AABB Standards volume 3

In the previous standards chat, we discussed how the *Quality Program* and *Internal Audits* lay the groundwork for improving and assessing the Blood Bank. In this chat we will discuss the effect that AABB Standards have on our policies and procedures.

**1.3** **Policies, Processes and Procedures**

* Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these BB/TS Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.
  + Per AABB Standards, we even have a policy dictating how a policy/procedure is created and changed. *Policy and Procedure Creation/Revision Procedure*
    - Our Blood Bank SOPs may be constrained further by Lab-wide policies such as the *Policy and Procedure Creation/Revision-Global*.
    - If the global policy has a requirement, we must also follow that requirement, however, our Blood Bank specific policies are often more specific and specialized than the comparable global policies.
  + SOPs are to be considered written instructions from the BB Medical Director. This is especially important since Dr. Treml is legally responsible for the Blood Bank (as discussed in vol 1).
  + Did you know? When a revision is implemented in a procedure, all prior versions of the SOP are saved in Policystat!

**1.3.1** The medical director shall approve all medical and technical policies, processes, and procedures.

* \*42 CFR 493.1251(b)
  + This is the first AABB Standard to list an applicable federal guideline. The CFR guideline listed above is a detailed list of what a procedure manual should consist of, such as: control procedures, limitations of the methodology, pertinent literature references, and more.
  + Per the *Policy and Procedure Creation/Revision Procedure* policy, the Blood Bank Manager and Medical Director must approve every new policy or procedure which is then given an immediate effective date.
* It is vital that our procedure manuals are kept current, therefore all policies, training materials and downtime forms are required to be reviewed by Chris on a biennial basis.

**1.3.2** Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and preapproval by the medical director. Chapter 7, Deviations, Nonconformances, and Adverse Events, applies.

* + This standard may be more familiar as we frequently access the *Exceptions to Policies, Processes, and Procedures* policy in our day-to-day in the Blood Bank.
  + To accommodate this standard, the Exception to Policy Process or Procedure form was created and is used to document any situation that the Medical Director deems an exception is required.
  + A justification must be included on every form, and must be retained for a minimum of 10 years.

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