

CHANGES TO AATB STANDARDS FOR TISSUE BANKING

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)

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.

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)

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

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.

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.

Publication date: March 23, 2015 (AATB Bulletin No. 15-6)

Effective date: September 23, 2015 (in 6 months)