when performing preventive maintenance, periodic inspection, and performance testing for all lab instruments and equipment?
- How the laboratory ensures that instrument function checks are performed according to approved schedules?
- How the organization documents the activities and frequencies for inspecting, testing, and maintaining laboratory equipment?
- How long documentation is retained on regular performance testing and function checks for instruments and equipment?
- The appropriate education, training, and competency level needed for laboratory staff performing maintenance, inspection, and testing?
- The intervals for competency reassessments?

Interview staff

☐ Is staff aware of maintenance and testing schedules per written policy?

☐ Does staff have access to manufacturer's instructions or instructions for use for maintenance of equipment (when appropriate)?

☐ When preparing, testing, and inspecting laboratory equipment, does staff understand how to effectively document these processes?

☐ What are the necessary steps and/or actions taken when equipment in not functioning properly?

- How are repairs and parts replacement for each instrument or piece of equipment documented?

Assess your environment

☐ Review maintenance and storage requirements for each equipment or instrument per manufacturing policy.

☐ Does staff have access to the written policies and procedures to effectively sustain the laboratory and its equipment?

- Does the laboratory have a written inventory of all its equipment and instruments?
- Are manufacturer's instructions or IFUs easily available and accessible to staff (e.g. posted near equipment)?

Evaluate implementation

☐ Directly monitor performance testing and review quality control records and test results.

☐ Review documentation of an equipment repair process to verify that it is completed per organization and/or manufacturing policy.

☐ Review employee files and records to ensure that competence assessments related to equipment maintenance is documented and performed annually.

☐ Assess staff knowledge and comprehension of testing and maintenance protocols.

☐ Review policies and procedures annually to ensure they are updated.

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

- Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). Complete description of the requirement is located at https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m