

CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION B - GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

B1.000 GENERAL INSTITUTIONAL REQUIREMENTS

B1.500 Multi-Facility Tissue Banking

Current (13th edition)

B1.510 Written Agreements/Contracts

Each *Tissue Bank* shall have written agreements or contracts with all other organizations that perform or for whom they perform donor screening, donor acceptability, tissue *Recovery*, *Processing* or *Distribution* for their organization. Written agreements or contracts shall indicate the nature of the relationships, division of tasks performed, division of issues of liability, specific responsibilities of each party and a summary of the protocols and procedures relating to the services provided. The tissue bank shall maintain a copy of each such agreement, which shall be made available for review if requested by AATB inspectors.

- 1) A tissue bank that recovers tissue that is processed and/or distributed by another tissue bank shall be responsible for being in compliance with these *Standards* for all operations it performs. This includes, but is not limited to, the requirement to have a Medical Director (See B2.220 Responsibilities) and to share records (see D4.500 Information Sharing, and K1.100 Basic Elements of a Quality Assurance Program).
- 2) A tissue bank that processes tissue recovered and/or distributed by another tissue bank shall be responsible for being in compliance with these *Standards* for all operations it performs. The tissue *Processing* organization must bear the burden of proof, and document in writing, that operations performed by other organizations prior to the receipt of tissue for *Processing* were performed in a manner consistent with these *Standards* as well as the *Processing* tissue bank's requirements.
- 3) A tissue bank that distributes tissue recovered and/or processed by other tissue banks shall be responsible for being in compliance with AATB *Standards* for all operations it performs. The distributor must also bear the burden of proof, and document in writing, that operations performed by other organizations prior to its receipt of tissue for *Distribution* were performed in a manner consistent with AATB *Standards*.
- 4) A tissue bank that determines donor suitability shall develop and maintain policies and procedures that clearly describe donor records they deem relevant to their operations. Agreements must address how this information is to be communicated in a timely fashion and clearly define expectations and responsibilities of the appropriate entities.

(with amendments, relevant parts only)

B1.510 Written Agreements/Contracts

Each *Tissue Bank* shall have written agreements or contracts with all other organizations that perform or for whom they perform [*Authorization, Informed Consent*](#), donor screening, donor acceptability, tissue *Recovery, Processing* or *Distribution* for their organization. Written agreements or contracts shall indicate the nature of the relationships, division of tasks performed, division of issues of liability, specific responsibilities of each party and a summary of the protocols and procedures relating to the services provided. The tissue bank shall maintain a copy of each such agreement, which shall be made available for review if requested by AATB inspectors.

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5) *A tissue bank that provides another tissue bank with Critical supplies, reagents, materials, and/or equipment shall develop and maintain policies and procedures that clearly describe responsibilities for notification of changes and recalls, and both entities should report problems (e.g., defects). The tissue bank providing supplies containing labels is responsible for archiving and notification responsibilities described at standard G2.330.*

(as amended, relevant parts only)

B1.510 Written Agreements/Contracts

Each *Tissue Bank* shall have written agreements or contracts with all other organizations that perform or for whom they perform *Authorization, Informed Consent*, donor screening, donor acceptability, tissue *Recovery, Processing* or *Distribution* for their organization. Written agreements or contracts shall indicate the nature of the relationships, division of tasks performed, division of issues of liability, specific responsibilities of each party and a summary of the protocols and procedures relating to the services provided. The tissue bank shall maintain a copy of each such agreement, which shall be made available for review if requested by AATB inspectors.

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5) A tissue bank that provides another tissue bank with *Critical* supplies, reagents, materials, and/or equipment shall develop and maintain policies and procedures that clearly describe responsibilities for notification of changes and recalls, and both entities should report problems (e.g., defects). The tissue bank providing supplies containing labels is responsible for archiving and notification responsibilities described at standard G2.330.

Publication date: March 30, 2015 (AATB Bulletin No. 15-7)

Effective date: September 30, 2015 (in 6 months)