AABB Standards volume 9

In the previous standards chat, we discussed equipment and how new equipment and new processes are evaluated. In this chat we will discuss assessments both internal and external and the follow up actions taken based on the results of the assessments.

**8.0 Assessments: Internal and External**

* The BB/TS shall have policies, processes, and procedures to ensure that internal and external assessments of operations and quality systems are scheduled and conducted.
* The *Quality Management Manual* policy outlines external audits performed for the laboratory. These external audits may include: CAP (performed every two years), AABB, FDA, JC, CLIA, OSHA, State of WI DHHS, DOT, and FAA. They are formally planned, organized, and conducted by qualified personnel at a pre-defined frequency. This policy also states that internal, peer assessments are performed every other year to ensure quality and compliance with company policy.
  + Lab-wide inspections are coordinated by the Regulatory Compliance Manager in conjunction with department leaders.
  + Interim inspections, using the inspecting agency’s checklist, are conducted to maintain inspection readiness. Any findings from these inspections, along with a corrective action plan and timeline, are submitted to the Regulatory Compliance Manager who will follow up with the department to ensure completion of corrective action prior to inspection.
  + During inspection a similar process is followed. The Regulatory Compliance Manager will submit corrective action responses to the inspecting agency. Departmental leaders monitor the effectiveness of the corrective action using evidence based auditing techniques.
* The Transfusion Services policy *Internal Audits* policy describes our process for internal quality audits. Audits are performed to assess compliance with applicable regulations, standards, current Good Manufacturing Practices, and WDL policies and procedures.
* *Internal Audits* states that audits will define the auditor, the purpose of the audit, the scope of the audit, observations, and audit findings.

**8.1 Management of Assessment Results**

* The results of internal and external assessments shall be reviewed by personnel having responsibility for the area being assessed.
* The *Quality Management Manual* policy states that the results of internal and external audits are communicated to management. Action plans and effectiveness monitoring are carried out on audit findings to improve processes.
* BB Leadership is responsible for corrective actions resulting from our internal audits and external assessments. Corrective actions may include updates to policies or procedures, staff education, or competency testing. Follow up actions are used to monitor the effectiveness of BB Leadership’s corrective actions.
* Audit files are maintained form a minimum of 10 years.

**8.1.1** When corrective action is taken, it shall be developed, implemented, and evaluated in accordance with Chapter 9, Process Improvement Through Corrective Action.

* + Corrective actions include an investigative process to determine the underlying cause of the problem. Changes to processes are documented and tested for effectiveness.
  + BB Leadership or other department Leadership will reply to the audit with corrective action to each critical, major, or minor finding.

**8.1.2** The results of internal and external assessments and associated corrective and preventive actions shall be reviewed by executive management.

* Per policy, the Medical Director, or designee, reviews and evaluates the corrective action response to internal audits. If the response is deemed unacceptable, the appropriate leadership team will determine an acceptable corrective action.
* Once the corrective action response is acceptable, the Manager will:

1. Assemble the contents of the audit file, mark the audit closed, and file the audit file appropriately.

2. Reschedule an audit to repeat in an appropriate amount of time, to determine if the corrective actions taken were appropriate.

* Section directors and Medical Director review and approve a written corrective action plan resulting from external assessment findings.

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.