AABB Standards Chat Volume 13

In the previous standards chat we discussed information systems in the blood bank. In this chat we will discuss supplier and customer issues.

**4.0 Information Systems**

The BB/TS shall evaluate and participate in the selection of suppliers, when possible, before acceptance of an agreement.

* Blood bank policy *Supplier Qualification* states that the suppliers of critical materials, services, and equipment must be qualified and then reviewed periodically to assure that they continuously meet agreed upon requirements.

**4.1** **Supplier Qualification**

The BB/TS shall evaluate and participate in the selection of suppliers, when possible, before acceptance of an agreement.

* The *Supplier Qualification* policy list parameters on which supplier qualification is based including licensure, certification, and accreditation, supply or product requirements, review of supplier-relevant quality documentation and/or quality summary reports, results of audits or inspections, review of customer complaints, customer satisfaction, review of past experience with supplier, cost, delivery system, financial security, and support.
* WDL may also qualify suppliers, however, the blood bank must validate the acceptability of the materials. If found unacceptable, documentation must be provided to justify a different vendor.

**4.1.1** When a supplier fails to meet specified requirements, it shall be reported to the management with contracting authority.

* Requirement failures are documented by BB Leadership on the Supplier Issues form. This form is attached to the *Supplier Qualification* policy. The form includes documentation of the problem and the supplier’s response to the problem, as well as resolution acceptability.

**4.1.2** Testing or services required by these *BB/TS Standards* shall be performed in a laboratory accredited by the AABB or equivalent accrediting body.

**4.1.2.1** Laboratory testing shall be performed in a laboratory certified by the Centers for Medicare and Medicaid

Services (CMS) and registered with the FDA, if indicated by 21CFR 610.40(f).

**4.1.2.2** Testing performed by facilities outside the United States shall be carried out by a laboratory authorized as

a testing center by the Competent Authority.

* The Critical Supply Checklist form documents the supplier’s licensure, certification, and/ or accreditation. This form can also be found attached to the *Supplier Qualification* policy.
* As stated in the *Quality Program* policy, Froedtert Hospital maintains a contract with the current blood supplier. The blood supplier is licensed by the FDA and is accredited by the AABB. The blood supplier manufactures its products according to current Good Manufacturing Practices.

**4.2 Agreement Review**

Agreements, or changes to agreements, shall define supplier and customer expectations and shall reflect agreement.

**4.2.1** Agreements and any incorporated changes shall be reviewed and communicated.

**4.2.2** The responsibilities for activities covered by these *BB/TS Standards* when more than one facility is involved

shall be specified by agreement.

* The *Supplier Qualification* policy states that agreements and contracts are reviewed periodically to ensure satisfaction. This review may occur on a corporate level, hospital level, or by the blood bank. This review is documented on the Critical Supply Checklist.

**4.3 Incoming Receipt, Inspection, and Testing**

Incoming blood, blood components, tissue, derivatives, and critical materials shall be received, inspected, and

tested, as necessary, before acceptance or use.

* All supplies received will be inspected for acceptability. The *Quality Program* policy states that supplies that require lot/shipment comparisons will be sequestered until comparisons can be performed. Any supplies not meeting the blood bank’s specifications will be removed from use and BB Leadership will be notified.
* The *Receipt of Critical Reagents* *and Supplies* policy explains that critical supplies such as reagents will be tested and found acceptable prior to use. This includes routine quality control and lot to lot comparisons.
* The details of lot to lot comparisons are laid out in the *Blood Bank New Lot and Shipment Acceptability* policy. The list of reagents requiring lot to lot comparisons is attached to the policy. This testing ensures that there is consistency in reagent reactivity and that storage conditions during shipping did not affect the reagent’s ability to perform as expected.
* The *Blood Product Receipt* policy describes the inspection of incoming blood products and how to handle products that fail inspection. Products that are deemed unacceptable are logged into inventory for tracking purposes and immediately quarantined and subsequently returned to the blood supplier.

**4.3.1** Each container used for collection, preservation, and storage of blood and blood components shall be

inspected to ensure that it is intact. The label shall be complete, affixed, and legible.

**4.3.2** Critical materials shall meet specified requirements.

* The *Receipt of Critical Reagents* *and Supplies* policy explains that critical supplies are examined for acceptability upon receipt. This is documented on the Supplier Quality Control Log.

**4.3.2.1** All containers and solutions used for collection, processing, preservation, and storage and all reagents used

for required tests on blood samples shall meet or exceed applicable FDA or Competent Authority criteria.\*

\*21CFR660, 606.65, 640.2(b), and 640.4(d)

* 21CFR660 explains all the specifics of reagent labeling and potency required.
* 21CFR 606.65 and 21CFR 640.2(b) describe blood collecting container requirements and reagent QC frequency requirements.
* 21CFR 640.4(d) states that the blood storage anticoagulant solution shall be sterile and pyrogen-free and used according to a formula approved by the Director of CBER.

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.