CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION J - GENERAL OPERATIONS

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

Current (13th edition, relevant parts only)
J1.200 Contents

The *SOPM* shall specifically include, but shall not be limited to:

6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery*, *Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:
…

d) requiring notification of *Management with Executive Responsibility* of any *Recalls*, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);

e) for the *Recall* of tissue unacceptable for transplantation. (H5.000, L6.000 and M6.000);

…

(with amendments, relevant parts only)
J1.200 Contents

The *SOPM* shall specifically include, but shall not be limited to:

6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery*, *Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:
…

d~~e~~) ~~for the *Recall* of tissue unacceptable for transplantation~~ *for the performance of Corrections and Removals, if applicable, and/or the timely notification of affected parties regarding information related to tissue safety or regulatory requirements*. (H5.000, L6.000 and M6.000);

e~~d~~) requiring notification of *Management with Executive Responsibility* of any *Corrections or Removals* ~~*Recalls*~~, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);

…

(as amended)
J1.200 Contents

The SOPM shall specifically include, but shall not be limited to:

1) Donor policies and procedures, including *Informed Consent* or *Authorization*, donor suitability criteria, donor screening methods, time limits for tissue recovery, notification of confirmed positive test results, information sharing and, if applicable, reconstruction and final disposition of a deceased donor's body (D2.000, D3.000, D4.000 and D5.000);

2) *Tissue Collection*, *Recovery* and handling policies and procedures, including supplies and methods used in all aspects of the operation involving the assessment of the *Recovery Site*, *Recovery, Processing*, packaging, quarantine, labeling, storage, donor suitability review, and/or release of tissue (D5.000, D6.000 and Sections E, F and G);

3) Laboratory procedures for tests performed in-house, including establishment of appropriate specifications, standards, and test procedures to assure that tissue is safe; and for contracted laboratory testing, policies and procedures defining which tests shall be performed and how test results shall be received, reviewed, interpreted, and managed (D4.350);

4) Policies and procedures for purchasing controls, order receipt, unit selection, final inspection of *Container,* and package and shipping of tissue, as well as criteria for returning and reissuing tissue (K1.300, M3.000, M4.000, M5.000 and Section H);

5) Record management policies and procedures designed to maintain *Traceability* and facilitate (if necessary) product *Recall* and *Recipient* notification by documentation of each step of tissue production from the point of *Collection*, *Recovery* and identification to final *Distribution* of the tissue (C1.000, C1.400, H5.000, L4.000, M6.000 and M7.000);

6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection*, *Recovery*, *Processing,* packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:

    a) for labeling of cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) (D4.350, D5.000 and Section G);

    b) for monitoring storage temperatures, for defining *Tolerance Limits*, and for describing what, when, and how corrective actions are to be taken for implementing emergency transfers and determining alternative storage and monitoring methods for tissue and reagents (E4.000, F4.200 and M2.000);

    c) the investigation, documentation, and reporting of *Accidents*, *Errors*, *Complaints*, and *Adverse Outcomes* (K4.000);

    d) for the performance of *Corrections* and *Removals*, if applicable, and/or the timely notification of affected parties regarding information related to tissue safety or regulatory requirements. (H5.000, L6.000 and M6.000);

e) requiring notification of *Management with Executive Responsibility* of any *Corrections* or *Removals*, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);

f) that establish which supplies, reagents, materials and equipment are considered *Critical* (D5.100, E1.300, J5.100);

g) and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);

h) describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of *Containers*, packaging materials, labels, reagents, and supplies (D5.000, E1.000, E2.000, J5.500 and Section G); and

i) for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (Section K).

7) Policies and procedures for assigning expiration dates (E4.200, H3.300 and K1.200);

8) Policies and procedures for handling requests for research tissue (H2.000);

9) Procedures for disposal of medical waste and other hazardous waste (J3.000);

10) Emergency and safety policies and procedures, including reporting of staff injuries and potential exposure to blood-borne pathogens (J3.000);

11) Procedures assigning responsibility for the sanitation of facilities and describing the cleaning schedules, methods, equipment and materials to be used (J4.000);

12) Policies and procedures describing manual methods for tissue banking activities in the event of electronic or equipment malfunction (K6.000);

13) Policies and procedures describing requirements of training programs for technical and *QA* staff (J2.000); and

14) Policies and procedures for identification and control of procedures and forms including requirements (J1.100, J1.400).

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