AABB Standards Chat Volume 10

In the previous standards chat, we discussed internal and external assessments along with the follow up actions that are taken based upon the results of the assessment. In this chat we will the use of equipment including monitoring, maintenance, and calibration.

**3.3 Use of Equipment**

* Equipment shall be used in accordance with the manufacturer’s written instructions.
* All equipment in the department has defined instructions for use included in policy. The policies are directly based off the manufacturer’s instructions.

**3.4 Unique Identification of Equipment**

* Equipment shall have unique identification. Standard 5.1.6.2 applies.
* Plant Ops is responsible for equipment identification, per *Lab Equipment Management*.
* Our department also assigns unique numbers to each piece of equipment to allow for tracking of any issues and repairs for the life of the instrument. These numbers are never reused on new equipment when old equipment is retired.

**3.5 Equipment Monitoring and Maintenance**

* The BB/TS shall have a process for scheduled monitoring and maintenance of equipment that at a minimum is in accordance with manufacturer’s written instructions. The process shall include frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results.
  + *Equipment Quality Assurance* describes the monitoring and maintenance of most pieces of equipment used in the department. Other equipment is addressed in their respective SOPs.

**3.5.1 Calibration of Equipment**

* Calibrations and/or adjustments shall be performed using equipment and materials that have adequate accuracy and precision. At a minimum, calibrations and/or adjustments shall be performed as described below unless otherwise indicated by the manufacturer:

1. Before use.

2. After activities that may affect the calibration.

3. At prescribed intervals.

* + *Quality Program* states that equipment calibration is performed upon receipt, after major adjustments and repairs, and at manufacturer’s suggested intervals.
  + Bi-annually, due to Cesium 137 decay Blood Bank Leadership recalculates the Irradiation Exposure Time under the direction of the Medical Director
  + Helmer water baths have temperature calibration performed quarterly.
  + Saline volume for the cell washers is checked daily and with each saline cube change. Cell washer RPM’s and timers are checked semi-annually.
  + Fixed speed centrifuges are calibrated annually.
  + Dry heating blocks have daily temperatures recorded.
  + MLA pipettes are calibrated semi-annually by designated personnel.
  + Quarterly alarm calibrations, repairs, and adjustments on temperature surveillance monitoring and recording modules for freezer and refrigerators is performed by an outside vendor via a maintenance contract.
  + COBE cell washer had quality control performed biannually.

**3.5.1.1** There shall be safeguards to prevent equipment from adjustments that would invalidate the calibrated setting. Standard 5.1.3 applies.

* The irradiation exposure time setting is secured with a password.
* Calibrations are performed and adjustments are made only by the designee assigned to perform the calibration.
* Any failures of equipment calibration are reported to BB Leadership. BB Leadership will make decisions on appropriate follow up actions.

**3.5.1.2** Calibration procedures shall follow the manufacturer’s written instructions and shall include:

1. Instructions for performing calibrations.

2. Acceptance criteria.

3. Actions to be taken when unsatisfactory results are obtained.

* *Equipment Quality Assurance* gives instructions for calibrations of most pieces of equipment in the department and includes acceptance criteria and follow up actions for unsatisfactory results.
* For equipment not included in *Equipment Quality Assurance*, a policy for the specific equipment contains this information. For example, the blood product freezers and blood storage refrigerators, COBE cell washer, and the irradiator have calibration procedures defined within their respective policies.

**3.5.2 Investigation and Follow-up**

* Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

1. Assessment of blood, blood components, tissue, derivatives, and services provided since the equipment was last known to be functioning per manufacturer’s written instructions, or facility-defined specifications.

2. Assessment of the effect on donor eligibility and donor and patient safety.

3. Steps to ensure that the equipment is removed from service.

4. Investigation of the malfunction, failure, or adverse event, and a determination if other equipment is similarly affected.

5. Steps for requalification of the equipment.

6. Reporting the nature of the malfunction, failure, or adverse event to the manufacturer, when indicated.

Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

* Any failures of equipment calibration are reported to BB Leadership. BB Leadership will make decisions on appropriate follow up actions.
* Quality Assurance Work Report Forms are filled out and submitted to BB Leadership for any equipment failure. The equipment is taken out of service until failures can be resolved.

The goal of the AABB Standards Chat is to increase staff awareness as to their purpose and how they impact the Blood Bank’s policies and procedures. If you have a question about AABB standards, please see a member of BB Leadership.