CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION K - QUALITY ASSURANCE

Current (13th edition, relevant part only)
K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA Program.

K1.100 Basic Elements
…

8) Documentation of formal conclusion of all *Accident*, *Error*, *Complaint*, *Adverse Outcome,* and *Recall* incidents;

…

(with amendments, relevant part only)
K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA Program.

K1.100 Basic Elements
…

8) Documentation of formal conclusion of all *Accident*, *Error*, *Complaint*, *Adverse Outcome,* and ~~*Recall*~~ *Correction or Removal* incidents;

…

(as amended)
K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA Program.

K1.100 Basic Elements

QA programs shall include, at a minimum:

1) Designation and management of *Quality Control* functions, including:

   a) Environmental monitoring at designated intervals;

   b) Performance and documentation in maintenance records or logs of periodic equipment and facility inspections;

   c) Review of equipment monitoring records for maintenance within specified *Tolerance Limits,* and reviewing records of other equipment or *Processing* functions that have specified *Tolerance Limits*;

d) Inspection and monitoring *In-Process Control* results, including collection and testing of representative samples;

e) Performing qualification of reagents, supplies, materials, or equipment when deemed *Critical* or applicable; and

f) Monitoring laboratory performance, if applicable.

2) *Process Validation Studies* are performed where the results of a process cannot be fully verified by subsequent inspection and test. Each tissue bank shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each tissue bank shall ensure that validated processes are performed by qualified individual(s). For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented. When changes or process deviations occur, the tissue bank shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented;

3) *Equipment Qualification Studies* are performed as necessary;

4) Purchasing controls are established;

5) Procedures are established for implementing corrective and preventive action is taken when appropriate. The procedures shall include requirements for:

a) Analyzing processes, work operations, concessions, quality audit reports, quality records, errors, accidents, complaints, returns, and other sources of quality data to identify existing and potential causes of nonconforming tissue, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

b) Investigating the cause of nonconformities relating to tissue, processes, and the quality system;

c) Identifying the action(s) needed to correct and prevent recurrence of quality problems;

d) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the *Finished Tissue*;

e) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f) Ensuring that information related to quality problems is disseminated to those directly responsible for assuring the quality of *Finished Tissue* or the prevention of such problems; and

g) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review;

6) Review and approval of donor screening, *Informed Consent* or *Authorization*, *Recovery* or *Collection*, and *Processing* records prior to release of tissue for transplantation;

7) Performance of audit procedures;

8) Documentation of formal conclusion of all *Accident*, *Error*, *Complaint*, *Adverse Outcome,* and *Correction* or *Removal* incidents;

9) Maintenance of documentation including, but not limited to:

    a) Master copy of current *SOPM*s;

    b) For those authorized to perform or review tasks, records of names, signatures, initials or identification codes and inclusive dates of employment shall be maintained (e.g., by Human Resources, Quality Assurance, or by department);

    c) Reports and conclusions of process *Validation* and *Equipment Qualification Studies*;

    d) Records of supply and reagent acceptance or rejection;

    e) Archived documents; and

    f) Master lists of preprinted labels.

10) Evaluation of training of personnel and, where possible, the *Competency* of personnel, and requiring that staff are appropriately oriented and trained concerning any modifications to the *SOPM*;

11) Maintenance of labeling controls, including all brochures, pamphlets, and promotional materials; and

12) A process for sharing information with other *Tissue Banks* that are known to have recovered and/or received tissue from the same donor.

Publication date: April 6, 2015 (AATB Bulletin No. 15-8)
Effective date: October 6, 2015 (in 6 months)