CHANGES TO AATB STANDARDS FOR TISSUE BANKING, 14TH EDITION
Effective May 31, 2018

SECTION A
GENERAL INFORMATION

Current (14th Edition)
A2.000 Definitions of Terms

QUARANTINE – The identification of *tissue* as not suitable for *transplantation*, including *tissue* that has not yet been characterized as being suitable for *transplantation*. Quarantine includes the *storage* of such *tissue* in an area clearly identified for such use, or other *procedures*, such as automated designation, to prevent the release of this *tissue* for *transplantation*. This also applies to reagents, supplies, materials and equipment pending approval for use or that has been determined to be nonconforming.

With Amendments
A2.000 Definitions of Terms

QUARANTINE – The identification of *tissue*, *reagents, supplies, materials and equipment* as not suitable for *use*, *or that has not yet been characterized as being suitable for use*. ~~*transplantation*, including *tissue* that has not yet been characterized as being suitable for *transplantation*. Quarantine includes the *storage* of such *tissue* in an area clearly identified for such use, or other *procedures*, such as automated designation, to prevent the release of this *tissue* for *transplantation*. This also applies to reagents, supplies, materials and equipment pending approval for use or that has been determined to be nonconforming.~~

As Amended
A2.000 Definitions of Terms

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Current (14th Edition)
A2.000 Definition of Terms

SKIN PREP - The application of antiseptic solution to decontaminate the *skin*. This is a continuous process that is performed without delay between steps; it does not include shaving hair, although this can be done if preferred. The manufacturer's written recommendations *must* be followed, including that the antiseptic solution *should* remain in place for the recommended contact time and be allowed to air dry completely before the surgical drapes are placed.

With Amendments
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SECTION D
AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY, COLLECTION, AND ACQUISITION

Current (14th Edition)
D5.000 RECOVERY, COLLECTION, AND ACQUISITION

D5.100 Reagents, Supplies, Materials, and Equipment
All *critical* supplies, reagents, materials, and equipment approved for use for *recovery, collection,* or *acquisition 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 reagents, supplies, materials and equipment *shall* be used and stored in accordance with manufacturers' instructions, unless qualified/*validated* for intended use or storage.

All non-disposable surgical instruments and parts of mechanical/ electrical equipment which come in contact with *tissue shall* be properly cleaned, *decontaminated*, and *sterilized* prior to use for *recovery, collection,* or *acquisition* 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 unless qualified/validated for intended use or storage.

With Amendments
D5.000 RECOVERY, COLLECTION, AND ACQUISITION

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As Amended
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Current (14th Edition)
D5.500 Recovery Environment

D5.520 Recovery Cleansing and Preparation

Environment:
An evaluation of the *recovery site must* be performed to identify potential sources of contamination (see Appendix IV). All working surfaces (e.g., back table, Mayo stand, recovery

table) used during *recovery must* be *decontaminated* using a bactericidal/antimicrobial agent. All cleansing and disinfecting events performed by *tissue bank* personnel *shall* be documented. For guidance, refer to Guideline for environmental cleaning in Guidelines for Perioperative Practice. Denver, CO: AORN, Inc. (current edition).

Technician:
Technician gowning, gloving, and movement *shall* be accomplished with the same diligence as used routinely for operative procedures. Aseptic technique *shall* be followed. For guidance, refer to AORN's Guideline for sterile technique (current edition). Persons performing the surgical *recovery shall* perform a surgical scrub or wash of their hands and forearms prior to *recovery.* For guidance, refer to AORN's for hand hygiene (current edition). A head cover, eye shields and mask *shall* be worn at the time of scrub, and a *Sterile* gown and gloves *shall* be donned after the scrub/wash. For guidance, refer to AORN's Guideline for surgical attire (current edition).

Donor:
Cleansing, preparing (i.e., *skin prep*), and draping the *skin shall* be accomplished with the same diligence as used routinely for operative procedures. Agents used *shall* be antimicrobial *skin* preparation products, as specified in the *SOPM*, and *shall* be used in accordance with manufacturers' guidelines/instructions. For guidance, refer to AORN's Guideline for preoperative patient skin antisepsis (current edition).

With Amendments
D5.500 Recovery Environment

D5.520 Recovery Cleansing and Preparation

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Current (14th Edition)
D6.000 STORAGE OF TISSUE

D6.100 Quarantine Areas
Quarantine tissue storage areas including *storage* areas within freezers, refrigerators or other *tissue storage* equipment, *shall* be physically separated and clearly labeled as "*quarantine*."

With Amendments
D6.000 STORAGE OF TISSUE

D6.100 Quarantine ~~Areas~~ *Controls*
~~*Quarantine tissue storage* areas including *storage* areas within freezers, refrigerators or other *tissue storage* equipment, *shall* be physically separated and clearly labeled as "*quarantine*."~~
Adequate controls must exist to prevent mix-ups, contamination, cross-contamination, and ensure tissue is identified as acceptable or unacceptable during all stages of recovery, receipt, storage, processing and distribution. If physical segregation is deemed unnecessary, justification must be

established, and must include a risk assessment and use of a validated electronic system. Considerations for the risk assessment shall include:

1) *potential severity of impact if controls fail to prevent mix-up, contamination or cross-contamination;*
2) *probability of failure to occur;*
3) *likelihood of identifying a failure before it reaches a customer;*
4) *existing controls to prevent failure; and*
5) *back-up plan for failure of validated electronic system.*

If physical segregation is deemed necessary, segregated areas must be appropriately labeled.

As Amended
D6.000 STORAGE OF TISSUES

D6.100 Quarantine Controls

Adequate controls *must* exist to prevent mix-ups, contamination, *cross-contamination*, and ensure *tissue* is identified as acceptable or unacceptable during all stages of *recovery*, receipt, *storage*, *processing* and *distribution*. If physical segregation is deemed unnecessary, justification *must* be established, and *must* include a risk assessment and use of a *validated electronic system*. Considerations for the risk assessment *shall* include:

1) potential severity of impact if controls fail to prevent mix-up, contamination or *cross-contamination*;
2) probability of failure to occur;
3) likelihood of identifying a failure before it reaches a customer;
4) existing controls to prevent failure; and
5) back-up plan for failure of *validated electronic system*.

If physical segregation is deemed necessary, segregated areas *must* be appropriately labeled.

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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.

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As Amended

E2.000 PROCESSING

E2.400 Reagents, Supplies, Materials and Equipment

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Current (14th Edition)
E3.000 STORAGE
E3.100 Quarantine

E3.110 Quarantine Areas
Quarantine tissue storage areas including *storage* areas within freezers, refrigerators or other *tissue storage* units, *shall* be physically separated and clearly *labeled* to distinguish *quarantine tissues* from *tissues* not suitable for *transplant* and from *tissues* available for *distribution*.

With Amendments
E3.000 STORAGE
E3.100 Quarantine

E3.110 Quarantine ~~Areas~~ Controls
Refer to D6.100 for requirements related to quarantine controls. ~~*Quarantine tissue storage* areas including *storage* areas within freezers, refrigerators or other *tissue storage* units, *shall* be physically separated and clearly *labeled* to distinguish *quarantine tissues* from *tissues* not suitable for *transplant* and from *tissues* available for *distribution*.~~

As Amended
E3.000 STORAGE
E3.100 Quarantine

E3.110 Quarantine Controls
Refer to D6.100 for requirements related to *quarantine* controls.

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Current (14th Edition)
E3.000 STORAGE

E3.200 Segregation of Tissue
The *SOPM must* address whether the segregation of *tissue* during *storage* is indicated and how it will be appropriately segregated to avoid contamination, *cross-contamination* and mix-ups.

Except for *reproductive tissue*, considerations for assessment of risk include, where applicable:

1) *donor* infectious disease test results are unavailable or this testing will not be performed;

2) the intended use of the *tissue* is primarily for *transplantation* or is restricted to research or education;

3) *autologous tissue* is segregated from *allogeneic tissue*;

4) the *donor* has been determined to be ineligible;

5) the ability of *packaging* and *labeling* to withstand *storage* temperatures; and/or

6) the ability to *decontaminate storage* equipment or the *storage* area should an *accident* occur.

Appropriate segregation *must* include considerations above and *storage must* be in clearly defined and labeled areas (shelves or compartments) of the *storage* equipment or *storage* area.

(R) *Cryopreserved reproductive tissues* from untested *client depositors shall* be *stored* in a physically separate area clearly defined from those of tested *client depositors*. *Tissues* from *client depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, or HBsAg or any other test excluding CMV without subsequent negative confirmatory testing as approved by the *reproductive tissue bank's* Medical Director *shall* be *stored* in a physically separated area clearly identified from *tissue* of seronegative *client depositors*. See F2.200 for documentation required for release.

With Amendments

E3.000 STORAGE

E3.200 Segregation of Tissue

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~~4) the *donor* has been determined to be ineligible;~~

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~~6) the ability to *decontaminate storage* equipment or the *storage* area should an *accident* occur.~~

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As Amended
E3.000 STORAGE

E3.200 Segregation of Tissue
(R) *Cryopreserved reproductive tissues* from untested *client depositors shall* be *stored* in a physically separate area clearly defined from those of tested *client depositors*. *Tissues* from *client depositors* known to be reactive on tests for anti-HIV-1, anti-HIV-2, anti-HCV, or HBsAg or any other test excluding CMV without subsequent negative confirmatory testing as approved by the *reproductive tissue bank's* Medical Director *shall* be *stored* in a physically separated area clearly identified from *tissue* of seronegative *client depositors*. See F2.200 for documentation required for release.

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CHANGES TO AATB STANDARDS FOR TISSUE BANKING, 14TH EDITION
Effective March 3, 2018

SECTION A
GENERAL INFORMATION

Current (14th Edition)
A2.000 Definitions of Terms

QUALITY – The conformance of *tissue* or a process to pre-established specifications or standards.

With Amendments
A2.000 Definitions of Terms

QUALITY – ~~The~~ cConformance ~~of *tissue* or a process~~ to pre-established specifications, *attributes, requirements, regulations, and/or* standards.

As Amended
A2.000 Definitions of Terms

QUALITY – Conformance to pre-established specifications, attributes, requirements, regulations, and/or standards.

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CHANGES TO AATB STANDARDS FOR TISSUE BANKING, 14TH EDITION
NEW STANDARDS
Effective March 3, 2018

SECTION B
GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK

B2.100 Management Responsibility

New Article

B2.160 Contingency Plan

The tissue establishment *shall* have a contingency plan in place for *tissue* that remains in inventory and *record* retention in the event of merger, acquisition or dissolution.

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

D1.000 GENERAL POLICIES

New Article

D1.300 Consideration for the Donor

A policy *shall* be established requiring the *donor* always be treated with dignity and respect.

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