AABB Standards Chat Volume 14

In the previous standards chat we discussed supplier and customer issues in the blood bank. In this chat we will discuss elements of process control including change control, proficiency testing programs, and quality control.

**5.0 Process Control**

The BB/TS shall have policies and validated processes and procedures that ensure the quality of the blood, blood components, tissue, derivatives, and services. The BB/TS shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

**5.1** **General Elements**

**5.1.1 Change Control**

The BB/TS shall have a process to develop new processes and procedures or to change existing ones. This process shall include identification of specifications and verification that specifications have been met. Before implementation, the new or changed processes or procedures shall be validated. Standard 2.1.2 applies.

* Standard 2.1.2 states that the BB/TS shall have a process for identifying training needs and shall provide training for personnel performing critical tasks. This standard is met with the individual training checklists that are required of Blood Bank staff each time new equipment or a new procedure is put into place. For example, prior to the new MTP cooler being put into use each staff member was required to read and sign the training document.
* The *Policy and Procedure Creation/ Revision Procedure* explains the process of writing policies and procedures. This policy describes the written format of policies and procedures. Included in the process of writing policies is feedback from staff and review by BB Leadership as well as the Medical Director. The Medical Director is legally responsible for Blood Bank’s adoption, implementation, and compliance with sectional SOPs. If applicable, staff training must take place using the final procedure. Training will include reading and acknowledging the policy, knowledge assessments (if applicable), and annual competency assessments if the policy is new or has major revisions.
* The *Validation of Critical Processes* policy describes the process of writing and performing a validation plan. Validation must occur for all new processes and equipment as well as any significant changes in processes or use of equipment. The validation plan is reviewed, approved, and accepted by the Medical Director, Manager, and Supervisor prior to performing the validation. An experienced staff member performs the validation plan activities. After the validation is performed, the results and any corrective actions are reviewed and a determination is made as to whether the new or modified processes or equipment may be implemented or implemented with specified limitations.

**5.1.2** **Proficiency Testing Program**

The BB/TS shall participate in a proficiency testing program, if available, for testing regulated by the Clinical Laboratory Improvement Amendments and performed by the facility.\* When a CMS-approved program is not available, there shall be a system for determining the accuracy and reliability of test results. Results shall be reviewed and when expected results are not achieved, investigation and corrective action shall be taken where appropriate.

\*42 CFR 493.1236

* The *Proficiency Testing* policy describes Blood Bank’s participation in external proficiency testing programs. Blood Bank participates in CAP surveys for DATs, eluates, antibody titers, red cell antigen typing, ABO subgrouping, fetal cell detection (fetal cell screen portion only), and the comprehensive Transfusion Medicine survey, electronic crossmatch survey, and Transfusion Medicine automated survey as well as the expanded Transfusion Medicine exercises. PT testing for the hemoglobin S sickle screen is shared with hematology. Hematology submits their results to CAP and then the Blood Bank performs the testing. Once results from CAP are given to hematology they are shared with Blood Bank for evaluation of acceptability. Acceptability parameters are defined by this policy and are in accordance with the CFR (see details of the CFR below).
* The *Proficiency Testing Survey Process* is a global lab policy that explains acceptability criteria and follow up actions for failed PT testing. The policy also lists guidelines for follow up of unacceptable results including review of original testing paperwork, review of relevant QC performed before and after the failed testing, retesting of the sample, and discussion with the staff performing the testing. A formal response is required by CAP for any failed tests. CAP accesses the acceptability of the investigation and corrective action. When all reviews of critique/evaluation have been completed, Blood Bank will retain a copy and return the original to the Accreditation office. Timely review of PT evaluations ensure that any unsuccessful scores are investigated and corrective actions are completed well in advance of the next PT challenge.
* 42 CFR 493.1236 **Standard: Evaluation of proficiency testing performance.**

1. The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

* Subpart H describes acceptability of score of responses to the PT testing for ABO group and D typing, unexpected antibody detection, compatibility testing, and antibody identification. It also describes acceptable course of action in the event of failure to obtain an acceptable score.
* See BB Leadership for Subpart H if interested.

1. The laboratory must verify the accuracy of the following:
   1. Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.
   2. Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return of results).
2. At least twice annually, the laboratory must verify the accuracy of the following:
   1. Any test or procedure it performs that is not included in subpart I of this part.
   2. (2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.
3. All proficiency testing evaluations and verification activities must be documented.

* 42 CFR 49.1236 refers to the Code of Federal Regulations, Title 42 which applies to public health. Blood Bank is bound to regulations in Title 42 as well as Title 21 Food and Drugs.
  + - 1. **Proficiency Testing for Facilities not Subject to US Regulation**

Facilities not subject to US regulation shall participate in an external proficiency testing program, if available, for each analyte.

* + This standard does not apply as the Blood Bank is subject to US regulation.
    - * 1. When an external proficiency testing program is not available, there shall be a system for determining the accuracy and reliability of test results.
        2. Proficiency testing shall include comparison of test results from an outside laboratory.

**5.1.3 Quality Control**

A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods perform as expected. Chapter 9, Process Improvement Through Corrective and Preventive Action, applies.

**5.1.3.1** The validity of test results and methods and the acceptability of products or services provided shall be evaluated when quality control failures occur.

**5.1.3.2** Quality control failures shall be investigated before release of test results, products, or services.

* + Transfusion Services QAQC policy area in PolicyStat contains 31 policies that detail Blood Bank’s quality control/ quality assurance of reagents, equipment, and methods. All reagent and equipment quality control is described within these policies as well as follow up actions for failed quality control and preventive maintenance. BB Leadership is notified of any failures. In most instances of failure, BB Leadership determines follow up actions. Reagents that fail quality control are immediately removed from use and quarantined if necessary. Equipment that fails quality control/preventive maintenance is also immediately taken out of use.

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.