CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

D5.100 Reagents, Supplies, Materials, and Equipment

Current (13th edition)
D6.100 Reagents and General Supplies

All instruments, solutions, and supplies used to recover human tissue used for transplantation shall be *Sterile*, unless otherwise indicated. All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with tissues during tissue *Recovery* shall be properly cleaned, disinfected, and *Sterilized* between donor recoveries according to written procedures prepared to control the prevention of infectious disease contamination or *Cross-Contamination* by tissues. All reagents shall be used and stored in accordance with manufacturers' instructions.

(with amendments)
D6*5*.100 Reagents, ~~and General~~ Supplies, *Materials, and Equipment*

All Critical supplies, reagents, materials, and equipment approved for use for Recovery or Collection shall be identified and specifications (e.g., Sterile where applicable) documented A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, Lot number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of the staff performing the inspection. The tissue bank shall maintain records of all supplies, reagents, materials, and equipment from receipt through period of time used..

~~All instruments, solutions, and supplies used to recover human tissue used for transplantation shall be *Sterile*, unless otherwise indicated.~~ All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with tissue~~s during tissue~~ shall be properly cleaned, disinfected, and *Sterilized* ~~between~~ *prior to use for* ~~donor~~ *Recovery or Collection* according to written procedures ~~prepared to control the~~ prepared to prevent~~ion of infectious disease~~ contamination or *Cross-Contamination* ~~by tissues~~. *Records shall be maintained that document sterilization steps. All* reagents*, supplies, and materials* shall be used and stored in accordance with manufacturers' instructions.

(as amended)
All *Critical* supplies, reagents, materials, and equipment approved for use for *Recovery* or *Collection* shall be identified and specifications (e.g., *Sterile* where applicable) documented A record shall be made of all reagents, supplies, and materials following receipt including, as applicable, the type, quantity, manufacturer, *Lot* number, date of receipt, and expiration date or manufacturing date (as applicable). Inspection shall be documented, including identification of the staff performing the inspection. The tissue bank shall maintain records of all supplies,

reagents, materials, and equipment from receipt through period of time used.

All non-disposable surgical instruments and parts of mechanical/electrical equipment which come in contact with tissue shall be properly cleaned, disinfected, and *Sterilized* prior to use for *Recovery* or *Collection* according to written procedures prepared to prevent contamination or *Cross-Contamination*. Records shall be maintained that document sterilization steps. All reagents, supplies, and materials shall be used and stored in accordance with manufacturers' instructions.

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