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SECTION B
GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK

B1.000 GENERAL INSTITUTIONAL REQUIREMENTS

B1.100 Purpose, Institutional Identity, and Affiliations

The purpose of the *tissue bank shall* be clearly formulated and documented. The *tissue bank shall* state whether it is a freestanding entity or part of an institution.

B1.200 Governing Body

The *tissue bank shall* have a Governing Body that *may* consist of a Board of Trustees, Board of Governors, Board of Directors or a designated responsible individual in whom policy- making authority resides, unless otherwise provided by the institution of which it is a part. A Board *shall* consist of individuals from various professions. This Board or designated individual *shall* determine the scope of activities to be pursued by the *tissue bank*.

The Governing Body *shall* designate one or more senior employees as *management with executive responsibility.* Issues of liability, ethical considerations, fiduciary responsibility, and compliance with applicable laws and regulations, these *Standards*, and the *tissue bank's SOPM shall* be the responsibility of the Governing Body and *management with executive responsibility.*

B1.300 Medical/Scientific Support

A *tissue bank should* establish and maintain a mechanism to access medical, technical, and scientific advice as needed. Decisions *shall* be documented.

B1.400 Satellite Facilities

Satellite facilities shall be operated in accordance with the *tissue bank's SOPM*.

Current (14th Edition)
B1.500 Written Agreements/Contracts

Each *tissue bank shall* have written agreements or contracts with all other individuals or organizations that perform or for whom they perform tissue banking activities or services such as, but not limited to:

1) *donor* referral;

2) *authorization;*

3) *informed consent*;

4) *donor eligibility assessment*;

5) *recovery, collection,* and/or *acquisition*;

6) post-delivery functions;

7) laboratory services (see exception at B1.600);

8) testing services;

9) *processing*;

10) *storage*;

11) *tissue* release;

12) *distribution*; and/or

13) *consignment.*

For additional controls regarding testing services and other services performed by others, see the *series of standards* at K1.300.

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. Compliance with *Standards* by all parties *shall* be required and documented in a *quality agreement*. The following examples provide a few of these expectations:

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), to follow applicable standards in Section D and Appendix II, and to share records (see D4.300). A *tissue bank* that *recovers tissue* is not required to *audit* its contracted *tissue bank* processor(s).

   (BT) There *shall* be a written agreement/contract with the entity that performs post-delivery functions and/or *acquisition* on behalf of the *tissue bank*; or, if there is no written agreement or contract, there *must* be an attestation *record* from a *responsible person* that post-delivery protocols and *procedures* are followed.

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.

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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*. Any *records* necessary to demonstrate compliance *shall* be readily accessible to the *distributing tissue bank.*

4) A *tissue bank* that determines *donor* eligibility *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.

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 G2.330.

6) A *tissue bank* that *distributes tissue* for *transplantation shall* restrict *distribution* to entities described in *Standards* (see H1.100). If *tissue* is provided to a *tissue distribution intermediary*, the *tissue distribution intermediary shall* meet the requirements of Section M of these *Standards*.

If an AATB-accredited *tissue bank* obtains from and *processes tissue* for a *tissue bank* not accredited by the AATB that is located outside of the United States (U.S.), the requirement for compliance with *Standards* does not apply to the foreign *tissue bank* if the *processed tissues* will not be *distributed* within, or to, the U.S. All *tissues* imported from entities that do not follow AATB *Standards shall* be appropriately *quarantined* throughout import, *storage, processing*, and export. The AATB-accredited *tissue bank must verify* that the foreign *tissue bank* not accredited by the AATB complies with regulations of the governmental authority having jurisdiction in their country for the functions they perform (e.g., *informed consent*/*authorization*, *donor eligibility assessment*, *recovery*, *acquisition, donor* testing). Additionally, the *tissue bank* not accredited by the AATB *should* be *verified* to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's ''Safety of Human Cells, Tissues and Organs for Transplantation Regulations;'' the Directive (and Commission Directives) 2004/23/EC of the European Parliament and the Council; or, expectations as described in the World Health Organization's ''Aide Mémoires for Human Cells and Tissues for Transplantation.''

With Amendments

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Each *tissue bank shall* have written agreements or contracts with all other individuals or organizations that perform or for whom they perform tissue banking activities or services such as, but not limited to:

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For additional controls regarding testing services and other services performed by others, see the *series of standards* at K1.300.

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   (BT) There *shall* be a written agreement/contract with the entity that performs post-delivery functions and/or *acquisition* on behalf of the *tissue bank*; or, if there is no

written agreement or contract, there *must* be an attestation *record* from a *responsible person* that post-delivery protocols and *procedures* are followed.

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*. Any *records* necessary to demonstrate compliance *shall* be readily accessible to the *distributing tissue bank.*

4) A *tissue bank* that determines *donor* eligibility *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.

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 G2.330.

6) A *tissue bank* that *distributes tissue* for *transplantation shall* restrict *distribution* to entities described in *Standards* (see H1.100). If *tissue* is provided to a *tissue distribution intermediary*, the *tissue distribution intermediary shall* meet the requirements of Section M of these *Standards*.

If an AATB-accredited *tissue bank* obtains from and *processes tissue* for a *tissue bank* not accredited by the AATB that is located outside of the United States (U.S.), the requirement for compliance with *Standards* does not apply to the foreign *tissue bank* if the *processed tissues* will not be *distributed* within, or to, the U.S. All *tissues* imported from entities that do not follow AATB *Standards shall* be appropriately *quarantined* throughout import, *storage, processing*, and export. The AATB-accredited *tissue bank must verify* that the foreign *tissue bank* not accredited by the AATB complies with regulations of the governmental authority having jurisdiction in their country for the functions they perform (e.g., *informed consent/authorization*, *donor eligibility assessment*, *recovery*, *acquisition, donor* testing). Additionally, the *tissue bank* not accredited by the AATB *should* be *verified* to be in compliance with existing standards or guidelines, as appropriate. Examples of established standards include the current editions of: Health Canada's ''Safety of Human Cells, Tissues and Organs for Transplantation Regulations;'' the Directive (and Commission Directives) 2004/23/EC of the European Parliament and the Council; or, expectations as described in the

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As amended

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Announcement Date: January 31, 2019 (Bulletin 19-1)
Effective Date: July 31, 2019 (6-month implementation period)

B1.510 On-site Inspections

(Refers to any AATB accreditation inspection.)

A *tissue bank* will be inspected and accredited for the specific activity(ies) or service(s) that it performs. However, if the *tissue bank* participates jointly with other entities that provide *tissue banking* activities or services on their behalf, the accredited *tissue bank* is responsible for providing evidence of compliance to these *Standards* for all *tissue banking* activities or services performed by other entities on its behalf.

B1.520 Inspections/Audits of Other Facilities

(Refers to inspections/*audits* that an accredited *tissue bank must* perform for activities/services rendered by another entity.)

Before an entity performs any activity/service under contract, agreement or other arrangement, the accredited *tissue bank must* ensure that the entity will comply with applicable *Standards*, laws and regulations. Thereafter, the accredited *tissue bank* is responsible for *verifying*, at least biennially, that the activity(ies) or service(s) has/have been performed in conformance with applicable *Standards*, laws and regulations. This requirement does not apply to any other AATB-accredited entity. The *verification* of activities or services performed by others *shall* be documented (e.g., a paper *audit*, on-site *audit*, on-site inspections, etc.).

Regardless of whether the facility performing activities or services for others is accredited, it is the responsibility of the *tissue bank* receiving those activities/ services to periodically *verify* that *procedures* related to the activities/services are in compliance with these *Standards*, the written agreement/contract, and applicable laws and regulations. The inspection/*audit* plan, policies, and *procedures shall* be specified in the *SOPM*.

Documentation that an *audit*/inspection specific for activities or services performed *shall* be maintained by the *tissue bank*. Such documentation *shall* itemize all operational systems that were *verified* to determine compliance with these *Standards*, the agreement/contract and applicable laws and regulations. This itemization of the systems reviewed *shall* be provided to AATB on-site inspectors upon request. For an *audit* tool and requirements to be used for a partner performing *recovery* services, refer to Appendix V.

If, during the course of this contract, agreement, or other arrangement, information suggests that the entity may no longer be in compliance with such requirements, the accredited *tissue bank must* take steps to ensure compliance. If it is determined that the entity will not comply, the contract, agreement, or other arrangement *must* be terminated.

B1.600 Contracted and Non-contracted Laboratory Services for Donor Infectious Disease Testing

Tissue banks that contract laboratory services for donor infectious disease testing *shall* retain in their *records* the name and address of the contracted facility and documentation of the inclusive dates of the contract period. Proof of current laboratory licensure and accreditation *must* be maintained. Additionally, all requirements in the *series of standards* at K1.300 *shall* apply. *Tissue banks* that obtain *donor* infectious disease test results from non-contracted laboratory services (e.g., other *tissue banks*, organ procurement organizations) *shall* maintain the name, address, licensing and accreditation information for each laboratory from which test results are obtained for the purpose of *donor* eligibility or *tissue* suitability assessments. Appropriate *management with executive responsibility shall* ensure a *responsible person* understands the principles of bacteriological and/or infectious disease test *procedures* employed by a laboratory as well as the interpretation of results. *Records* of infectious disease laboratory results used to assess *donor* eligibility *shall* become part of the *donor record*.

NOTE: For international members that do not export *tissues* to the U.S., applicable requirements of the government/competent authority having jurisdiction apply regarding establishment registration, laboratory certification, test kit licensing/approval, and test run record retention.

The *tissue bank must* ensure (and maintain documentation of activities obtained by either paper *audit* or on-site *audit*) that a laboratory performing *donor* infectious disease testing for the *tissue bank* is:

1) registered with the FDA as a tissue establishment and lists 'testing' as a function;

2) using the appropriate FDA-licensed, approved, or cleared *donor* screening tests;

3) following manufacturers' instructions for these tests;

4) certified in accordance with the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by

the Centers for Medicare and Medicaid Services;

5) retaining *donor* infectious disease test run *records* for ten years; and

6) aware of the requirement of the *tissue bank* to comply with D4.240.

B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK

B2.100 Management Responsibility

B2.110 Quality Policy

Management with executive responsibility shall ensure the establishment of the *tissue bank's* policy and objectives for, and commitment to, *quality*, and *shall* ensure that the *quality policy* is understood, implemented, and maintained at all levels of the organization.

B2.120 Organization

Each *tissue bank shall establish* and maintain an adequate organizational structure to ensure that all *tissue banking* activities or services comply with the requirements of these *Standards*.

B2.121 Responsibilities and Authority

Each *tissue bank shall* establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting *quality*, and provide the independence and authority necessary to perform these tasks in accordance with these *Standards*. The *tissue bank shall* ensure that responsibilities and authorities are defined, documented and communicated within the *tissue bank*.

B2.122 Resources

The *tissue bank shall* have sufficient resources, including the assignment of trained personnel, for management, performance of work, and assessment activities to meet the requirements of these *Standards.*

B2.123 Management Representative

Management with executive responsibility shall appoint a member of management who, irrespective of other responsibilities, *shall* have established authority over and responsibility for ensuring that *quality system* requirements are effectively established and effectively maintained. The management representative *shall* periodically report on the performance of the *quality system* to *management with executive responsibility* for their review.

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B2.130 Management Review

Management with executive responsibility shall review the suitability and effectiveness of the *quality system* at defined intervals and with sufficient frequency according to established *procedures* to ensure that the *quality system* satisfies the requirements of these *Standards* and the *tissue bank's* established *quality policy* and objectives. The dates and results of *quality system* reviews *shall* be documented.

B2.140 Technical Policies and Procedures

Technical policies and *procedures* utilized in the operation of the *tissue bank must* be established and maintained. The *tissue bank may* adopt current standard *procedures*, such as those in a technical manual prepared by another organization, provided that the *tissue bank* has *verified* that the *procedures* are consistent with, and at least as stringent as, the requirements of these *Standards* and appropriate for operations.

B2.150 Quality Assurance Program

A *quality assurance (QA) program shall* be established and maintained to ensure that the entire operation is in conformity with the *tissue bank's SOPM*, these *Standards,* and applicable laws and regulations. A documented annual internal review or *audit* to ensure compliance *must* be performed.

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. (*Effective March 3, 2018)*

B2.200 Medical Director

Current (14th Edition)
B2.210 Qualifications

The *tissue bank shall* have a Medical Director who maintains a valid medical license from any state or U.S. territory (or for international members, the physician *must* maintain an equivalent medical license). He/she *should* have training and experience in evaluating and determining *donor* eligibility particularly with regard to infectious diseases or use a Medical Advisory Committee or consultants to assist in those areas.

With amendments
B2.210 Qualifications

The *tissue bank shall* have a Medical Director who maintains a valid medical license from any state or U.S. territory (or for international members, the physician *must*

maintain an equivalent medical license). He/she *should* have training and experience in evaluating and determining *donor* eligibility particularly with regard to infectious diseases or use a Medical Advisory Committee or consultants to assist in those areas. An AATB-accredited *tissue bank recovering tissue* for an AATB-accredited *processing tissue bank* may fulfil this requirement by securing a written agreement with the processing tissue bank that defines the responsibilities of the *processing tissue bank's* Medical Director to provide required oversight over *donor screening* and *donor testing operations conducted by the recovery tissue bank.*

As amended
B2.210 Qualifications

The *tissue bank shall* have a Medical Director who maintains a valid medical license from any state or U.S. territory (or for international members, the physician *must* maintain an equivalent medical license). He/she *should* have training and experience in evaluating and determining *donor* eligibility particularly with regard to infectious diseases or use a Medical Advisory Committee or consultants to assist in those areas. An AATB-accredited *tissue bank recovering tissue* for an AATB-accredited *processing tissue bank* may fulfil this requirement by securing a written agreement with the processing tissue bank that defines the responsibilities of the *processing tissue bank's* Medical Director to provide required oversight over *donor screening* and *donor testing operations conducted by the recovery tissue bank.*

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B2.220 Responsibilities

The Medical Director *shall* establish, review and approve all policies and *procedures* of a medical nature. See J1.300, J1.400, J1.600.

B2.221 Donor Eligibility Criteria

The Medical Director *shall* be responsible for establishing *donor* eligibility criteria. See the *series of standards* at D4.000 and Appendix II.

The *tissue bank's donor* eligibility criteria *may* be adopted from criteria used by another organization, provided that the Medical Director has *verified* the criteria are consistent with, and at least as stringent as, the requirements of these *Standards* and applicable laws and regulations.

When a *tissue bank* is responsible for determining *donor* eligibility, the Medical Director, or licensed physician designee, *shall* make a determination regarding the eligibility of each *donor* based on a comparison with predetermined *donor* criteria as established in the *SOPM*. This determination *must* occur prior to the release of *tissue* for *transplantation*. See Section F.

B2.222 Adverse Outcomes

The Medical Director *shall* establish policies and *procedures* regarding *adverse outcomes*. See K4.300.

B2.223 Positive Infectious Disease Test Results

The Medical Director *shall* be responsible for notifying appropriate parties of the availability of positive infectious disease test results, and for reporting positive test results when required, in accordance with D4.232.

B2.300 Technical Staff

B2.310 Qualifications

Staff *must* possess the educational background, experience, and training sufficient to assure assigned tasks will be performed in accordance with the *tissue bank's* established *procedures*. Staff training *shall* be documented in individual employee training files.

B2.320 Responsibilities

Staff *shall* be responsible for implementation of policies and *procedures* as established by the *tissue bank*. Duties of each staff member *shall* be described in written job descriptions. Staff *must* demonstrate *competency* in the operations to which they are assigned.

B2.400 Quality Assurance Program

B2.410 Staff Qualifications

A designated individual, generally familiar with, but not having performed, the specific work being reviewed, *shall* be responsible for each *quality* review.

B2.420 Staff Responsibilities

Quality assurance program personnel *shall* have responsibility for assuring compliance with the *SOPM* regulatory requirements. The individual responsible for the *quality* review *shall* have the responsibility and authority to approve or reject *tissue*, as well as discontinue *processing* and/or release of *tissue* when *deviations* from *SOPM* warrants. *Quality assurance* personnel *shall* be responsible for managing *audits*.