



Accreditation Policies
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ACCREDITATION POLICIES

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Association for Advancing Tissue and Biologics Accreditation Policies

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The Association for Advancing Tissue and Biologics (“AATB” or “Association”) Accreditation Policies is specifically for *Tissue Establishments* that voluntarily agree to abide by the current AATB *Standards for Tissue Banking* and/or the *Standards for Non-Transplant Anatomical Donation* in order to demonstrate their respect for donor families and a commitment to the *quality* and *safety* of human tissue through participation and compliance with the AATB Accreditation Program.

I. ACCREDITATION PROGRAM—GENERAL PROVISIONS

A. Interpretive Guidance

1. As used throughout these Accreditation Policies, the word “including” means including but not limited to.
2. All expressions of time are calendar days, unless otherwise specified.
3. Words that appear in *italics* (e.g., *satellite facility*, *nonconformity*, etc.) are defined at Standard A2.000 Definitions of Terms in AATB *Standards* or defined below in these Accreditation Policies.

B. Definitions

AATB *Standards* - AATB Transplant *Standards* and AATB Non-Transplant *Standards* are referred to collectively as “AATB *Standards*”. The term “AATB *Standards*” is used herein to refer either to AATB Transplant *Standards*, to AATB Non-Transplant *Standards*, or to both, as contextually appropriate.

Words that appear in *italics* (e.g., *satellite facility*, *nonconformity*, etc.) are defined at A2.000 Definitions of Terms in the AATB *Standards*. The following terms and definitions, which are not found in AATB *Standards*, apply to these Accreditation Policies and appear in *italics* and are underlined:

1. *Accreditation Application* – required documentation, in a format directed by AATB, used to assess eligibility of a *Tissue Establishment* for institutional accreditation.
2. *Acquisition* - Obtaining *NTAD* that is intended for use in education and/or research.
3. *Authorization* - Permission given after *adequate information* concerning the donation, *recovery* or *acquisition*, and use of tissue is conveyed.
4. *Distribution* - Process that includes receipt of a request for tissue, selection of appropriate finished tissue, preparation for transport, any required inspections, and subsequent shipment and delivery of tissue to another *tissue bank*, *tissue distribution intermediary*, *tissue dispensing service*, or end-user.
5. *Donor Screening* - evaluation of the donor’s available medical/social information for risk

factors for, and clinical evidence of, relevant communicable disease agents and disease and communicable disease risks including tissue bank specific criteria. This does not include donor eligibility determination.

6. Donor Eligibility Determination - a determination that a donor was either eligible or ineligible to donate cells or tissue, based on the results of donor screening and testing.
7. Hearing Panel – as defined below in Section VIII.C.2.
8. Informed Consent – Permission given by a living donor (LD) who is presented with a description of the scope, use and any risks or benefits of the proposed donation, and who has been given the opportunity to ask questions and receive accurate answers. An LD who gives *informed consent* to donation *shall* sign a record of the *informed consent*.
9. Major Change – as defined below in Section IX.A.2.
10. Management Representative – *Management with Executive Responsibility (MwER)* *shall* appoint a member of management, or themselves, 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 the *MwER* for their review.
11. Owner - means any person who, directly or indirectly, (a) owns, controls, or has the power to vote or sell, or direct the vote or sale of, or interests in, a *Tissue Establishment*, or (b) otherwise has the power to control the actions, decisions, policies and/or management of a *Tissue Establishment* whether, or not, through ownership of securities.
12. Preparation – Any activity performed other than *donor screening*, *donor testing*, *acquisition*, *storage*, or *distribution* to enable the use of *NAM* for education and/or research. It includes but is not limited to, cleaning, *preservation*, disarticulation, dissection, skeletonization and/or plastination, *packaging*, and *labeling* of *NAM*.
13. Processing - Any activity performed on *tissue* other than *donor screening*, *donor testing*, *recovery*, *storage*, or *distribution*. It includes but is not limited to preparation, *disinfecting*, *sterilizing*, *primary* and / or *secondary packaging*, *labeling*, and testing *tissue*.
14. Recovery - obtaining cells or tissues from a human donor that are intended for use in human transplantation, implantation, infusion, transfer, research, or education. For birth tissue, recovery is synonymous with *acquisition*. For reproductive tissue, recovery is synonymous with *collection*.
15. Regulatory Event – as defined below in Section IX.A.1.
16. Reportable Event - as defined and described in Section IX.
17. Storage – the maintenance of tissue for future use

18. Tissue Establishment - collectively referred to as “Tissue Establishments” - a *tissue bank, reproductive tissue bank, tissue distribution intermediary, tissue dispensing service, satellite facility*, or a Non-Transplant Anatomical Donation Organization (NADO) that facilitates *Non-Transplant Anatomical Donation (NTAD)* as defined in the current edition of the AATB Standards.
19. Written Notification – communication to AATB on matters related to Tissue Establishment accreditation sent electronically (accreditation@aatb.org) or by using a reputable nationwide courier service.

C. Eligibility

1. To be eligible to apply for accreditation:
 - a. the Tissue Establishment must demonstrate that it has been in continuous compliance with AATB Standards and the Accreditation Policies, for all tissue banking functions it performs, for a minimum of six (6) months prior to the date of application; and/or
 - b. the Tissue Establishment must have conducted a sufficient level of activity to support an inspection to evaluate compliance. This assessment of activities shall be determined at the sole discretion of AATB. Mock records shall not be used to approximate actual activities.
2. All *satellite facilities* and their tissue banking function(s):
 - a. must be identified to AATB when a Tissue Establishment applies for accreditation;
 - b. must be in compliance with the AATB Standards and the Accreditation Policies; and
 - c. are subject to inspection.
3. When a Tissue Establishment has been determined by the AATB to be eligible, an Accreditation Application will be considered pursuant to the procedures described in Section V.

II. IMPARTIALITY, CONFIDENTIALITY AND DISCLOSURE

A. Impartiality and Confidentiality

1. To maintain impartiality and confidentiality, all materials submitted to the AATB Accreditation Committee (“Accreditation Committee” or “Committee”) will have identifying information redacted or otherwise blinded. AATB will treat all information and documents regarding Accreditation Applications and Tissue Establishments as confidential. All AATB staff, contract inspectors, and Committee members shall comply with the AATB Compliance Program.
2. Committee members will receive information only in blinded form. Un-blinded information may be available to the AATB Accreditation Staff, contracted inspectors, Committee Chairperson, and the Hearing Panel, who shall treat all information as confidential and shall comply with the AATB Compliance Program.

B. Disclosure

1. Information obtained during or in connection with the Accreditation Application, Accreditation process, or an inspection will be maintained as confidential and will not be

released by AATB unless:

- a. the Tissue Establishment has specifically authorized release of such information;
 - b. the information is included in aggregate form or with other information to ensure that an individual Tissue Establishment cannot be identified;
 - c. the information is already available to the public;
 - d. release of the information is required by federal, state or local statute, regulation or other law, or court or administrative order.
2. In the event that AATB has knowledge of information relating to an accredited Tissue Establishment, or an applicant for Accreditation, that reflects the existence of an actual or potential hazard to human health, AATB will provide such information to the responsible international, federal, state and/or local government agencies or authorities having jurisdiction over the Tissue Establishment.
 3. AATB will identify accredited Tissue Establishments on its website (refer to Section VI). AATB will respond to telephone inquiries regarding a Tissue Establishment's accreditation status by indicating that all current accredited Tissue Establishments may be located by accessing the AATB website at www.aatb.org/accredited-bank-search.

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 the Tissue Establishment's Management Representative or MwER.

C. Conflict of Interest

When the Chair of the Accreditation Committee is identified, either by self-reporting, third party, or by the Accreditation Staff, as having a conflict of interest regarding review of the application, documentation, or other matter pertaining to a particular applicant or accredited Tissue Establishment, the Vice Chair will assume the Chair's role and responsibilities for that applicant or accredited Tissue Establishment. 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 for purposes of review of the particular matter.

D. Inquiries Related to the Accreditation Process

All inquiries related to the accreditation process *shall* be addressed to AATB Accreditation Staff. Contracted AATB inspectors and members of the Accreditation Committee *shall* not answer inquiries related to accreditation applications, Accreditation Committee activities, or any topics related to an inspection.

III. RESPONSIBILITIES

A. Board of Governors

The Board of Governors is responsible for the Association's Accreditation Program, including the Accreditation Policies.

B. Accreditation Committee

1. The Accreditation Committee:

- a. reviews blinded inspection reports and responses, makes requests for additional information, orders special inspections, and makes decisions regarding accreditation;
 - b. acts on a request to review an application for accreditation or to transfer accreditation, to approve or deny such request, as provided for in these Accreditation Policies (refer to Section I. C.); and
 - c. reviews and approves changes to accreditation policies.
2. The Accreditation Committee renders its decision by majority vote, in the presence of a quorum.
3. A Committee member *shall* not vote or actively participate in accreditation discussions when a potential conflict of interest is identified.

C. Accreditation Committee Composition and Member Requirements

The appointments of the Accreditation Committee members and its Chair (“Chair”) are subject to the current adopted charter.

D. Non-voting Participants in Meetings of the Accreditation Committee

Certain members of the AATB Accreditation Staff and contracted AATB Inspectors *may* participate in Accreditation Committee meetings on a non-voting *ex officio* basis.

IV. 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. Onsite inspections *must* be performed to verify compliance for initial and renewal Accreditation Applications and can occur at any time, with or without advance notification. Remote inspections *may* be conducted in addition to onsite inspections at AATB’s sole discretion.

B. Additional Compliance

1. An accredited Tissue Establishment *must* also comply with the following additional requirements. Failure to meet any of these additional requirements *may* result in suspension, withdrawal, or denial of transfer of accreditation. To maintain accredited status, the Tissue Establishment *must*:
 - a. fully cooperate with and complete AATB-sanctioned surveys;
 - b. tender payment to AATB of its annual maintenance fee before January 31st of each year;
 - c. tender payment to AATB within forty-five (45) days of an invoice related to a special inspection, interim, level B inspection, or an international inspection; and
 - d. continue to perform tissue banking functions for which it is accredited.

2. To maintain continuous accreditation, a *Tissue Establishment* must submit a properly completed *Accreditation Application* at least seven (7) months, but not more than nine (9) months, before the current AATB accreditation expiration date.

C. Good Faith Provisions and Ethical Considerations

1. 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, withdrawal, or denial of transfer of accreditation. In addition, if any of these conditions are noted during an inspection, the inspection may be suspended or terminated immediately.
2. Accredited *Tissue Establishments* and/or applicants for accreditation shall not present any false or misleading information, or omit any material information, regarding their accreditation status and their compliance with the requirements of the AATB Accreditation Policies.
3. Accredited *Tissue Establishments* agree to operate in accordance with AATB's Bylaws, objectives, rules, policies, AATB Standards and codes, including, without limitation, the Ethical Standards and Codes of the Association, all of which are available as part of the application materials.

D. 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* cannot elect to be accredited for certain tissue banking activities and not for other tissue banking activities it performs. Tissue banking activities include, but are not limited to, the following:

1. Donor (Transplantable and Non-Transplantable Tissue(s))
 - a. authorization;
 - b. informed consent;
 - c. donor screening;
 - d. donor-eligibility determination;
2. Transplantable and Non-Transplantable Tissue(s)
 - a. storage; and/or
 - b. distribution.
3. Non-Transplantable Tissue
 - a. acquisition; and/or
 - b. preparation;

E. Joint Activities and/or Services

1. 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.
2. When two or more Tissue Establishments participate jointly in tissue banking activities and/or services (multi-facility tissue banking), accreditation is awarded only to the applicant Tissue Establishment. A non-accredited entity *shall* not state or claim, expressly or by implication, that it is accredited by AATB.

F. AATB Membership and Council Participation

As described immediately below, documentation of AATB membership and meetings participation *may* be provided with the Accreditation Application and *may* be requested by the inspector during an accreditation inspection.

1. Medical Director

By the time of inspection, a designated Medical Director *must* have participated in one (1) or more Physicians Council meetings, annually, within the three-year period prior to the application of accreditation.

2. Management Representative

By the time of inspection, the person designated as Management Representative

a. *must* be a member of an AATB Council; and

b. *must* have signed the AATB Standards and Accreditation Policies pledge.

G. 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 by the Tissue Establishment to vote at meetings of the Council.

V. **ACCREDITATION PROCESS**

A. Application

Prior to submitting an application for accreditation, a Tissue Establishment *must* be determined to be eligible. Refer to Section I. C. Upon being deemed eligible to apply for accreditation, the Tissue Establishment will be provided the Accreditation Application via the AATB electronic platform. Information required by the Accreditation Application *must* be submitted to AATB via the secured AATB electronic platform. AATB staff will not create a user profile or use Tissue Establishment specific document control systems.

1. Initial Application for Accreditation

A Tissue Establishment *must* complete the New Applicant Interest Form, which will be reviewed by AATB Accreditation Staff. AATB will notify the interested applicant if additional documentation or information is required. Payment of the non-refundable application fee *must* be received to gain access to the application materials.

2. **Renewal Application for Accreditation**

A renewing Tissue Establishment will receive the Accreditation Application from AATB via electronic notification nine (9) months prior to the expiration of its accreditation. A Tissue Establishment, seeking accreditation renewal, *shall* submit the Accreditation Application within 45 days of receipt of the Accreditation Application.

3. **Recent Action Against the Applicant**

If an international, federal, state or local agency or other authority initiates or has initiated any formal or informal inquiry, investigation, proceeding or other action (“action”) against an applicant seeking AATB accreditation, or gives or has given notice of any of the foregoing, the applicant *must* inform AATB as soon as possible, but no later than the confirmation of the AATB inspection. 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 action 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/or the suspension, denial or withdrawal of accreditation.

B. **Scheduling the Inspection(s)**

Upon determination that the Accreditation Application is complete, the Tissue Establishment will be contacted to schedule the onsite inspection and, when applicable, remote inspection days. Unless otherwise approved by AATB, inspections *shall* be scheduled and completed within 90 days of submitting the Accreditation Application. AATB will determine the length of time necessary for each onsite and remote 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 operations. Once the inspection has begun, the actual duration *may* be adjusted after consultation between the inspector(s) and AATB.

C. **Right to Inspect**

AATB reserves the right to perform onsite inspections at any time during a Tissue Establishment’s period of accreditation or in connection with an application for accreditation, with or without notice. Conducting an inspection without notice does not necessarily indicate a suspected violation of AATB accreditation requirements.

D. **Scope of Inspections**

1. The scope of the renewal or initial 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.
2. The inspector(s) *must* be granted access to all spaces, records, and personnel pertinent to all tissue banking functions. The inspection *shall* include but is not limited to record reviews, interviews with staff, observation of activities, and tours of facilities.
3. Management Representative *must* be available during the inspection. Appropriate *MwER*, relevant quality staff, and the Medical Director *should* be available for the inspection.

E. **Ordering an Inspection**

1. With the concurrence of the AATB Accreditation Department, either the Accreditation Committee, the Accreditation Committee Chair, the President and Chief

Executive Officer, or the Board of Governors *may* order an inspection for cause and/or as a stipulation of accreditation.

2. It *may* also be determined that an inspection is warranted of an accredited Tissue Establishment's recovery, acquisition or collection partner that is not accredited by AATB. If possible, the accredited Tissue Establishment will be notified when such an inspection(s) is (are) being scheduled; 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 be in compliance with AATB *Standards*, the following actions *may* be taken:
 - a. the accredited Tissue Establishment will be required to immediately terminate the business relationship with the non-conforming entity, if the non-conforming partner will not comply with AATB *Standards* within a period designated by AATB; and
 - b. if the accredited Tissue Establishment does not immediately terminate the business relationship, AATB *may* suspend or withdraw the accreditation of the accredited Tissue Establishment.

F. 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 V.E). Inspections take place as described in Section V. D. An inspection *may* occur if the Tissue Establishment's location, facilities and/or activities change, or another Reportable Event has occurred. The need to investigate a Reportable Event or a report of a violation of accreditation requirements *may* be cause to hold a special inspection. AATB Accreditation Staff will review the report of any Reportable Event or a report of a violation of accreditation requirements to determine if an onsite or remote inspection is necessary.

G. 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.

H. Reviews and Decisions

Review of, and decision on, the final inspection report will take place as described in Section VI.

I. Inspection Costs and Fees

1. AATB will establish an Accreditation Fee Schedule. The Accreditation Fee Schedule will be distributed with the application materials.
2. Costs, fees, and expenses related to an inspection will be charged to the applicant based on the current AATB Accreditation Fee Schedule. All applicants for accreditation *must* pay the application fee as described above in Section V.A.
3. At the discretion of AATB, Tissue Establishments *may* be assessed fees for the following:
 - a. costs incurred by AATB if an inspection is due to a report of or to investigate an alleged violation of accreditation requirements.

- b. expenses, including the inspector's(s') fees and travel expenses related to the inspection(s) if any applicant voluntarily withdraws from, does not comply with, or does not complete the accreditation process after the commencement of any inspection.

J. Inspection Report

The contract inspector's report will identify and describe *nonconformities*. The inspector(s) will complete the report and deliver it to AATB Accreditation staff. AATB will prepare the report and deliver it, in the appropriate format, to the Accreditation Committee Chair or designee in cases where conflicts of interest arise. Following the Chair's review, the draft inspection report will be sent in blinded format to the Accreditation Committee members for discussion at the next scheduled meeting.

VI. ACCREDITATION COMMITTEE DECISIONS

A. General

1. Accreditation of a *Tissue Establishment* may be approved, suspended, denied or withdrawn pursuant to these policies.
2. 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 evaluation of an accreditation inspection report and/or response(s).

B. Accreditation Committee Review and Decision

The Accreditation Committee will review and finalize the blinded inspection report. The Committee will also take into consideration an *Establishment's* preliminary response to its inspections finding(s). Accreditation Committee decisions will be made based on a majority vote, in the presence of a quorum. Decisions may include special provisions under specific circumstances. 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 which of the following actions is appropriate; the process related to each decision is described as follows:

Options	DRAFT report	Level A response	Level B response	Other response (e.g., RFI, Draft, appeal)
Level A	X			
Level B (reinspection of <u>only</u> the listed NCs)	X	X		
RFI	X	X	X	
Accredit	X	X	X	X
Accredit with interim inspection (full quality system reinspection) (AC determines time frame and announced/unannounced)	X	X	X	X
Suspend (Committee determines length, 90-day increments up to one year)	X	X	X	X
Deny (Committee determines length up to one year)	X	X	X	X

1. Level A—Requires Corrective Action(s)

Following a report that indicates there are *nonconformities*, and that the applicant's compliance with AATB accreditation requirements *must* improve, the Committee *may* determine that the *nonconformities* can be corrected and documented without need for a re-inspection to verify compliance. In such instances, 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 or electronic documentation. If desired, the applicant *may* contact the AATB Accreditation Staff for clarification of any *nonconformity(ies)*. When a Level A designation has been issued:

- a. AATB will transmit the final inspection report to the applicant. The report will describe all nonconformities that require corrective action. Within 30 days of the applicant's receipt of the final inspection report, the applicant *must* submit, to AATB, sufficient documentation demonstrating that corrections have been made to comply with AATB accreditation requirements. If a preliminary response was submitted, the *Establishment* must submit a final response to the final inspection report. Failure to meet the deadline or to sufficiently demonstrate compliance *may* result in a decision to deny, suspend, withdraw or deny transfer of accreditation, unless exceptional *corrective action* or *preventive action* circumstances exist to justify a one-time extension of this deadline.
- b. If needed, AATB, the Committee Chair, or designee *may* request additional information. The requested information and/or documentation *must* be received by AATB from the applicant within 15 days of the applicant's receipt of the request.
- c. Following the review of the blinded response, 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.
- d. Following the review of the blinded response, 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 AATB from the applicant within 15 days of the applicant's receipt of the request;
 - ii. determine that a Level B onsite re-inspection be performed; or
 - iii. determine that accreditation be suspended, denied or withdrawn.

2. Level B - Requires Corrective Action(s) and Onsite Re-Inspection

Following an onsite inspection and an inspector's report that indicates compliance with AATB accreditation requirements *must* improve, the Committee *may* require corrective action(s) and an additional onsite re-inspection to determine compliance. An applicant assigned a Level B status *may* receive only one (1) additional onsite re-inspection. When a Level B designation has been issued:

- a. AATB will transmit the final inspection report to the applicant. The report will describe all nonconformities that require corrective action. Within 30 days of the applicant's receipt of 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 *may* result in a recommendation to deny, suspend, withdraw or deny transfer of accreditation, unless exceptional circumstances exist to justify a one-time extension of the response period.

- b. If additional information is needed and requested by AATB, the requested information and/or documentation *must* be received by AATB within 15 days of the applicant's receipt of the request.
 - c. Once AATB determines from the applicant's submission that the applicant has adequately responded to all *nonconformities*, the Level B onsite re-inspection will be scheduled.
 - d. Following the Level B onsite re-inspection,
 - i. if needed, AATB, the Committee Chair, or designee may request additional information. The requested information and/or documentation must be received by AATB from the applicant within 15 days of the applicant's receipt of the request.
 - ii. the Committee will review the blinded inspector's findings, including any continued, new, or additional findings, and all response(s) from the applicant. If the Committee determines the applicant has failed to demonstrate that all *nonconformities* have been resolved, the Committee *may*:
 - a) request additional information; or
 - b) request a written response to any continued, new, or additional findings to be submitted to AATB within 15 days of the applicant's receipt of the request; or
 - c) decide that accreditation be suspended, denied or withdrawn.
3. Denial or Withdrawal of Accreditation
- a. In the event that the 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.
 - b. If a decision is made to deny or withdraw accreditation, the Committee *may*, in its discretion, impose a waiting period of up to one (1) year (from the notice of denial) before re-application for accreditation is allowed. At that time, the Tissue Establishment *must* submit a new Accreditation Application.
4. Suspension of Accreditation
- a. There *may* be instances where the inspector's report of the onsite or remote 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 *may* also 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 that do not warrant withdrawal of accreditation, and that the Tissue Establishment could address satisfactorily in a short period of time. In such cases, the Committee *may* suspend the Tissue Establishment's accreditation for a period of time, not to exceed 90 days to allow it to correct the *nonconformities*.

- b. If the Tissue Establishment does not come into compliance with the accreditation requirements within the suspension period, the Committee *may*, in its discretion, extend the suspension for an additional period, 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.
- c. 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 *tissue* product 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, social media and/or website(s) during the suspension period.

C. Notification and Public Recognition

1. The Accreditation Committee's decision on an application for accreditation is final. The Tissue Establishment will be notified via email or comparable electronic service.
2. 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.
3. A *satellite facility* is not searchable using the AATB website accredited bank search function unless it is separately accredited. A *satellite facility* of an accredited Tissue Establishment *may* identify itself as being accredited by AATB using the official written notification letter from AATB [See VII.B below].
4. The following circumstances will result in removal from the accredited bank search function on the AATB website:
 - a. suspension of accreditation;
 - b. expiration, denial or withdrawal of accreditation; or
 - c. cessation of all tissue banking operations.

VII. ACCREDITATION CERTIFICATE AND EXPIRATION OF ACCREDITATION

A. 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:

1. accreditation approval date;
2. accreditation expiration date;

3. the tissue type(s) and tissue banking activity(ies) for which accreditation is awarded (refer to Section IV.D);
4. the Tissue Establishment name and primary address, such as city and state (or similar identifier if outside of the United States).

B. Satellite Facility(ies)

Satellite facility(ies) of an accredited Tissue Establishment, if any, will be identified by name and address in a formal letter from AATB that accompanies the certificate.

C. 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 Certificate of Accreditation. Privileges of accreditation cease on the expiration date, unless AATB denies, withdraws, suspends or extends accreditation prior to that date.

1. Extension

- a. An accredited Tissue Establishment may apply for an extension so long as the Tissue Establishment meets published timelines, completes each stage of the process in good faith, and the delay does not exceed 180 days or adversely affect the safety of the public, including tissue recipients or Tissue Establishment employees. A request for extension *may* be granted by AATB Accreditation Staff or *may* be referred to the Accreditation Committee for evaluation on a case-by-case basis, in blinded fashion. If referred to the Committee, an extension will be granted by the AATB Accreditation Staff for the time period until a meeting of the Committee is convened. The Committee *may* grant the extension, or *may* suspend, deny, or withdraw accreditation. Refer to Section VI.

2. Request for Extension

- a. To extend accreditation, the Tissue Establishment *must* apply to the AATB Accreditation Staff for an extension, at least 30 calendar days prior to the expiration date of the applicant's current accreditation. Written Notification *must* include sufficient information, including justification for the extension. A request for extension *must* be submitted prior to the expiration of accreditation.
- b. An accredited Tissue Establishment that applies for renewal of accreditation may not have its accreditation extended beyond its current accreditation expiration date if it has not met published timelines.

3. Limit

An extension will not be granted for longer than sixty (60) days at a time. In the case where a Tissue Establishment requires an extension for more than 180 days, the Establishment's written notification, in blinded format, will be sent to the Accreditation Committee for review. An additional extension *may* be granted by the AATB Accreditation Staff only for the time period until a meeting of the Committee is convened.

4. Extension(s) and the Accreditation Expiration Date

Should an extension(s) be granted, as described above, and subsequently, a decision to

re-accredit results, the period of re-accreditation will run from the expiration date of the prior accreditation, not from the date of any extension(s).

D. Lapse of Accreditation

If a *Tissue Establishment* accreditation expires and it is not extended pursuant to these policies, the *Tissue Establishment* must immediately remove all indications of AATB accreditation (including, without limitation, all AATB logos or references to AATB trademarks and service-marks) from its forms, letters, signs, labeling and advertisements, and it *shall* not state or imply, directly or indirectly, that it continues to be accredited by AATB.

E. 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 AATB's requirements at any or all times.

F. Logo Use Privileges and Trademark Restrictions

1. 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 AATB Trademark User Guide, which is provided with the application materials. Accreditation does not confer the right to use any other trademark of the Association, including its Corporate Logo.
2. AATB does not authorize, and expressly prohibits, entities not accredited by AATB from using any AATB logo or trademark or 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 logos or trademarks. For specific information, refer to the AATB Trademark User Guide.

G. Unauthorized Use of AATB Accreditation Status

1. 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 the AATB Trademark User Guide.
2. In the event a *Tissue Establishment* is determined to have violated the aforementioned policy, AATB will use enforcement discretion as it relates to notifications and any actions taken to resolve the violation.

H. Agreement to Comply with Requirements

By accepting AATB accreditation, the *Tissue Establishment* agrees to comply with all accreditation requirements, including current AATB *Standards and Accreditation Policies*.

VIII. 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 to suspend, deny or withdraw accreditation, the Tissue Establishment's Management Representative and MWER will be notified of the decision in writing via email and/or comparable courier service.

C. Appeals, Hearings and Decisions

1. Appeals

- a. A Tissue Establishment whose application has been denied, suspended, or withdrawn (refer to Section VI and IX) *shall* have 15 days, from the date of receipt of the notification, to appeal (the "Appeal Period") the decision. The Written Notification of appeal *must* be submitted to AATB via email at accreditation@aatb.org and a carrier with package-tracking capabilities (e.g. USPS or FedEx).
- b. With proper notice, Accreditation *shall* remain in force during the Appeal Period, unless the reason for the decision was based upon public health or safety considerations, as determined by AATB and its legal counsel.
- c. In the event that the Tissue Establishment does not appeal the decision within the Appeal Period, the Accreditation Committee's ruling to suspend, deny, or withdraw the Establishment's application *shall* become final.

2. Hearing

- a. Should the Tissue Establishment file an appeal within the Appeal Period, a Hearing Panel will be established.
- b. The hearing will be held within 30 days of, but not fewer than twenty (20) days following, AATB's receipt of the request for a hearing. The hearing *may* be held in person or by teleconference upon mutual agreement of AATB and the appealing Tissue Establishment.
- c. The Hearing Panel will be comprised of voting and non-voting members:
 - i. Voting members: Vice President of Accreditation and Standards, Director of Accreditation, Director of Standards, Director of Government and Regulatory Affairs, and the Accreditation Committee Chair;
 - ii. Non-voting members: AATB's legal counsel representative, AATB's President and Chief Executive Officer, and any subject matter expert(s) that *may* be invited to advise the Hearing Panel.
 - iii. AATB's President and Chief Executive Officer *shall* act as Chair of the Hearing Panel.

- d. At least seven calendar days prior to the date of the hearing, the Tissue Establishment must submit a written statement, electronically, to support its rebuttal of the decision. The statement must provide specific justification and include documentary evidence.
 - e. At the hearing, the Tissue Establishment's designated Management Representative and/or the Medical Director may appear and may be accompanied by up to three other representatives of the Tissue Establishment. The Tissue Establishment will be allotted one hour to present its position and additional time, as needed, to respond to the Hearing Panel's questions.
3. Decision
 - a. The Hearing Panel will reach its decision by consensus.
 - b. The designated Management Representative of the Tissue Establishment will be notified in writing of the Hearing Panel decision, via email and/or a carrier with package-tracking capabilities (e.g., USPS or FedEx) within seven days of the conclusion of the hearing.
 - c. If the Hearing Panel upholds the Accreditation Committee's decision, see Section VII.E and VII.F.

IX. REPORTABLE EVENTS

A. Required Reporting

Accredited Tissue Establishments and applicants must send Written Notification to AATB Accreditation Staff as soon as possible, but not later than 15 calendar days following a Reportable Event(s). Reportable Events become part of the Tissue Establishment's records and may be cause to hold a special inspection.

1. Regulatory Event

A regulatory event includes, but is not limited to:

- a. any international, federal, state or local authority action, including:
 - i. any *tissue* Orders of Retention, Recall, Destruction, or Cessation of Manufacturing;
 - ii. receipt of any FDA Form 483 or state, local or international equivalent inspection report or list of inspection findings where components of tissue allografts, tissue allografts, or related tissue activities were evaluated or referenced;
 - iii. receipt of any FDA Warning Letter, Untitled Letter, or other communications from the FDA that reflects notice of potential violation of Acts or regulations or an equivalent warning by another federal, state, local or international authority where tissue activities, components of tissue allografts, or tissue allografts were evaluated or referenced; and
 - iv. all submissions of FDA adverse reports (e.g., MedWatch) or adverse reaction reports originating from another country involving *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 *tissue*;

- c. any disease transmission suspected to be caused by *tissue* or *NAM* processed and/or distributed by the accredited Tissue Establishment or applicant; and
- d. any HCT/P Deviation report submitted to the FDA or equivalent report submitted to an international government authority.

2. Major Change

A major change includes changes to personnel or operations, including but not limited to:

- a. changes to key personnel, including:
 - i. the designated representative to the Accredited Tissue Banks Council;
 - ii. the Medical Director(s); or
 - iii. the person designated as the Management Representative.

Note: Current curriculum vitae for the Management Representative, and for the Medical Director, *must* be submitted with the Written Notification of change.

- b. change in scope of operations of the Tissue Establishment, including the following services and/or activities:
 - i. cessation or suspension for a period of six 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.
- c. 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*.
- d. change in the Owner of the Tissue Establishment or merger with, acquisition by or of, or transfer of control to or of, another Tissue Establishment;
- e. 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;

- f. legal name change or d/b/a (doing business as) designation; or
 - g. dissolution, bankruptcy or insolvency of the Tissue Establishment.
3. Other events
- a. 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
 - b. the FDA Establishment Inspection Report (EIR) or equivalent report from any state, local, or international inspection authority.

B. Required Information

Failure to notify AATB of a Reportable Event may result in proceedings to suspend, withdraw or deny accreditation.

- 1. Written Notification sent pursuant to this section *must* be sufficiently detailed to explain the nature and extent of the Reportable Event to enable AATB to determine the implications for the accredited Tissue Establishment's current and future compliance with AATB accreditation requirements.
- 2. All documents submitted relating to Reportable Events *must* be submitted in their entirety and not redacted. Such documents include, without limitation, responses by the Tissue Establishment to all international, federal, state and/or local agencies or authorities until the matter is closed at each level.
- 3. At the direction of the AATB Accreditation Staff, an AATB Facilities Change Form *must* be completed.
- 4. The following information *must* be submitted regarding any *recall*, *voluntary notification*, or *market withdrawal of finished tissue*, whether a domestic or an international distribution:
 - i. name of Tissue Establishment;
 - ii. type(s) of tissue;
 - iii. number of tissue donors involved;
 - iv. number and identification (e.g., donor number or lot number) of tissue grafts involved;
 - v. identification of the consignees to which each tissue graft was distributed;
 - vi. date of occurrence, date of discovery, and, when applicable, the date reported (e.g., to FDA or HTA);
 - vii. reason for taking action;
 - viii. nature (voluntary, mandatory); and

- ix. description of corrective action(s) taken and planned to be taken.
- 5. Accreditation *shall* not be transferred to or assumed by a successor or acquiring party without written approval from AATB. For a change of ownership or transfer of accreditation the following *must* be provided:
 - i. the identity(ies) of the party(ies) to which ownership or control of the accredited Tissue Establishment will be transferred;
 - ii. the nature and extent of the ownership and operational changes that will result from the transaction;
 - iii. any changes in the scope of the Tissue Establishment's operations or management responsibilities following consummation of the transaction;
 - iv. any post-consummation changes that would alter the Tissue Establishment's continuing compliance with accreditation requirements;
 - v. any outstanding governmental audits, findings, enforcement actions by or proceedings involving any of the parties to the ownership change; and
 - vi. that the party acquiring ownership or control will remain in compliance after the ownership change.

C. Review of Reportable Events

AATB Accreditation Staff will review each notification of a Reportable Event and consider whether a special inspection should be performed prior to expiration of the Tissue Establishment's current accreditation or during the consideration of an application for accreditation (refer to Section V). If a special inspection is necessary, AATB Accreditation Staff *shall* notify the Tissue Establishment in advance or *may* schedule the inspection to take place without advance notification.

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, AATB will review and investigate the report. If it concludes that there is sufficient reason to believe that a violation has occurred, an inspection, with or without notice, *may* be ordered. AATB *may* also refer the alleged violation to the Accreditation Committee, who *may* order an investigation and an onsite inspection.

C. Further Review and Action

Following an investigation and any inspection, AATB Accreditation Staff *may* submit a blinded written report to the Accreditation Committee Chair. If a violation of the accreditation requirements is noted in the report, AATB Accreditation Staff and Committee Chair *may* convene an emergency meeting of the Accreditation Committee. The Accreditation Committee will determine what, if any, action should be taken.

END