Changes to Standards - Identification and Control of Procedures and Forms

SECTION J - GENERAL OPERATIONS

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

Current (13th edition)
J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

J1.100 Purpose and Design
Each tissue bank shall develop written detailed policies and procedures in a standardized format, which shall be collected into a Standard Operating Procedures Manual (*SOPM*). These shall be available at all locations for which they are designated, used, or otherwise necessary, and shall be utilized to ensure that all tissue released for transplantation is in compliance to these *Standards* and applicable laws or regulations.

(with amendments)
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J1.100 Identification and Control

Policies and procedures shall be established for identification and control of procedures and forms including requirements for:

1) *approval for adequacy prior to use;*
2) *the review, revision and re-approval as needed;*
3) *identification of the current revision status and of changes to previous revisions ;*
4) *distribution to points of use (i.e., all locations where access to procedures is needed);*
5) *legibility and ease of identification; and*
6) *prevention of the unintended use of obsolete documents and suitable identification controls if obsolete documents are retained for any reason.*

(as amended)
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SECTION J - GENERAL OPERATIONS

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

Current (13th edition)
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 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).

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); and

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

J1.400 Modifications

The *SOPM* shall be updated to reflect modifications or changes, and shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

Prior to implementation, each modification shall be approved by appropriate individuals or the Medical Director, as dictated by content, and training shall be provided to pertinent staff. Implementation dates shall be recorded for all affected procedures. Obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.

(with amendments, relevant parts only)
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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).

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