

# CHANGES TO AATB STANDARDS FOR TISSUE BANKING

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## 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:
  - a) 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);
  - b) the investigation, documentation, and reporting of *Accidents, Errors, Complaints*, and *Adverse Outcomes* (K4.000);
  - c) requiring notification of *Management with Executive Responsibility* of any *Recalls*, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);
  - d) for the *Recall* of tissue unacceptable for transplantation (H5.000, L6.000 and M6.000);
  - e) that establish which supplies, reagents, materials and equipment are considered *Critical* (D5.100, E1.300, J5.100);
  - f) and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);
  - g) 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
  - h) for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (Section K).

*(with amendments, relevant parts only)*

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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);

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*(as amended, relevant parts only)*

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