CHANGES TO AATB STANDARDS FOR TISSUE BANKING
14th Edition

SECTION E
PROCESSING AND STORAGE

Current (14th Edition)
E2.000 PROCESSING

E2.400 Reagents, Supplies, Materials and Equipment
All *critical* supplies, reagents, materials, and equipment approved for use for *processing* and *preservation shall* be identified and specifications (e.g., *sterile* where applicable) documented. It is expected that the *tissue bank* has the ability to link all supplies, reagents, materials, and equipment to *tissue processed* over the period of time they were in use.

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 staff performing the inspection. All reagents, supplies, materials and equipment *shall* be used and stored in accordance with manufacturers' instructions.

All non-disposable surgical instruments and mechanical/electrical equipment used in *tissue processing shall* be cleaned, *decontaminated*, and, where applicable *sterilized,* between use for *tissue* from different *donors* according to written *procedures*. For non-disposable surgical instruments and mechanical/electrical equipment deemed *critical*, written *procedures must* be prepared and methods *shall* be *validated*, to prevent contamination or *cross-contamination* during *processing*.

With Amendments
E2.000 PROCESSING

E2.400 Reagents, Supplies, Materials and Equipment
All *critical* supplies, reagents, materials, and equipment approved for use for *processing* and *preservation shall* be identified and specifications (e.g., *sterile* where applicable) documented. It is expected that the *tissue bank* has the ability to link all supplies, reagents, materials, and equipment to *tissue processed* over the period of time they were in use.

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 staff performing the inspection. *Unless otherwise qualified/validated, a*~~A~~ll reagents, supplies, materials and equipment *shall* be used and stored in accordance with manufacturers' instructions.

All non-disposable surgical instruments and mechanical/electrical equipment used in *tissue processing shall* be cleaned, *decontaminated*, and, where applicable *sterilized,* between use for *tissue* from different *donors* according to written *procedures*. For non-disposable surgical instruments and mechanical/electrical equipment deemed *critical*, written *procedures must* be prepared and methods *shall* be *validated*, to prevent contamination or *cross-contamination* during *processing*. *Adequate controls must exist to prevent mix-ups between acceptable and unacceptable items.*

As Amended
E2.000 PROCESSING

E2.400 Reagents, Supplies, Materials and Equipment
All *critical* supplies, reagents, materials, and equipment approved for use for *processing* and *preservation shall* be identified and specifications (e.g., *sterile* where applicable) documented. It is expected that the *tissue bank* has the ability to link all supplies, reagents, materials, and equipment to *tissue processed* over the period of time they were in use.

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 staff performing the inspection. Unless otherwise *qualified/validated*, all reagents, supplies, materials and equipment *shall* be used and stored in accordance with manufacturers' instructions.

All non-disposable surgical instruments and mechanical/electrical equipment used in *tissue processing shall* be cleaned, *decontaminated*, and, where applicable *sterilized,* between use for *tissue* from different *donors* according to written *procedures*. For non-disposable surgical instruments and mechanical/electrical equipment deemed *critical*, written *procedures must* be prepared and methods *shall* be *validated*, to prevent contamination or *cross-contamination* during *processing*. Adequate controls *must* exist to prevent mix-ups between acceptable and unacceptable items.

Publication Date: November 30, 2017 (AATB Bulletin No. 17-14)
Effective Date: May 31, 2018 (6-month implementation period)