CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION J - GENERAL OPERATIONS

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

J1.200 Contents

Current (13th edition)
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:

   a) Policies and procedures 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) Policies and procedures for the investigation, documentation, and reporting of *Accidents*, *Errors*, *Complaints*, and *Adverse Outcomes* (K4.000);

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

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

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

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

   g) Policies and procedures 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)
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) ~~Policies and procedures~~ 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) ~~Policies and procedures~~ for the investigation, documentation, and reporting of *Accidents*, *Errors*, *Complaints*, and *Adverse Outcomes* (K4.000);

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

   d) ~~Policies and procedures~~ 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);

   ~~e~~f) ~~Policies, procedures~~ and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);

   ~~f~~g) ~~Policies and procedures~~ 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

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

...

(as amended)
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) for 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).

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