American Association of Tissue Banks®

AATB Standards Supplement: Quality Agreements

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I. Background and Overview

The American Association of Tissue Banks requires, as a requirement of accreditation, tissue establishments to execute Quality Agreements with any individual or organization that performs activities or services in relation to the organization's scope of business. As defined in Standards for Tissue Banking:

> **QUALITY AGREEMENT** – an agreement that establishes the *quality* specifications or standards that *must* be met for defined activities and delineates responsibilities of each entity involved. It *may* be a separate document or included as part of a written agreement/contract.

This Standards supplement was developed to help tissue establishments develop quality agreements with the individuals or organizations they do business with, where appropriate. **Use of this guidance is not an AATB requirement, nor is it intended to contain all necessary terms of an agreement. As a reminder, the examples provided should be modified based on the business relationship and the requirements for which it is intended by the tissue bank.**

Quality agreements are used to clearly define the scope and responsibilities with regard to quality and regulatory objectives between two or more parties. Quality Agreements should specify quality, operational, and regulatory requirements, as well as the limitations of the scope of the agreement. AATB, in recognizing the critical nature of defining these relationships, has defined and described Quality Agreements in both the Accreditation Policies and Standards as required by AATB-accredited establishments. Approval signatures captured in a Quality Agreement ensure that terms outlined are mutually agreed upon by both parties.

IMPORTANT NOTICE: AATB Standards are subject to revision at any time pursuant to the Association's procedures. Notice of each such revision is given by AATB by posting on the Association's website, and distributing via email, a "Bulletin" that announces those changes and their respective effective dates. Persons seeking to determine the current provisions of Standards should always review the Bulletins for any such announcement of revisions to Standards or may request a current and effective copy of the Standards by sending a request to standards@aatb.org.

II. Recommended Elements of a Quality Agreement

The AATB Standards have specific expectations defined to address the presence and content of Quality Agreements for tissue establishments. Quality Agreements should describe the following elements for the supplier and the company, as appropriate.

- Scope of the Agreement
- List of regulatory references for performance
- Definitions of quality terms
- Regulatory and quality compliance
- Communication and notification of reportable events
- Procedures and change management
- Facilities management and control
- Equipment and supplies management and control
- Product-specific considerations
- Laboratory controls
- Deviation and non-conformance management
- Tracking and traceability
- Written agreements/contracts
- Audits
- Contracted and non-contracted laboratory testing services

- Construction of records
- Donor screening and relevant medical records review and information sharing
- Purchasing controls and subcontracting
- Terms of agreement

III. Recommendations

- Organizations should evaluate their current policies and quality systems to ensure that terms within the quality agreement are captured appropriately.
- Draft quality agreements should be reviewed by the organization's legal team to ensure alignment with legal policies and compliance framework.

IV. Other Considerations

When developing the quality agreement with your supplier/service provider, consider the following:

- The organizations should include elements in the agreement specific to them and to their supplier.
- An organization may have more than one quality agreement for a supplier/service provider if more than one type of service is provided. Examples of this kind of arrangement care those between:
    - Recovery Tissue Bank and Processor
    - Recovery Tissue Bank and Testing Facility
    - Processor and Distributor
    - Processor and Sterilizing Facility
    - Processor and Subcontractor
- The Quality Agreement should be discussed with each supplier/service provider before obtaining approval signatures.
- Quality agreements should be evaluated when performing supplier monitoring activities.

V. SAMPLE QUALITY AGREEMENT for a Recovery/Processor Relationship

NOTE 1: Each organization in the partnership will have to decide what quality and/or regulatory elements are to be included. Oftentimes, the depth of the content of communication is based on trust and historical performance. This template is an example that can be used but can also be modified based on agreement between the partners in the relationship.

NOTE 2: The template is an example and is intended to be representative of one type of relationship, i.e., a recovery/processor relationship. Other relationships can use this as a template for the quality agreement that meets the needs of their business relationship, as they will have different specific quality and regulatory expectations.

NOTE 3: The use of "shall" in the example implies requirements of the parties within the hypothetical agreement and does not imply that a user must require certain elements in their own agreements.

ROLES AND RESPONSIBILITIES

The following terms set forth responsibilities for each of [insert Company Name] (referred to in this Agreement as "Company") and [insert Supplier Name] (referred to in this Agreement as "Supplier") with respect to quality activities and identify specific mechanisms and time frames for the resolution of quality issues for a Recovery/Processor Relationship. This Quality Agreement is entered into on [date] ("Effective Date") by and between Company and Supplier.

Section 1. Scope of the Agreement

This Quality Agreement outlines the responsibilities and mutual expectations between the Supplier and Company regarding tissue quality.

Supplier shall comply with the following provisions for all tissues provided by Supplier to Company on or after its effective date.

This Quality Agreement supersedes and replaces the Quality Agreement entered into between Company and Supplier dated [enter date].

In the event of any conflict between the terms of this Quality Agreement and if applicable supply agreement, the terms this Quality Agreement will govern with respect to the quality and regulatory terms.

Section 2. List of Regulatory references for performance

1. Standards for Tissue Banking: American Association of Tissue Banks (AATB) - current version
2. 21 C.F.R. Part 1271: FDA Regulations regarding Human Cells, Tissues, and Cellular and Tissue-Based Products
3. All other applicable international, federal, state, or local regulations or standards as modified from time to time.

Section 3. Definitions of Quality terms

(See potential definitions that could be included in the Quality Agreement at the end of the example agreement.)

Section 4. Regulatory and Quality Compliance

1. Supplier shall provide Company (or their designee) with tissue procured via aseptic recovery, suitable for subsequent processing and distribution for clinical implantation, education, or research, from donors, screened, recovered, stored, and shipped in accordance with:
    a. Applicable AATB Standards
    b. The FDA requirements set forth at 21 C.F.R. Part 1271
    c. All other applicable international, federal, state, or local regulation or standards as modified from time to time.
    d. Applicable Company specifications.

2. Company shall receive, process, store, or distribute tissue in accordance with:
    a. Applicable AATB Standards
    b. The FDA requirements set forth at 21 C.F.R. Part 1271
    c. All other applicable international, federal, state, or local regulation or standards as modified from time to time.
    d. The donor authorization or donor designation disclosure form and any restrictions, limitations or conditions indicated on such forms.

Section 5. Communication and Notification of Reportable Events

1. Required Reporting

Company and Supplier are required to send written notification (email is acceptable) as soon as possible but not to exceed fifteen (15) calendar days following a major change in operations or any contrary event (collectively “Reportable Events”)

a. Regulatory Events, which include, but are not limited to:
    i. Any international, federal, state or local authority action, including but not limited to:
        - Any order to cease manufacturing or recall tissue;
        - Receipt of any FDA Form 483 or state, local or international equivalent where tissue allografts or components of tissue allografts were evaluated or referenced;
        - Receipt of any FDA Warning Letter, Untitled Letter, or an equivalent warning by another federal, state, local or international authority where tissue allografts or components of tissue allografts were evaluated or referenced;
        - 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;
        - All submissions of FDA MedWatch reports or adverse reaction reports originating from another country involving tissue processed or distributed by Company or Supplier (or equivalent report if located outside of the United States); and
        - Any Biological Product Deviation Report (BPDR) submitted to the FDA or equivalent report submitted to an international government authority.
    ii. Any voluntary recall, notification, or market withdrawal of tissue;
    iii. When provided, the FDA Establishment Inspection Report (EIR) or equivalent report from any state, local or international inspection authority;
    iv. Any disease transmission confirmed to be caused by tissue processed and/or distributed by the accredited tissue establishment or applicant; and

b. Major changes, including changes to personnel or operations, including but not limited to:
    i. Changes to key personnel, including:

- The designated representative to the Accredited Tissue Banks Council
- The person designated as the management representative or MwER
- The Medical Director(s)

ii. Change in scope of operations, including changes to the following services and/or activities:
- 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;
- 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;
- Addition of tissue donation activities or services involving living donors when tissue only from deceased donors was previously handled; or
- Addition of tissue donation activities or services involving deceased donors when tissue only from living donors was previously handled.

iii. Change in facilities that affect tissue banking operations such as:
- Expansion;
- Relocation;
- Renovation; or
- Addition or removal of a satellite facility.

c. 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;
d. Subcontracting or assignment of any tissue banking activities to a third party;
e. Legal name change or d/b/a (doing business as) designation; or
f. Dissolution, bankruptcy or insolvency of the tissue establishment.

2. Required Information
   a. Written Notification must be sufficiently detailed to explain the nature and extent of the reportable event to enable Company or Supplier to determine the implications for the establishment's current and future compliance with this quality agreement.
   b. Upon request, the establishment must provide Company or Supplier with summaries of all documents relating to a reportable event. Such summaries include responses by the establishment to all international, federal, state and/or local agencies or authorities until the matter is closed at each level.
   c. Summaries of 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 and identification (e.g., donor number or lot number) of tissue grafts involved;
      - Date of occurrence, date of discovery, and, when applicable, the date reported (e.g. to FDA or HTA);
      - Reason for taking action;
      - Nature (voluntary, mandatory); and
      - Description of corrective action(s) taken and planned to be taken.

Section 6. Procedures and Change Management

1. Company shall notify Supplier of all relevant revisions to Company's requirements. Supplier shall implement all revisions by dates agreed by the parties.

2. If training is required, then the Company is responsible for providing the information and, if necessary, providing the actual training. Otherwise, the Supplier is responsible for completing the training and providing any applicable records. Both parties are responsible for retaining these records.

3. Supplier shall ensure all changes that may impact tissue quality or regulatory status are agreed to by both parties in writing prior to implementation.
    a. Supplier shall ensure this clause is communicated to all sub-tier suppliers.

4. Supplier shall ensure that any change to the Donor Information (Recovery) Form or the Donor Medical History & Behavioral Risk Assessment interview form is provided to Company for review prior to implementation.

Section 7. Facilities Management and Control

1. Supplier shall maintain facility used for the recovery of human tissues and/ or organs in a clean, sanitary, and orderly manner to prevent the introduction, transmission, or spread of communicable diseases.

2. Supplier shall maintain records of cleaning and decontamination activities performed to prevent contamination of HCT/Ps. Records must be retained for three years after their creation and made available for inspection purposes.

Section 8. Equipment and Supplies Management and Control

1. Supplier shall ensure all equipment is calibrated and maintained in accordance with manufacturer's recommendations, regulatory and AATB requirements, and any Company SOPs or other requirements that have been communicated to Supplier.

2. Supplier shall ensure the qualification of suppliers of critical materials and services.

3. Company shall ensure the qualification of suppliers of critical materials and services who are under contract or agreement with Company to provide supplies or services to Supplier.

4. Supplier shall be responsible for performing verification of supplies and reagents selected and purchased directly by Supplier.

5. Company shall be responsible for performing verification of supplies and reagents that Company provides to Supplier or requires Supplier to purchase.

6. Both parties shall provide verification of supplies and reagents as required to the other upon request without unreasonable delay.

7. Both parties shall maintain records of supplies and reagents as required and necessary to ensure the proper investigation and completion of a recall if necessary.

8. Supplier shall use standard surgical preparation with sterile packs, instrumentation, and technique to recover all Tissue in an aseptic or clean fashion.

Section 9. Product-Specific Considerations

1. Recovery environment
2. Packaging Requirement

3. Labeling Requirements
4. Etc.

Section 10. Laboratory Controls

1. Supplier shall only use Clinical Laboratory Improvement Amendments ("CLIA") certified and FDA registered laboratories for tissue donor microbiologic and infectious disease testing and approved for use by Company for testing performed on tissue provided to Company.

2. Supplier shall maintain copies of such laboratories' current certifications and registrations and shall make these available to Company upon request.

3. Supplier shall provide to Company with each donor test report a listing of all infectious disease test kits used by its laboratory or laboratories from which it accepts test results. Supplier shall inform the Company when changes to test kits and methods are known to occur that will affect Company.

4. Supplier shall provide to Company results of all required microbiologic and infectious disease testing, as evidenced by (i) copies of original test reports, or (ii) provision of microbiologic and/or blood samples to Company for testing to be performed or initiated by Company. Company shall provide Supplier with documentation attesting to CLIA certification and FDA registration for any donor testing laboratory services when requested.

Section 11. Deviation and Non-conformance Management

1. In the event of a deviation (defined below) associated with donor screening, testing, storage, recovery, or shipping processes, the Supplier shall conduct an investigation and implement corrective actions to prevent the recurrence of the deviation and verify the effectiveness of corrective actions. “Deviation” shall be defined as a departure, whether or not intentional, from a procedure, AATB Standards, or governmental regulations during donor screening, testing, recovery, quarantine, labeling, storage, or shipping of Tissues that may affect performance, biocompatibility, or freedom from transmissible pathogens of the Tissue or the ability to trace Tissue to the donor.

2. Upon reasonable request by Company, the Supplier shall provide documentation of such activities to Company.

3. The Supplier shall notify Company Quality department as soon as possible after discovery of the deviation.

4. Company shall be responsible for determining the suitability of tissue associated with a deviation.

Section 12. Tracking and Traceability

Supplier shall ensure that all tissues, specimens, and records are labeled appropriately, and labeling is performed concurrently with recovery activities.

Section 13. Written Agreements/Contracts

1. Company and Supplier shall have written agreements or contracts with all other individuals or organizations that perform or for whom they perform tissue banking activities or services such as, but not limited to:
    a. Donor referral
    b. Authorization

c. Informed consent
d. Donor eligibility assessment
e. Recovery, collection, and/or acquisition
f. Post-delivery functions
g. Laboratory services
h. Testing services
i. Processing
j. Storage
k. Tissue Release
l. Distribution
m. Consignment

2. Written agreements or contracts shall indicate the nature of the relationship, division of tasks performed, division of issues of liability, specific responsibilities of each party and a summary of the protocols and procedures relating to the services provided.

Section 14. Audits

1. Both parties shall allow the other to conduct on-site audits at the requesting party's expense during normal business hours and upon reasonable frequency and notice, to assess compliance with all applicable AATB Standards, government regulations, procedures, and contractual obligations.

2. Supplier shall allow Company to review Supplier's compliance by observing Supplier's processes, review of applicable records or documents, and interviewing and discussing with personnel of Supplier any matters relating to the screening, testing, storage, recovery, or shipping of tissue. Supplier hereby agrees to provide such access to Company employees and other representatives and to cooperate with Company in connection therewith.

3. All such access shall be at reasonable, mutually agreeable times and subject to the supervision of Supplier personnel.

4. Supplier shall develop and provide a written corrective/preventive action plan for any non-conformances identified within thirty (30) days of written notification from Company, or as soon thereafter as reasonably practicable if conditions warrant a longer period.

5. Supplier shall perform routine internal audits to monitor compliance with written procedures and activities related to core cGTPs and AATB Standards (e.g., authorization, donor risk assessment interviews). Evidence of audit activities shall be made available to Company upon reasonable request.

6. Company shall allow the Supplier to review Company compliance through Supplier’s review of applicable records or documents and interviewing and discussing with personnel of Company any matters relating to the processing and distribution of tissue. Company hereby agrees to provide such access to Supplier's employees and other representatives and to cooperate with Supplier in connection therewith. All such access shall be at reasonable, mutually agreeable times and subject to the supervision of Company personnel.

7. Company shall develop and provide a written corrective/preventive action plan for any cited non-conformances within thirty (30) days of written notification from Supplier, or as soon thereafter as reasonably practicable if conditions warrant a longer period.

Section 15. Contracted and Non-contracted Laboratory Testing Services

1. Prior to subcontracting any services related to Supplier's tissue recovery, equipment sterilization or donor screening, Supplier shall:

a. Qualify all subcontractors according to an established procedure and exert controls and/or oversight necessary to ensure that all activities are performed in accordance with the agreement.
b. Obtain Company written consent to the subcontracting arrangement, which consent shall not be unreasonably withheld.

2. Prior to Company subcontracting any tissue processing services related to Tissue sent by the Supplier, Company shall obtain prior written consent from the Supplier, which consent shall not be unreasonably withheld.

Section 16. Construction of Records

1. The Supplier shall maintain records to ensure traceability and proper storage of tissues from recovery to shipment to Company.

2. The Supplier shall store, and ship recovered tissue in accordance with Company SOPs and regulatory and AATB requirements.

3. The Supplier and Company shall maintain and store records according to AATB Standards and applicable federal and state regulations, whichever is more stringent. Examples of records include donor records, equipment records, validation records, and training records.

4. Both Parties shall use Good Documentation Practices to make corrections to quality records and clearly identify by whom and when documentation was modified.

5. Copies of all recovery documentation will be maintained for a period of ten (10) years following the recovery of human tissues and/or organs or as otherwise specified in 21 CFR 1271.270(d), AATB Standards, or other applicable requirements.

6. Make records related to the recovery of the human organ/ tissue, including requested donor record, instrumentation records, etc., available for Company during an on-site audit.

7. Maintain and supply, upon request, documentation that supports the transportation of human tissues and/or organs on behalf of Company.

Section 17. Donor Screening and Relevant Medical Records Review and Information Sharing

1. Supplier shall provide Company with documentation necessary for Company to determine the suitability of tissue (the "documentation"). This documentation (both initially from the time of referral/donation and any subsequent updated information) shall include, at a minimum:

a. Donor's medical, social, and behavioral risk assessment.
b. Hospital records related to the donor eligibility determination (e.g., test reports, evaluations, treatments, etc.).
c. Final infectious disease test results.
d. Final microbiology results, if applicable.
e. Autopsy report, if performed.
f. Post-recovery deferral or discard notices from other tissue processors.
g. Donation authorization in accordance with all applicable local, state, federal, and AATB requirements.
h. Any other document or information that Supplier becomes aware of that could potentially influence the donor eligibility determination.

2. Both parties shall notify each other (with confirmed receipt of information) of any repeatedly reactive, confirmed positive infectious disease test result within one (1) business day of receipt of the test results relating to allograft tissue produced from donor tissue supplied by Supplier to Company.

3. If the Supplier provides revised or updated donor records to Company, the records shall be transmitted in a manner that clearly identifies changes to previously transmitted documentation.

4. If Supplier becomes aware of additional information that is likely to have an impact on the tissue donor eligibility determination, Supplier shall immediately or within 2 business days from receipt of the additional information notify Company Quality department via phone and/or in writing (which includes via email).

5. Company shall notify the Supplier of any tissue donor that has been determined to be unsuitable for transplantation and include the reasons for the determination.

Section 18. Purchasing Controls and Subcontracting

1. Company and Supplier shall establish and maintain processes to ensure that all purchased or otherwise received products and services, including testing services, conform to specified requirements.

2. Company and Supplier shall establish and maintain the requirements, including quality requirements, that must be met by their suppliers, contractors and consultants.

3. Prior to subcontracting any services related to Supplier's tissue recovery, equipment sterilization or donor screening, Supplier shall obtain Company’s written consent to the subcontracting arrangement. Consent shall not be unreasonably withheld.

Section 19. Terms of Agreement

1. Agreement duration (sunset clause)

2. Periodic Review of agreement

3. Signatures and dates of responsible individuals

VI. EXAMPLE Quality Agreement Responsibility Table – This example is not inclusive of all requirements. Your Quality Agreement should be updated based on your specific business relationship with your supplier.

*[*Recommendations of assignability are indicated in parentheses at the end of each line item. Assignments may include department names and level of responsibility (e.g., RACI, RAPID) may be listed.]*

Responsibilities **(Note: Ensure to incorporate AATB specific requirements throughout)**	***Company Name***	**Supplier Name (*Supplier*)**
Regulatory and Quality Compliance		
Compliant to AATB Standards, current version	(functional group, checkmark, yes/no, etc.)	(functional group, checkmark, yes/no, etc.)
Compliant to 21 CFR 1271		
Communication and Notification of Reportable Events		
Any order to cease manufacturing or recall tissue		
Changes to key personnel		
Procedures and Change Management		
Facilities Management and Control		
Equipment and Supplies Management and Control		
Product-Specific Considerations		
Laboratory Controls		
Deviation and Non-conformance Management		
Tracking and Traceability		
Written Agreements/Contracts		
Audits		

Contracted and Non-contracted Laboratory Testing Services		
Construction of Records		
Donor Screening and Relevant Medical Records Review and Information Sharing		
Purchasing Controls and Subcontracting		
Terms of Agreement		

Quality Contact Information: [list all appropriate staff of Company and Supplier responsible for abiding by this Agreement]

Communication Type	***Company*** **Contact Name**	**Contact Information**
Deviations		
Complaints/ Feedback/ Adverse Reactions		
Specification/ Procedure Changes		
Regulatory Notifications/ Audits		
Reactive Communicable Disease Test Results		

Communication Type	**Supplier Contact Name**	**Contact Information**
Complaints/ Feedback/ Adverse Reactions		
Specification/ Procedure Changes		
Compliance Notifications/ Audits		

Communication Type	Supplier Contact Name	Contact Information
Reactive Communicable Disease Test Results		
Site Management		

Definitions- [example terms to be defined in a Quality Agreement]

Term	Definition
Adverse outcome	An undesirable effect or untoward complication in a recipient consequent to or reasonably related to tissue transplantation.
Audit	A documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or suppliers to evaluate adherence to the written SOPM, standards, applicable laws and regulations.
Clinical project	Any research project that is or can be regulated by or reported to the FDA.
Complaint	Any written, electronic, or oral communication concerning dissatisfaction with the identity, quality, packaging, durability, reliability, safety, effectiveness, or performance of tissue.
Corrective Action	Action to eliminate the cause and prevent recurrence of a nonconformity or other undesirable situation; may be performed in conjunction with preventive action(s).
Deviation	An event that is a departure from a regulation, standard, procedure or normal practice, see error.
Human cells, tissues, or cellular or tissue-based products (HCT/Ps)	Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer to a human recipient.
Nonconformity	A finding that identifies non-fulfillment of an accreditation requirement, a standard, policy, process, procedure, or specification.
Out of Specification Results (OOS)	A test result that falls outside of established specifications or acceptance criteria
Preventive Action	Action to eliminate the cause of a potential nonconformity or other undesirable situation in order to prevent occurrence; may be performed in conjunction with corrective action(s).
Record	Information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
Recovery	Obtaining tissue other than reproductive tissue from a donor that is intended for use in human transplantation, therapy, research or education.

Term	Definition
Relevant Medical Records	A collection of documents including a current donor risk assessment interview, a physical assessment/physical examination, laboratory test results (in addition to results of testing for required relevant communicable disease agents), relevant donor records, existing coroner and autopsy reports, a certified copy or verified copy of the death certificate (when applicable), as well as information obtained from any source or records which may pertain to donor eligibility regarding high-risk behaviors, and clinical signs and symptoms for any relevant communicable disease agent or disease (RCDAD), and/or treatments related to medical conditions suggestive of such risk.
Significant Changes	Any changes, which, if implemented, could result in an outcome different from that intended and/or proven through process validation/qualification. This would include changes, such as, but not limited to: donor screening/acceptance criteria, donor preparation methods or chemicals, storage requirements, recovery methods, etc.
Specification	A list of tests, references to analytical procedures, and appropriate acceptance criteria which are numerical limits, ranges or other criteria for the tests described
Standard Operating Procedures Manual (SOPM)	A group of standard operating procedures (SOPs) detailing the specific policies of a tissue bank and the procedures used by the staff/personnel to carry out the functions of the tissue bank.
Validation	Confirmation through the provision of documented objective evidence that predefined specifications have been fulfilled and can be consistently reproduced.

Signature and Execution

_____ _____

Name & Title, Supplier Date

_____ _____

Name & Title, Company Date

Version, date	Description of changes
2, June 1, 2025	Converted from an Educational Resource Tool to a Standards Supplement
1, March 1, 2024	First release