AABB Standards volume 8  
In the previous standards chat, we discussed competency and the storage of personnel records. In this chat we will discuss Equipment and how new equipment and new processes are evaluated.

**3.0 Equipment**

* The BB/TS shall identify the equipment that is critical to the provision of blood, blood components, tissue, derivatives, and/or services. The BB/TS shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these BB/TS Standards and other specified requirements
* Standard 3.0 applies to every procedure that references equipment. Examples include *Calibration of Fixed Speed Centrifuge, Blood Product Freezers and Blood Storage Refrigerators, Equipment Quality Assurance,* and also *COBE Cell Washer Quality Control.*
* Because this standard affects so many different procedures, changes in this standard result in significant changes in the lab.
  + As new equipment is brought into the lab, new procedures are created to ensure that the equipment functions as intended.

**3.1 Selection of Equipment**

* The BB/TS shall have a process to define the selection criteria for equipment.
* Factors to be considered when selecting equipment include cost, service, history, and support.
* According to the global lab policy *Lab Equipment Management, DLO-ALL 059*, potential new lab equipment must have an assessment prior to starting the equipment selection process, an initial survey of available vendors and equipment, site visits including conversations with known users, identification of 1 or more comparable pieces of equipment, and a solicitation of bids from the vendors.
* Care must be taken to ensure any new equipment does not alter the process unless there are limited competing manufacturers.
  + Along with not altering a process, it is vital that requirements of the equipment is reviewed prior to purchasing. Items like humidity, temperature, and power/socket requirements can significantly delay or halt implementation.

**3.2 Qualification of Equipment**

* All equipment shall be qualified for its intended use. Equipment repairs and upgrades shall be evaluated and equipment requalified, as appropriate, based on the facility’s policies and manufacturer recommendations
  + Supplier qualification is a process whereby an organization determines whether or not a supplier can meet its requirements.
    - These requirements usually include the ability to meet regulations, the availability of supply, the timeliness of delivery, responsiveness to issues and problems, cost, and support.
  + As seen in the *Supplier Qualification* policy, suppliers of critical materials, services, and equipment are reviewed periodically to assure requirements are continuously met. That could include surveys to the supplier, surveys to the customers, or onsite audits of the supplier.
    - In general, the more critical the supply/equipment/service, the more stringent the qualifications should be.
  + If a supplier fails to successfully qualify, documentation is provided to justify a different vendor. Our purchasing team keeps a list of approved suppliers that are routinely reviewed so that adjustments to the supplier can be made as needed.
  + *Validation of Critical Processes* is another procedure that correlates with this standard. Processes that could affect the safety, purity, potency, or identity of the blood supply, patient testing, or the safety of the patient, are considered a critical process and require validation prior to implementation. Validations are approved by the Medical Director and Manager prior to execution.
    - Some examples of critical processes are product storage, product labeling, component production, new software, and more.
    - Validations include verifying the equipment is properly installed, operational, and performs as indicated. See the next standards for a deeper dive into these topics.

**3.2.1 Installation Qualification**

* As Equipment shall be installed per the manufacturer’s specifications.
  + The instillation qualification section, outlined in the *Validation of Critical Processes* procedure, asks us to demonstrate the capability of the equipment to operate within the established limits and specifications.
  + Sometimes the manufacturer instillation specifications include a basic set of instructions such as the distance to water or drain, the type of power required, and/or the relative humidity/temperature required, and other times manufacturers require their own technicians for instillation.
  + In accordance with *Lab Equipment Management, DLO-ALL 059* policy, plant ops should be notified anytime an installation requires special electrical/water hookup and drainage requirements so the space can be prepared prior to the arrival of new equipment.

**3.2.2 Operational Qualification**

* The functionality of each piece of equipment and each component of a computer system shall be verified before actual use and shall meet the manufacturer’s operational specifications.
  + The operational qualification section, outlined in the *Validation of Critical Processes* procedure, requires that a process or equipment demonstrates the desired result or defines the process limits.
  + Any equipment used in measurements require routine calibration.
    - If routine calibration is necessary and the manufacturer has no guidance for frequency, standard practice in the industry should be used.
    - Depending on the process or equipment, you may find a specific procedure that outlines maintenance and use such as *Echo Monthly Maintenance*, or you may find a general procedure such as *Equipment Quality Assurance*.
  + Preventative maintenance must be established in line with the manufacturers recommendations
  + The operational qualification is further defined by the FDA as a means establishing confidence that process equipment and sub-systems are capable of consistently operating within established limits and tolerances.

**3.2.3 Performance Qualification**

* The BB/TS shall demonstrate that equipment performs as expected for its intended use. Performance specifications established by the manufacturer shall be met.
  + The product qualification section, outlined in the *Validation of Critical Processes* procedure, asks for assurance that the process results in acceptable measurable or quantifiable specifications attributed to the product.
  + Although manufacturers perform extensive testing before a product reaches market, it is vital the Blood Bank performs our own validation to prove it works with our SOPs and environment. Our validation will also challenge to new equipment to check for flaws, incompatibilities, and misconceptions. Generally speaking, the greater the risk in adopting the new software/equipment, the greater the amount of testing/validation.

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.