AABB Standards Chat Volume 12

In the previous standards chat, we discussed storage devices and alarm systems for the storage devices. In this chat we will discuss information systems in the blood bank.

* 1. **Information Systems**

The BB/TS shall have processes to support the implementation and modification of software, hardware, and databases relating to the requirements of these *BB/TS Standards*. Standard 5.1.1 applies. These processes shall include:

1. Risk analysis, training, validation, implementation, and evaluation of post implementation performance.
2. System maintenance and operation.
3. Documentation written in language understandable to the user.
4. Display and verification of data before final acceptance, when data are added, or when data are amended.
5. Evaluation, authorization, and documentation of modifications to the system.

* Blood bank policy *Computer System Definition, Validation, and Change Control* addresses information systems implementation and modifications.
* The training required is defined for user training competency (new users) and for system changes/ modifications. Training for modifications to the system may include one or more of the following methods: staff notification via email, SOP distribution, instructional presentation at staff meetings, training leader education with subsequent shift co-worker training.
* Validation processes are also described in this policy. Validation protocols include the following: a description of the function(s) to be tested to include expected results, procedural steps performed, application and/or peripherals used, output of results via computer inquiries, interface transmission, and chart, and acceptance evaluation criteria. Validations utilize test plans that exemplify normal, boundary, invalid, and data integrity testing. The test plans are executed by a blood bank designee and are reviewed by BB Leadership with subsequent approval by the BB Medical Director.
* Software modifications processes are defined as well. The processes describe how the changes are handled within the LIS, EPIC, and the notification process for campus and outreach clients.

**3.9.1** **Information System Records**

Records of the following shall be maintained:

1. Validation of system software, hardware, databases, user-defined tables, electronic data, transfer, and/or electronic data receipt.
2. Fulfillment of applicable life-cycle requirements for internally developed software. (21CFR 820.30)
3. Numerical designation of system versions, if applicable, with inclusive dates of use.
4. Monitoring of data integrity for critical data elements.

* The *Record Retention* policy explains our method of archiving these records as well as the minimum retention time and the retention time our blood bank utilizes.
* Generally, information system records have a required retention time of life of the system plus 2 years. Blood bank uses a retention time of life of the system plus 7 years.

**3.9.2** An alternate system shall be maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. The alternate system shall be tested at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.

* As discussed in the *Computer Downtime PTC Export-Database Inquiry* policy, the entire Blood Bank history file is backed up in the PTC Export database and is updated daily.
* The *Inventory* policy states that the PTC Report is checked daily to ensure patients are correctly uploaded into the report. This check is documented on the Weekly
* The *Transfusion Service Computer Downtime Manual Backup* policy outlines the processes and procedures to follow in the event Cerner is unavailable and describes the recovery plan once Cerner functionality is restored.

**3.9.3** Personnel responsible for management of information systems shall be responsible for compliance with the regulations that affect their use. Standard 1.1, #3 applies.

Standard 1.1, #3 states, the BB/TS shall have a defined executive management. Executive management shall have the responsibility for the compliance with these BB/TS Standards and applicable laws are regulations.

* The *Compliance Program Charter* policy describes the compliance program and the parties responsible for each aspect of the program.

**3.9.4** There shall be processes and procedures to support the management of information systems.

* The LIS department maintains policies on the management of information systems.

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**3.9.5** A system designed to prevent unauthorized access to computers and electronic records shall be established and followed.

* The LIS department maintains the *IT Security Policy* which describes security measures in place for our electronic information.

**3.9.6** A process shall be in place to ensure that the facility has measures in place to minimize the risk of an internal or external data breach.

* The LIS department maintains the *IT Security Policy* which describes security measures in place for our electronic information.

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.