Accreditation Policies
for
Transplant Tissue Banks

March 30, 2016
# ACCREDITATION POLICIES FOR TRANSPLANT TISSUE BANKS

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American Association of Tissue Banks
Accreditation Policies for Transplant Tissue Banks

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The American Association of Tissue Banks’ (“AATB”, or “Association”) Accreditation Policies for Transplant Tissue Banks (“Accreditation Policies”) are specifically for tissue banks that provide human tissue for transplantation or transfer.

A tissue bank, reproductive tissue bank, tissue distribution intermediary, tissue dispensing service, or satellite facility as defined in the current edition of the AATB’s Standards for Tissue Banking (“AATB Standards”), that voluntarily agrees to abide by these Accreditation Policies is eligible to apply for AATB accreditation as a transplant tissue bank. For use in the Accreditation Policies, these entities are collectively referred to as a “tissue establishment.”

I. ACCREDITATION PROGRAM—GENERAL PROVISIONS

A. Definitions
Words that appear in italics (e.g., satellite facility, nonconformity, etc.) are defined at standard A2.000 Definitions of Terms in the AATB Standards.

As used throughout these Accreditation Policies, the word “including” means including but not limited to.

The following terms and definitions are not found in AATB Standards but apply to these Accreditation Policies and appear in italics and are capitalized:
1. Accreditation Application – required documentation, in a format directed by AATB, used to assess eligibility of a tissue establishment for institutional accreditation.

2. Owner - means any person who, directly or indirectly, (i) owns, controls or has the power to vote or sell, or direct the vote or sale of, 25 percent or more of any class of shares or ownership units of, or interests in, a tissue establishment, or (ii) otherwise has the power to control the actions, decisions, policies and/or management of a tissue establishment whether or not through ownership of securities.

3. Reportable Event - a major change in operations or the report to an authority of any contrary event, as described in Section V.
4. **Written Notification** – communication to the AATB on matters related to institutional accreditation submitted using the firm’s corporate letterhead, dated and signed by a *responsible person*, and sent electronically (i.e., by email) or by using a reputable nationwide courier service.

B. **Eligibility**
An eligible tissue establishment may submit an application for accreditation at any time. To be eligible, a tissue establishment must demonstrate that it has been in continuous compliance with AATB Standards for a minimum of six (6) months prior to the date of application for all tissue banking functions it performs. Additionally, the amount of activity for these functions may be considered by the Accreditation Committee in making a determination whether an adequate level of activity has been reached to support an inspection to evaluate compliance. Mock records may not be used to approximate actual activities.

All *satellite facilities* and their tissue banking functions:
- must be identified to AATB when a tissue establishment applies for accreditation or when reportable as a major change (refer to Section V. A. 2.);
- must be in compliance with the AATB Standards and these Accreditation Policies; and
- are subject to inspection.

When a tissue establishment has been determined by the AATB to be eligible, its application will be considered pursuant to the procedures described in Section VIII.

C. **Limitation of Assurances of Accreditation**
Awarding accreditation is intended to indicate that the general operation and procedures of the tissue establishment were found to be in compliance with the Association’s requirements for accreditation at the time of its review. Accreditation is not to be construed as reflecting or warranting that the accredited tissue establishment, in any or all instances, either before or after accreditation, has properly followed the AATB’s requirements at all times.

D. **Logo Use Privileges and Trademark Restrictions**
AATB accreditation confers the privilege to use the AATB Accredited Institution logo. It may be used only by an AATB-accredited tissue establishment in accordance with the Association’s current “Policy for the Use of Trademarks, Servicemarks and Certification Marks” and current “Policy on the Use of Internet Links to the Association’s Website.” Accreditation does not confer the right to use any other trademark of the Association, including its Corporate Logo.
The AATB does not authorize, and expressly prohibits, entities not accredited by the AATB from stating or implying, directly or indirectly, that they are AATB-accredited even if a tissue banking services (multi-facility tissue banking) agreement is in place. It is the responsibility of the accredited tissue establishment to include a clause to this effect in written agreements/contracts that such entities are prohibited from using AATB trademarks. For example, when a distributor receives tissue supplied by an AATB-accredited tissue bank, the distributor may not use any AATB trademark if the distributor is not accredited by AATB. For specific information, refer to AATB’s current “Policy for the Use of Trademarks, Servicemarks and Certification Marks.”

An accredited tissue establishment that desires a *satellite facility* to be shown in the results of an "Accredited Bank" search available to the public on the AATB website must submit a separate and complete application for accreditation for such a site, and the site will be inspected and considered separately for accreditation. Any and each claim of AATB accreditation by a *satellite facility* that has not separately applied for and been granted AATB accreditation must be linked prominently to the parent institution's AATB accreditation.

E. Certificate of Accreditation

Upon a final decision to accredit, one certificate of accreditation will be issued to the tissue establishment. The certificate will indicate the following:

- accreditation approval date;
- accreditation expiration date;
- the tissue types and tissue banking activities for which accreditation is awarded (refer to Section II. E.); and
- the tissue establishment’s name and its primary address such as city and state (or similar identifier if outside of the United States).

An accredited tissue establishment’s *satellite facility(ies)* will be identified by name and address in a formal letter that accompanies the certificate.

F. Agreement with Requirements

By accepting AATB accreditation, the tissue establishment agrees to comply with all accreditation requirements, including current AATB Standards.

II. REQUIRED ELEMENTS

A. Compliance Requirements

AATB accreditation requires compliance with these Accreditation Policies and current AATB Standards, including periodic, published changes and their
effective dates. On-site inspections may be performed to verify compliance and can occur at any time, with or without advance notification.

B. **Additional Compliance**
An accredited tissue establishment must also comply with the following additional requirements. Failure to meet any of these additional requirements will result in steps to suspend or withdraw accreditation. To maintain accredited status, the tissue establishment must:
- fully cooperate with and complete AATB-sanctioned surveys;
- tender payment to AATB of its annual maintenance fee before May 15 of each year;
- tender payment to AATB within forty-five (45) calendar days of an invoice related to a special inspection, a level B inspection, or an international inspection; and
- continue to perform tissue banking functions for which it is accredited.

To maintain continuous accreditation, a tissue establishment must submit a properly completed *Accreditation Application* at least nine (9) months before the current AATB accreditation expiration date.

C. **Good Faith Provisions and Ethical Considerations**
Each tissue establishment that seeks accreditation must engage in the accreditation process in good faith. Failure to participate in good faith, including, but not limited to, falsification of documents, intentional or negligent provision of incorrect or incomplete information, withholding of requested information, or failure to cooperate in any inspection conducted in accordance with these policies, constitutes grounds for denial, suspension or withdrawal of accreditation. In addition, if any of these conditions is noted during an inspection, the inspection may be suspended or terminated immediately.

Accredited tissue establishments and/or applicants for accreditation may not present any false or misleading information, or omit material information, regarding their accreditation status.

Accredited tissue establishments agree to operate in accordance with AATB’s bylaws, objectives, rules, policies, standards and codes, including without limitation the ethical standards and codes, of the Association.

D. **Declaration**
Each applicant for accreditation will provide with its application, declarations, executed by the Owner(s), the Medical Director(s), and the person designated as the most senior position for tissue banking operations on a form prescribed
by the Association, in which the declarant will attest to the absence of criminal history and/or other designated factors that could render the applicant ineligible for accreditation. The Association reserves the right to also perform a criminal records history check regarding such persons. The Executive Committee of the Board of Governors will be informed of any declaration or records check that reflects any past or present criminal or otherwise potentially disqualifying conduct.

E. Inspections and Activities
AATB accreditation requires that a tissue establishment be inspected for compliance with requirements applicable to all tissue banking activities it performs. A tissue establishment may not elect to be inspected for certain tissue banking activities and not for other tissue banking activities it performs. Tissue banking activities include but are not limited to any of the following:

1. Donor
   a. eligibility assessment (screening and/or testing);
   b. authorization; and/or
   c. informed consent.

2. Tissue
   d. recovery and/or collection;
   e. processing;
   f. release or transfer;
   g. storage;
   h. distribution; and/or
   i. dispensing.

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

When two or more tissue establishments participate jointly in tissue banking activities and/or services (multi-facility tissue banking), accreditation awarded to one entity is independent of the other(s).
G. **Attendance at AATB Meetings/Workshops**
   As described immediately below, documentation of attendance must be provided with the *Accreditation Application* and may be requested by the inspector during an accreditation inspection. Such documentation must be in the form of the Certificate(s) of Attendance from the AATB. Continuing Medical Education units (CMEs) or Continuing Education Units (CEUs) from other sources or meetings do not qualify and may not be substituted. The AATB Executive Office is not responsible for producing previously issued CME or CEU Certificates of Attendance.
   1. **Medical Director**
      By the time of the inspection of an applicant for accreditation, a designated Medical Director for the applicant must have attended (in person) at least one AATB meeting/workshop within the three-year period prior to the expiration of accreditation if accredited, or within the previous three years for an initial applicant. At these AATB meetings, she/he must acquire a minimum of **10** CMEs or CEUs from the AATB.
   2. **Management with Executive Responsibility for Compliance Requirements**
      By the time of the inspection of an applicant for accreditation, a person designated as *management with executive responsibility* for the applicant who is responsible for compliance with AATB Standards and Accreditation Policies must attend (in person) at least one AATB meeting/workshop within the three-year period prior to the expiration of accreditation if accredited, or within the previous three years for an initial applicant. At these AATB meetings, she/he must acquire a minimum of **15** CMEs or CEUs from the AATB.

H. **Assignment of Representative to the Accredited Tissue Banks Council**
   An accredited tissue establishment must assign a representative to the Accredited Tissue Banks Council who is authorized and empowered to vote at meetings of the Council.

III. **Responsibilities**

A. **Board of Governors**
   The Board of Governors is responsible for the Association’s accreditation program, including these Accreditation Policies.

B. **Accreditation Committee**
   The Accreditation Committee:
   - develops accreditation requirements and submits recommendations for changes to these requirements to the Board of Governors for approval;
• reviews blinded inspection reports and responses, can make requests for more information, can order special inspections, and, by majority vote, makes decisions regarding accreditation; and

• acts on a request to review an application for accreditation to approve or reject it, as provided for in these Accreditation Policies (refer to Section I. B.).

A member may not vote or actively participate in accreditation discussions when a conflict of interest is identified.

C. Accreditation Committee Composition and Member Requirements
The appointments of the members and the Accreditation Committee Chair (“Chair”) are subject to the following requirements:
• the Chair must previously have served a full 2-year term as a member of the Accreditation Committee (“Committee”) and must be an Individual Member in good standing of the Association;

• each Committee member must have at least five years of experience in tissue banking (transplant) or anatomical donation and use (non-transplant) prior to appointment to the Committee;

• no Committee member may serve more than two consecutive 2-year terms;

• no more than two individuals from a tissue establishment and its satellites, if any, or from multiple tissue establishments operating under the same Owner may serve concurrently on the Committee;

• the Committee may have one, but not more than two, individual members from each council as provided in the Association’s Bylaws;

• the Chair appoints the Accreditation Committee Vice Chair (“Vice Chair”) from the Committee’s current membership and, as provided in the Association’s Bylaws, may appoint additional members to the Committee who must be Individual Members of the Association in good standing;

• each member is required annually to review, sign and date acknowledgement to the Association’s current AATB Policy Regarding Confidentiality Obligations and the current Policy Regarding Conflicts of Interest;

• the members shall meet in person or by conference call as needed to conduct the business of the Committee; and

• the Chair does not vote as a member of the Committee, except in the case
of a tie.

D. Non-voting Participants in Meetings of the Accreditation Committee
The Senior Vice President of Policy, the Accreditation Manager, the CAPA Analyst, the Accreditation Coordinator, and contracted inspectors, are non-voting participants in meetings of the Committee.

IV. IMPARTIALITY, CONFIDENTIALITY AND DISCLOSURE

A. Impartiality and Confidentiality
To maintain impartiality and confidentiality, all materials submitted to the Committee will have identifying information redacted or otherwise blinded. AATB will treat all information and documents regarding applicants seeking accreditation and accredited tissue establishments, according to the AATB Policy Regarding Confidentiality Obligations.

Committee members, including the Chair, will receive information only in blinded form. Un-blinded information is available only to the AATB Executive Office staff, contracted inspectors, and the Hearing Panel, who shall treat all information as confidential, according to the AATB Policy Regarding Confidentiality Obligations.

B. Disclosure
Information obtained as a result of the accreditation process will be maintained as confidential and will not be released by the AATB unless:
• the applicant has specifically authorized release of such information;

• the information is included in aggregate form or with other information so as to ensure that an individual tissue establishment cannot be identified;

• the information is already a matter of public record;

• release of the information is required by federal, state or local statute, regulation or other law, or court or administrative order; or

• release of the information pursuant to Section IV. B. 2. is deemed necessary.

In the event staff of the AATB Executive Office becomes aware of information relating to an accredited tissue establishment or an applicant for accreditation that presents a serious hazard to human health, the AATB will provide such information to responsible international, federal, state and/or local government agencies or authorities having jurisdiction over the tissue establishment.

AATB will identify accredited tissue establishments on its website (refer to Section VII. A.), and will respond to telephone inquiries regarding a tissue establishment’s current accreditation status by indicating only:
• whether the tissue establishment is accredited;
• for which activities the tissue establishment is accredited;
• the name and location of any satellite facility of the tissue establishment;
• the tissue establishment’s accreditation number; and
• the period(s) during which the tissue establishment has been accredited.

Except as noted above, AATB will not publicly disclose any information relating to an applicant or accredited tissue establishment without written consent from the person designated as management with executive responsibility most responsible for compliance with AATB Standards and Accreditation Policies.

C. Conflict of Interest
When the Chair is identified, by self-reporting or by the Accreditation Manager, as having a conflict of interest regarding review of documentation pertaining to a particular applicant, the Vice Chair will assume the Chair’s role and responsibilities for that applicant. If both the Chair and Vice Chair have a conflict of interest, the remaining members of the Accreditation Committee will select a member to serve as temporary Chair.

D. Inquiries Related to the Accreditation Process
All inquiries related to the accreditation process should be addressed to the Accreditation Coordinator, the CAPA Analyst, the Accreditation Manager, or the Senior Vice President of Policy. Contracted AATB inspectors and members of the Accreditation Committee may not answer inquiries related to accreditation applications, Accreditation Committee activities, or any topics related to an inspection.

V. REPORTABLE EVENTS
A. Required Reporting
Accredited tissue establishments and applicants must send Written Notification to the Accreditation Manager within fifteen (15) calendar days following a major change in operations or the report to an authority of any contrary event (collectively, “Reportable Events”). Failure to notify AATB of a Reportable Event may result in proceedings to suspend, withdraw or deny accreditation. All documents submitted related to Reportable Events must be submitted in their entirety and not redacted. Reportable Events become part of the accredited tissue establishment’s file at the AATB Executive Office and may be cause to hold a special inspection.

1. Contrary Events
Contrary events include, but are not limited to:
a. any international, federal, state or local action, including but not limited to:
   i. any order to recall tissue or to cease manufacturing;
   ii. receipt of an FDA Form 483 or state, local or international equivalent, and all responses until the citation(s) is(are) closed;
   iii. receipt of an FDA Warning Letter, Untitled Letter, or an equivalent warning by another federal, state, local or international authority, and all responses by the tissue establishment;
   iv. a change in licensure, permit, registration or similar listing with or authorization by a federal, state, local or international government authority related to tissue banking functions; and
   v. all submissions of FDA MedWatch reports or adverse reaction reports originating from another country involving finished tissue processed by or distributed by the accredited tissue establishment (or equivalent report if an accredited tissue establishment is located outside of the United States).

b. any voluntary recall, notification, or market withdrawal of finished tissue;

c. when provided, the FDA Establishment Inspection Report (EIR) or equivalent report from a state, local or international inspection authority;

d. any disease transmission confirmed to be caused by finished tissue processed and/or distributed by the accredited tissue establishment; and

e. any Biological Product Deviation Report (BPDR) submitted to the FDA or equivalent report submitted to an international government authority.

2. Major Changes
Major changes involving personnel or operations, including but not limited to:

   a. changes to key personnel, including:
      i. the Owner(s) and the person designated as the most senior position of authority for tissue banking
operations.

ii. the person designated as management with executive responsibility for compliance with AATB requirements including AATB Standards and Accreditation Policies;

iii. the Medical Director(s);

iv. the designated representative to the Accredited Tissue Banks Council; or

v. the person(s) designated to receive AATB Bulletins.

Note: A current curriculum vitae for management with executive responsibility most responsible for compliance with AATB Standards and Accreditation Policies and for the Medical Director must be submitted with the Written Notification of change.

b. change in the information contained in the declarations completed by the designated individuals identified in in Section II. D.;

c. change in scope of operations of the tissue establishment, including changes to the following services and/or activities:
   i. cessation or suspension for a period of six (6) months or longer of any tissue banking activities or services or of any tissue types handled, for which the tissue establishment is accredited;

   ii. addition of new, or resumption of previously provided, tissue banking activities or services, or tissue types handled, for which the tissue establishment is not accredited;

   iii. addition of tissue donation activities or services involving living donors when tissue only from deceased donors was previously handled; or

   iv. addition of tissue donation activities or services involving deceased donors when tissue only from living donors was previously handled.

d. change in facilities that affect tissue banking operations such as:
   i. expansion;
ii. relocation;

iii. renovation; or

iv. addition or removal of a satellite facility.

e. change in the Owner of or merger with, acquisition by or of, or transfer of control to or of, another tissue establishment;

f. subcontracting or assignment to a third party, whether or not accredited by AATB, of any tissue banking activities or services for which AATB accreditation applies;

g. legal name change or d/b/a (doing business as) designation; or

h. dissolution, bankruptcy, or insolvency of the tissue establishment.

B. Required Information

Written Notification sent pursuant to this section must be sufficiently detailed to explain the nature and extent of the contrary event and/or major change to enable AATB to determine the implications for the accredited tissue establishment’s current and future compliance with AATB accreditation requirements. All documents related to Reportable Events must be submitted in their entirety and not redacted.

The tissue establishment must provide the Accreditation Manager with copies of all pertinent documents relating to the major change. At the direction of the Accreditation Manager, an AATB Facilities Change Form must be completed.

The following information must be submitted regarding any recall, voluntary notification, or market withdrawal of finished tissue, whether a domestic or an international distribution:

- name of tissue establishment;

- type(s) of tissue;

- number of tissue donors involved;

- number of tissue grafts involved;

- identification of the consignees where each tissue graft was distributed;

- reason for taking action;

- nature (voluntary, mandatory); and
• description of corrective action(s) taken and planned to be taken.

C. Review of Reportable Events
The Senior Vice President of Policy, the Accreditation Manager, and the CAPA Analyst will review each notification of a contrary event or major change and consider whether a special inspection should be performed prior to expiration of the tissue establishment’s current accreditation (refer to Section IX.). If a special inspection is necessary, the Accreditation Manager may notify the tissue establishment in advance, or may schedule the inspection to take place without advance notification.

VI. EXPIRATION OF ACCREDITATION

A. Term of Accreditation
The term of accreditation, which is generally for a period of three years, begins and expires on the specific dates stated on the tissue establishment’s certificate of accreditation. Privileges of accreditation cease on the expiration date, unless AATB withdraws, suspends or extends accreditation prior to that date.

B. Re-accreditation Timelines
An accredited tissue establishment that wishes to apply for re-accreditation shall request an Accreditation Application from the Accreditation Manager or the Accreditation Coordinator. The properly completed application must be received by the Accreditation Coordinator no more than twelve (12) months and no fewer than nine (9) months before the tissue establishment’s accreditation expiration date.

1. Automatic Extension
An accredited tissue establishment that applies in a timely fashion for re-accreditation will not lose its current accredited status during the re-accreditation process as long as the tissue establishment meets published timelines, completes each stage of the process in good faith, and the delay does not adversely affect the safety of tissue recipients or tissue establishment employees.

2. Request for Extension
An accredited tissue establishment that applies for re-accreditation will not have its accreditation automatically extended beyond its current accreditation expiration date if it has not met published timelines. To extend accreditation in this circumstance, the tissue establishment must apply for an extension to the Accreditation Manager prior to the expiration date of the applicant’s current accreditation. Written Notification must include sufficient information including justification for an extension. A request for extension must be submitted prior to the expiration of accreditation. A request for extension may be granted by the Accreditation Manager, or may be evaluated on a case-by-case basis, in blinded fashion, by the Accreditation Committee. The
Committee may decide to award an extension or to proceed to suspend or withdraw accreditation. Refer to Section XI. An extension will be granted for the time period until a meeting of the Committee is convened.

3. Extension(s) and the Accreditation Expiration Date
Should an extension or extensions be granted as described above, and a decision to re-accredit results, the period of re-accreditation will run from the expiration date, not from the date of any extension(s).

4. Limit
An extension will not be granted for longer than sixty (60) calendar days at a time. In the case where a tissue establishment requires more than three extensions, information in blinded format will be sent to the Accreditation Committee for review. An additional extension will only be granted for the time period until a meeting of the Committee is convened.

C. Lapse of Accreditation
If a tissue establishment’s accreditation expires and it is not extended pursuant to these policies, the tissue establishment must immediately remove all indications of AATB accreditation from its forms, letters, signs, labeling and advertisements, and it may not state or imply, directly or indirectly, that it continues to be accredited by AATB.

VII. PUBLIC RECOGNITION

A. Publication
Approximately monthly, the database linked to the accredited bank search function on the AATB website will be updated to reflect changes in the status of accredited tissue establishments.

A satellite facility of an accredited tissue establishment may identify itself as being accredited by AATB as a satellite facility of its parent tissue establishment. However, a satellite facility is not searchable using the AATB-accredited tissue establishment search function, unless it is separately accredited.

B. Removal
The following circumstances will result in removal of the name of a tissue establishment from the accredited bank search function on the AATB website:
• accreditation has been suspended;

• accreditation has expired or has been withdrawn;

• accreditation has been denied; or
• all tissue banking operations have ceased.

C. Unauthorized Use of AATB Accreditation Status
A tissue establishment not currently accredited by AATB is forbidden from stating or implying, directly or indirectly, in its literature or elsewhere that it is accredited by AATB, that it has applied for AATB accreditation, or that it meets, complies with, follows or exceeds AATB accreditation requirements. Refer to the Association’s current “Policy for the Use of Trademarks, Servicemarks and Certification Marks.”

VIII. ACCREDITATION PROCESS

A. Application
Prior to submitting an application for accreditation, the tissue establishment must be determined to be eligible. Refer to Section I. B.
1. Internal Audit/Pre-Inspection Checklist
The applicant must properly complete the AATB Pre-Inspection Checklist (“Checklist”). The applicant must ensure that each response is complete and fully responsive in all respects. The applicant must cite the policy number and section and/or page number of the tissue establishment’s standard operating procedures manual (SOPM) or other official reference of the institution that corresponds to each AATB standard or policy referenced in the Checklist. This indicates that all AATB Standards and the Accreditation Policies have been addressed by the applicant and assists in performing the pre-inspection review. If an AATB standard does not apply, the tissue establishment should indicate “N/A” in the applicable entry on the Checklist. The Checklist is part of the Accreditation Application and is available from the Accreditation Coordinator or the Accreditation Manager.

2. Documentation Requirements
When steps required under Section VIII. A.1. have been completed, the applicant must submit the Checklist and a properly completed Accreditation Application. Information required by the Accreditation Application must be sent to the Accreditation Coordinator via compact disk or flash drive, and must be accompanied by payment of the non-refundable application fee. To ensure the integrity of these documents, it’s required that the package containing this confidential information be sent via carrier with return receipt or other package tracking capabilities.

3. Confirmation of Receipt of Application and Deadline
Within fourteen (14) calendar days of receipt of the Accreditation Application, the Accreditation Coordinator or the Accreditation Manager will send written acknowledgement of receipt. If additional
documentation or information is required, or if the application is incomplete or otherwise improperly completed, the Accreditation Coordinator or Accreditation Manager will request missing documents, information and/or corrections. The applicant’s corrected or properly completed information and/or documentation must be submitted to AATB bearing a postmark, or deposited with a nationally recognized courier for overnight delivery, within forty-five (45) calendar days of the date of the initial information request. Failure to do so may result in the applicant being required to submit a new application and application fee. If the applicant is required to submit a new application and fee, this requirement will be communicated in writing to the applicant.

4. Recent Action Against the Applicant
If an international, federal, state or local agency or other authority has initiated any formal or informal inquiry, investigation, proceeding or other action (“action”) against the applicant seeking AATB accreditation, or given notice of any of the foregoing, the applicant must immediately inform the Accreditation Manager by Written Notification. AATB will review the circumstances of the action in order to determine the impact of such matters on the tissue establishment’s Accreditation Application. Failure to disclose any such issue promptly as it occurs at any time during the accreditation process may be considered failure to participate in good faith and may result in denial of the Accreditation Application and the suspension, denial or withdrawal of accreditation.

B. Scheduling the On-site Inspection
Upon determination that the Accreditation Application is complete and acceptable, the Accreditation Coordinator or the Accreditation Manager will contact the applicant to schedule the on-site inspection. The Accreditation Manager will determine the length of time necessary for each on-site inspection based upon the size of the tissue establishment, inclusion of inspection of one or more satellite facilities, and the scope of the tissue establishment’s operations. Once the on-site inspection has begun, the actual duration may be adjusted after consultation between the inspector(s) and the Accreditation Manager. Costs, fees, and expenses relating to the on-site inspection will be charged to the applicant as follows:

• if the applicant is located within North America, the applicant will not be required to reimburse AATB for costs, fees, or expenses related to the inspection;

• if the applicant is located outside of North America, the applicant will be required to reimburse AATB for one-half of the inspector’s(s’) travel expenses (air travel, lodging, meals, ground transportation, etc.). An invoice for these expenses will be submitted to the applicant after the inspection; and
• if the applicant, whether located within or outside North America, voluntarily withdraws from, does not comply with, or does not complete the accreditation process after the commencement of any on-site inspection, the applicant will reimburse AATB for all costs, fees and expenses, including the inspector’s(s’) fees and travel expenses related to the inspection(s).

C. Scope of the On-site Inspection
The scope of the on-site accreditation inspection includes a quality systems audit approach to gain insight into control of the processes performed by the tissue establishment and how accreditation requirements are applied and satisfied. The inspection encompasses record reviews, interviews with staff, observation of activities, and tours of facilities. An Inspection Protocol Document that outlines general items to be made available during the inspection is sent to the applicant well ahead of the agreed date(s) of inspection. The inspector(s) must be granted access to all spaces, records and personnel pertinent to all tissue banking functions. The inspector(s) will conduct an opening conference and a closing conference. Appropriate management with executive responsibility as well as the Medical Director shall be available for the duration of the inspection.

D. Inspection report
The inspector’s report will identify and describe nonconformities.

Within fourteen (14) calendar days following the completion of the inspection, the inspector(s) will complete the inspection report and deliver it to the Accreditation Manager.

Within twenty-four (24) calendar days of receipt of the inspector’s(s’) inspection report, the Accreditation Manager or responsible designee will prepare the inspection report and deliver it in blinded format to the Accreditation Committee Chair. As applicable, refer to Section IV. A.

Following the Chair’s review, the inspection report will be sent in blinded format to the Accreditation Committee members for discussion at their next scheduled meeting.

E. Accreditation Committee Review and Decision
The Accreditation Committee will review and finalize the blinded inspection report and will take action by making a decision to recommend either immediate approval to accredit, designation as Level A, designation as Level B, or suspension, withdrawal or denial of accreditation. Whenever possible, inspectors will be present during the Accreditation Committee meetings and/or conference calls to answer questions about nonconformities or other issues pertinent to the Committee’s evaluation of a tissue establishment accreditation
Recognizing that there may be varying degrees of nonconformities noted during the inspection, as well as varying implications that may be drawn from the nonconformities, the Accreditation Committee will determine by majority vote which one of the following Committee actions is appropriate, and the process related to each decision is described as follows:

1. **Immediate Approval for Accreditation**

   Following a report of an on-site inspection that indicates that there are no nonconformities that require correction, and that the applicant is operating in compliance with AATB accreditation requirements, the Committee may decide that the accreditation application should be approved. The Accreditation Manager will transmit the decision and the final inspection report to the applicant.

2. **Level A - Requires Corrective Action(s)**

   Following a report of an on-site inspection that indicates that there are nonconformities, and that the applicant’s compliance with AATB accreditation requirements must be improved, the Committee may determine that the nonconformities can be corrected and documented without need for a re-inspection to verify compliance because the nonconformities do not appear to present a potential hazard to human health and the tissue establishment’s corrective action can be evaluated by reviewing paper documentation. The Accreditation Manager will provide to the applicant the final inspection report, which will be accompanied by a letter informing the applicant of the Committee’s decision for a Level A designation and describing all findings of non-compliance. If desired, the applicant may contact the Accreditation Manager or CAPA Analyst for clarification of any nonconformity(ies).

   When a Level A designation has been issued:

   a. within seven (7) calendar days of the date of the Committee’s decision, the Accreditation Manager will transmit the final inspection report to the applicant. The report will describe all nonconformities that require corrective action;

   b. within thirty (30) calendar days of applicant’s receipt of the final inspection report, the AATB must receive from the applicant sufficient documentation that demonstrates that corrections have been made to comply with AATB accreditation requirements. Failure to meet the deadline or to sufficiently demonstrate compliance will result in a decision to suspend, deny or withdraw accreditation, unless exceptional corrective action or preventive action circumstances exist to justify a one-time extension of this deadline;
c. upon receipt by the CAPA Analyst or Accreditation Manager, the applicant’s response will be examined for completeness and compliance with AATB accreditation requirements. If indicated, the CAPA Analyst or the Accreditation Manager will request more information. The requested information and/or documentation must be received by the CAPA Analyst from the applicant within fifteen (15) calendar days of the applicant’s receipt of the request. When it is determined that the application is complete, the CAPA Analyst will forward the blinded response to the Committee Chair or designee for review;

d. if indicated, the CAPA Analyst, the Accreditation Manager, and the Committee Chair or designee may request more information. The requested information and/or documentation must be received by the CAPA Analyst from the applicant within fifteen (15) calendar days of the applicant’s receipt of the request. When it is determined that the application is complete, the blinded response will be sent to the Committee for review at their next meeting;

e. if the Committee decides that the applicant has corrected the nonconformities, the Committee members will vote on whether to approve the tissue establishment’s accreditation; or

f. if the Committee decides that the applicant has not corrected the nonconformities, the Committee may, in its discretion:
   i. request that clarification and/or additional information be submitted by the applicant. The requested information and/or documentation must be received by the CAPA Analyst from the applicant within fifteen (15) calendar days of the applicant’s receipt of the request. If additional information is requested and it is not forthcoming before the deadline or it is not satisfactory, the Committee may determine that a Level B re-inspection be performed or may determine that accreditation should be suspended, denied or withdrawn. If accreditation is denied or withdrawn, the Committee may, in its discretion, impose a waiting period of up to one year (from the notice of denial) before re-application for accreditation is allowed; at that time, the tissue establishment must submit a new application. The applicant will reimburse AATB for all costs, fees and expenses, including the inspector’s(s’) fees and travel expenses related to a Level B inspection if a Level B inspection has been conducted;
ii. determine that a Level B re-inspection be performed. The applicant will reimburse AATB for all costs, fees and expenses, including the inspector’s(s’) fees and travel expenses related to a Level B inspection. After the Level B inspection is performed, the Level B process described below will be followed; or

iii. determine that accreditation be suspended, denied or withdrawn.

3. **Level B - Requires Corrective Action(s) and On-Site Re-Inspection**

Following an on-site inspection and an inspector’s report that indicates compliance with AATB accreditation requirements must be improved, the Committee may require corrective action(s) and an additional on-site inspection to determine compliance. The Accreditation Manager will notify the tissue establishment of the Committee’s decision for a Level B designation and that it requires a re-inspection. When a Level B designation has been issued:

a. the Accreditation Manager will transmit the final inspection report to the applicant. The report will describe all nonconformities that require corrective action;

b. within sixty (60) calendar days of receiving the inspection report, the AATB must receive from the applicant documentation that demonstrates correction of the noted nonconformities and compliance with AATB accreditation requirements. Failure to do so will result in a recommendation for suspension, denial or withdrawal of accreditation, unless exceptional circumstances exist to justify a one-time extension of the response period;

c. upon receipt by the CAPA Analyst or Accreditation Manager, the applicant’s response will be examined for completeness and compliance with AATB accreditation requirements. If additional information is required, the CAPA Analyst or the Accreditation Manager will send a request to the applicant. The requested information and/or documentation must be received by the CAPA Analyst from the applicant within fifteen (15) calendar days of the applicant’s receipt of the request. If the response appears to be complete, the Accreditation Manager will forward the blinded response to the Accreditation Committee Chair or designee for review;

d. if indicated, the Committee Chair or designee may request more information. If the Chair or designee determines that the applicant has not corrected the nonconformities, the following
may occur:

i. the Accreditation Committee Chair may request clarification and/or additional information, and the applicant’s response must be received by AATB within fifteen (15) calendar days of the applicant’s receipt of the request; and

ii. the tissue establishment’s response may be sent to the Accreditation Committee to determine if accreditation should be suspended, denied or withdrawn. If accreditation is denied or withdrawn, the Committee may, in its discretion, impose a waiting period of up to one year (from the notice of denial) before re-application for accreditation is allowed. At that time, the tissue establishment must submit a new application;

e. if the Chair or designee determines from the applicant’s submission that the applicant has corrected the *nonconformities*, the Level B on-site re-inspection will be scheduled. The applicant will reimburse AATB for all costs, fees and expenses, including the inspector’s fees and travel expenses related to a Level B inspection; and

i. following the Level B on-site re-inspection, the Committee will review the inspector’s findings. If the applicant has failed to demonstrate that *nonconformities* have been addressed, the Committee may:

   a) request additional information; or

   b) decide that accreditation be suspended, denied or withdrawn; and

ii. an applicant assigned a Level B status may receive only one additional on-site inspection. However, if the inspector notes new or additional findings as a result of the on-site Level B inspection, the Committee may assign a Level A or a Level B based on these new or additional findings. The Committee will then finalize this inspection report and it will be delivered to the applicant. The Committee may order another on-site inspection.

f. the Accreditation Committee may decide to either:

i. accredit;

ii. request further information;
iii. suspend;

iv. deny; or

v. withdraw accreditation.

4. **Denial or Withdrawal of Accreditation**

In the event that the on-site inspection and the inspector’s report reflect significant violations of AATB accreditation requirements, the Accreditation Committee may determine that accreditation be denied or withdrawn without an opportunity for corrective action.

If a decision is made to deny or withdraw accreditation, the Committee may, in its discretion, impose a waiting period of up to one-year (from the notice of denial) before re-application for accreditation is allowed. At that time, the tissue establishment must submit a new application.

5. **Suspension of Accreditation**

There may be instances where the inspector’s report of the on-site inspection indicates noncompliance with the accreditation requirements, but the Accreditation Committee believes that these nonconformities do not warrant withdrawal of accreditation, and that the tissue establishment could comply with the accreditation requirements in a short period of time. There also may be instances where regulatory agencies issue inspection-related violations, sanctions, or other actions against an accredited tissue establishment that raise questions about the tissue establishment’s compliance with the accreditation requirements. In such cases, the Committee may suspend the tissue establishment’s accreditation for a period of time not to exceed ninety (90) calendar days to allow it to correct its nonconformities.

a. If the tissue establishment does not come into compliance with the accreditation requirements within the ninety (90) calendar day suspension period, the Committee may, in its discretion, extend the suspension for additional periods of ninety (90) calendar days or more, not to exceed one year. The Committee also may determine that a Level B inspection should be performed or may proceed to withdraw accreditation and deny the application for accreditation.

b. During the period of suspension, the tissue establishment is not considered an accredited tissue establishment or otherwise in good standing with the Association. In addition, beginning on the effective date of the suspension and continuing until the suspension is lifted, the tissue establishment is prohibited from using the AATB accreditation logo on or in connection with any
finished tissue produced during the period of suspension. The tissue establishment is also prohibited from indicating AATB accreditation, directly or indirectly, including on its letterhead, brochures, advertising materials, and website.

F. Notification
The Accreditation Committee’s decision on an application for accreditation is final. After notice to the President and Chief Executive Officer, the tissue establishment and the AATB Board of Governors Chairman will be notified of the decision. The tissue establishment will be notified in writing using a carrier with return receipt or other package-tracking capabilities.

IX. INSPECTIONS WITH OR WITHOUT NOTICE

A. Right to Inspect
AATB reserves the right to perform on-site inspections at any time, with or without notice. Conducting an inspection without notice does not necessarily indicate a suspected violation of AATB accreditation requirements.

B. Ordering an Inspection
With the concurrence of the President and Chief Executive Officer, the Accreditation Committee, the Accreditation Committee Chair, the Senior Vice President of Policy, or the Board of Governors may order an inspection for cause and/or as a stipulation of accreditation.

It may also be determined that an inspection is warranted of an accredited tissue establishment’s recovery partner that is not accredited by the AATB. If possible, the tissue establishment will be notified when the inspection(s) is (are) being scheduled that one or more of their recovery partners will be inspected by AATB; however, AATB reserves the right to make this determination. If the non-accredited entity(ies) does(do) not allow the inspection or is(are) found to not comply with AATB Standards, the following actions may become necessary:

• the accredited tissue establishment will be required to immediately terminate the business relationship with the non-conforming recovery partner if the non-conforming recovery partner will not comply with AATB Standards; and

• if the accredited tissue establishment does not immediately terminate the business relationship, AATB may suspend or withdraw the accreditation of the accredited tissue establishment.

C. Types of Inspections
Inspections may be general or focused, and the scope will be defined by the entity that ordered the inspection (refer to Section IX. B.). Inspections take place as described in Section VIII. C. An inspection may occur if the tissue
establishment’s location, facilities, and/or activities change, or other major changes have been reported. The Accreditation Manager in conjunction with the Accreditation Committee Chair will review major changes to determine if an on-site inspection is required. Additionally, the need to investigate a report of a contrary event or a report of a violation of accreditation requirements may be cause to hold a special inspection. The Accreditation Manager in conjunction with the Senior Vice President of Policy will review the report of a contrary event or a report of a violation of accreditation requirements to determine if an on-site inspection is indicated.

D. **Notice of Inspection**
Without limiting AATB’s right to inspect without notice, where circumstances permit, AATB may give prior notice to the tissue establishment of its intent to inspect.

E. **Reviews and Decisions**
Review of, and decision on, the final inspection report will take place as described in Section VIII. E.

F. **Inspection Costs and Fees**
The tissue establishment will reimburse the AATB for all costs, fees and expenses, including the inspector’s fees and travel expenses, that are related to an on-site inspection performed due to a major change. The tissue establishment is not responsible for costs incurred by AATB if a special inspection occurs due to a report of a contrary event or to investigate a report of a violation of accreditation requirements.

**X. REPORTING VIOLATIONS OF ACCREDITATION REQUIREMENTS**

A. **Reporting**
Reports of suspected violations of the accreditation requirements by accredited tissue establishments should be made in writing to the President and Chief Executive Officer and signed with the name(s), address(es) and telephone number(s) of the individual(s) alleging the violations. The Association will treat the identity of the person(s) alleging a violation as confidential.

B. **Investigation**
Upon receipt of a report of an alleged violation of the accreditation requirements by an accredited tissue establishment, the President and Chief Executive Officer, the Senior Vice President of Policy, and the Accreditation Manager will review and investigate the report. If they conclude there is sufficient reason to believe that a violation has occurred, the Accreditation Committee, by majority vote, with the concurrence of the President and Chief Executive Officer, may order an investigation and an on-site inspection with or without notice as provided for in Section IX. If an inspection is ordered, the Association will assume the costs of the inspection.
C. **Further Review and Action**
Following an investigation and any on-site inspection, the Accreditation Manager will submit a written report to the Accreditation Committee. Upon receipt of the report and if a violation of the accreditation requirements is noted, the Accreditation Manager and Accreditation Committee Chair may convene an emergency meeting of the Accreditation Committee. The Accreditation Committee will determine what, if any, action to take. The procedures described in Section VIII. E. will be followed.

**XI. SUSPENSION, DENIAL OR WITHDRAWAL OF ACCREDITATION**

A. **General**
Accreditation of a tissue establishment may be suspended, denied or withdrawn pursuant to the following steps.

B. **Notification**
Following review and decision by the Accreditation Committee, the President and Chief Executive Officer will notify the AATB Board of Governors Chairman and the tissue establishment of the decision. The tissue establishment will be notified in writing using a carrier with return receipt or other package-tracking capabilities. The decision must indicate that the tissue establishment has violated the terms of its accreditation and is operating contrary to the AATB accreditation requirements. The notice will also state the reasons for the decision and the organization's right to appeal.

C. **Appeals**
If a tissue establishment is notified that its accreditation has been denied, suspended or withdrawn, or that transfer of accreditation has been denied (refer to Section XII. below), it shall have fifteen (15) calendar days from the date of receipt of the notification to appeal. The appeal must be submitted in writing to the President and Chief Executive Officer, using a carrier with return receipt or other package-tracking capabilities. If an accredited tissue establishment appeals the decision to withdraw its accreditation in a timely manner, the proposed withdrawal will be stayed pending the outcome of the appeal, provided there is no potential hazard to human health. In the event that the tissue establishment does not appeal the decision to deny, withdraw, suspend, or deny transfer of accreditation within the fifteen (15) calendar day period, the proposed suspension, denial or withdrawal of accreditation will become final.

Should the tissue establishment file an appeal within the fifteen (15) calendar day period after notification, a Hearing Panel will be established and shall consist of the following members: the President and Chief Executive Officer, who shall act as the non-voting Chair of the Hearing Panel, the Senior Vice President of Policy, the Accreditation Manager, the CAPA Analyst, and a legal
counsel representative of the AATB who shall be non-voting.

D. **Hearing**
The hearing will be held within thirty (30) calendar days of, but not fewer than twenty (20) days following, AATB's receipt of the request for such a hearing. The hearing may be held in person or by teleconference.

At the hearing, the tissue establishment's designated *management with executive responsibility* most responsible for compliance with AATB Standards and Accreditation Policies, and/or the Medical Director may appear and may be accompanied by up to three other members of the tissue establishment. At least seven (7) calendar days prior to the date of the hearing, the tissue establishment must submit to the AATB a written statement of specific reasons indicating why suspension, withdrawal or denial of accreditation is believed to be not warranted, as well as all written and documentary evidence in support of the organization's position. Testimony, if any, must be presented by sworn affidavit. The tissue establishment will be allotted one hour to present its position and such additional time as needed to respond to the Hearing Panel’s questions.

E. **Decision**
The Hearing Panel will reach its decision by simple majority vote. The tissue establishment and the AATB Chairman will be notified of the decision within seven (7) calendar days of the conclusion of the hearing. The tissue establishment will be notified in writing using a carrier with return receipt or other package-tracking capabilities.

A tissue establishment that has its accreditation denied or withdrawn is not eligible to reapply for accreditation for one year from the date of notification of denial or withdrawal.

**XII. TRANSFER OF ACCREDITATION**

A. **General**
An accredited tissue establishment may request that its accreditation, or any portion thereof, be transferred when the establishment is reorganized or dissolved and a successor entity is incorporated, or when the establishment is to be merge with or acquired by, or control is to be acquired by, another establishment whether or not the transferee is already accredited by the AATB. AATB accreditation, however, does not automatically transfer to the successor entity.

B. **Request for Transfer**
To transfer AATB accreditation, an accredited tissue establishment that is reorganizing, merging with, being acquired by, or control of which is being transferred to another organization must first request permission from the
AATB to transfer its accreditation to the transferee. The request must be made in writing, signed by the designated management with executive responsibility most responsible for compliance with AATB Standards and Accreditation Policies, and sent to the Accreditation Manager at least seven (7) calendar days prior to the transfer. The request must specify the reasons for the requested transfer, identify the entity to which the Accreditation is to be transferred, and provide necessary documentation as described below. At the time the request is made, the accredited tissue establishment must be in good standing and its accreditation must be current. Failure to file a timely and complete request may result in the denial of such a request, or suspension or withdrawal of accreditation.

C. **Documentation**

The documentation to be provided in addition to the written request for transfer of accreditation (refer to Section XII. B.), must be sufficient to show:

- the nature and extent of the ownership and operational changes that will result from the transaction giving rise to the request for transfer of accreditation;

- any changes in the scope of the tissue establishment’s operations or management responsibilities following consummation of the transaction giving rise to the request for transfer of accreditation;

- any post-consummation changes that would alter the tissue establishment’s continuing compliance with the accreditation requirements;

- any audits, findings, enforcement actions by or proceedings involving any governmental agency or authority, within the past three (3) years or outstanding as of the time of the request for transfer of accreditation), involving either the petitioning tissue establishment or the merging or acquiring entity; and

- continued compliance with accreditation requirements by the transferor prior to the transfer, and that the transferee will remain in compliance subsequent to the transfer.

D. **Review**

In the case of a request for transfer of accreditation to an entity that is not AATB-accredited, the procedures described in Section II. D. will be followed.

The Accreditation Manager and the Accreditation Committee Chair will review the request and documentation. The request to transfer accreditation may be cause to hold a special inspection. Based upon review of documentation, the Accreditation Manager and the Accreditation Committee Chair will decide whether to approve the transfer of accreditation.
E. **Consummation; Notification**
The tissue establishment and the AATB Board of Governors Chairman will be notified of the decision. The tissue establishment will be notified in writing using a carrier with return receipt or other package-tracking capabilities. In the event that the AATB grants the request, the reorganization, merger, acquisition or transfer of control that was the subject of the request to transfer accreditation must be completed within sixty (60) days of receipt of the AATB’s approval, and within seven (7) calendar days following consummation of the transaction the tissue establishment receiving the transfer of accreditation must provide *Written Notification* to the Accreditation Manager of the date on which the transaction was completed.