

# American Association *of* Tissue Banks

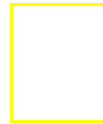
Self-assessment *T*ool / *A*udit *R*eport (STAR)

## TISSUE DISTRIBUTION INTERMEDIARY

Based on AATB *Standards for Tissue Banking*, 2008, 12<sup>th</sup> Edition

Includes Changes (in blue) from:

- AATB Accreditation Policies



November 2011

**Check one**

## AUDIT CONFIRMATION

- Internal Audit of Tissue Bank      Audit Date(s): \_\_\_\_\_
- External Audit of Outside Entities      Audit Date(s): \_\_\_\_\_

**For External Audits:**

Name and address of outside facility audited:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**This Audit Confirmation (page i) is to be submitted to AATB as follows:**

- 1. Internal audit of facility – By January 31 each year.**
- 2. External Audit of outside organization(s) – Submit with the completed Accreditation Application only when applying or reapplying for accreditation. One Audit Confirmation (page i) must be submitted for each entity audited.**

**ONLY submit the Audit Confirmation (page i); do NOT submit the completed audit form.**

Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Individual Completing the Audit Confirmation	Title	Telephone
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Signature of Person Completing the Audit Confirmation	Date
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Activities audited: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**PLEASE MAKE A COPY OF THIS PAGE AND COMPLETE FOR EACH ENTITY AUDITED**  
Submit to: AATB, 1320 Old Chain Bridge Rd, Ste. 450, McLean, VA 22101

# INSTRUCTIONS FOR COMPLETING THE STAR

## USES:

This Self-assessment Tool/Audit Report (STAR) was developed by the American Association of Tissue Banks (AATB) and must be used for the following activities. Written confirmation of its completion must be submitted to the AATB as outlined below:

- Performing an internal audit of the facility
- Performing external audits of facilities that perform activities or services for the facility.

**INTERNAL AUDIT:** As stated in item I.C. of the AATB *Accreditation Policies*, each accredited facility must complete the STAR, annually. If you have a form for internal audits that you believe is comparable to the STAR that you wish to use instead, you may submit a copy of the form to AATB for review. If AATB determines that your form is equivalent, we will notify you that your form may be used instead of the STAR. Only forms that have been approved for use by AATB may be substituted for the STAR. However, you still must submit the Audit Confirmation (page i of the STAR) to document that the audit was performed. The STAR (or your approved audit form) is to be completed and retained on file at the facility to document that the audit was completed.

**EXTERNAL AUDIT:** The AATB *Standards for Tissue Banking* indicates that before executing a contract, agreement, or other arrangement with an entity to perform any activity, the accredited tissue bank must ensure that the entity will comply with applicable AATB standards, federal regulations, and applicable state or local laws. Thereafter, the accredited tissue bank is responsible for certifying biennially, that the activities or service(s) performed by others have been performed in conformance with the *Standards*, federal regulations, and applicable state or local laws. This must be documented on a form provided by AATB (STAR), or pre-approved by the AATB Accreditation Program Manager. The verification of activities or services for others shall be documented (e.g. a paper audit, on-site audit, on-site inspection, etc.). Regardless of whether the facility performing activities or services for others is accredited by AATB, it is the responsibility of the tissue bank receiving those services/activities to periodically verify that procedures related to the activities/services performed are in compliance with the AATB *Standards*, federal regulations, applicable state or local laws, and the written agreement/contract. The information regarding the systems reviewed shall be provided to AATB inspectors upon request.

If you use a form for external audits that you believe is comparable to the STAR that you wish to use instead, you may submit a copy of the form to AATB for review. If AATB determines that your form is equivalent, we will notify you that your form may be used instead of the STAR. However, you still must submit the Audit Confirmation (page i of the STAR) to document that the audit was performed. Only forms that have been approved for use by AATB may be substituted for the STAR. The STAR (or your approved audit form) is to be completed and retained on file at the facility to document that the audit(s) was completed.

## COMPLETING THE FORM:

- Mark the appropriate response “Yes  No  N/A . If the entire section does not apply, mark the N/A box ( at the top of the section).
- Indicate, in each section, your procedure number(s) and SOPM volume number, or where the standard is addressed in other facility documents.
- If desired, you may use other forms in conjunction with the STAR.
- Attach additional pages if necessary.
- Photocopy the STAR and the Audit Confirmation (page i) as needed.

**AATB STANDARDS SECTION B  
GENERAL ORGANIZATIONAL REQUIREMENTS OF A TISSUE BANK**

N/A

**B1.000 GENERAL INSTITUTIONAL REQUIREMENTS**

A – Autologous; C – Cardiac; V – Vascular; MS – Musculoskeletal; OA – Osteoarticular; S – Skin;  
SB – Surgical Bone; LD - Living Donor; DM – Dura Mater

**B1.100 Purpose, Institutional Identity, and Affiliations (Mission Statement)**

Does the contracting facility maintain a mission statement? Yes  No  N/A

**B1.200 Governing Body**

Does the bank have a governing Body? Yes  No  N/A

If yes, what type? Board of Trustees \_\_\_\_\_ Board of Governors \_\_\_\_\_ Board of Directors \_\_\_\_\_

Who is the designated responsible individual in whom policy-making authority resides?  
\_\_\_\_\_

**B1.300 Medical Scientific Support**

Is there a mechanism to access medical, technical, and scientific data? Yes  No  N/A

Where do you document decisions resulting from medical, technical, or scientific advice?  
\_\_\_\_\_

**B1.400 Satellite Facilities**

N/A

Do the satellite facilities operate according to your SOPM? Yes  No  N/A

Review audits of your satellite facilities to make sure they are operating according to your SOPM, Standards, federal regulations, applicable state or local laws, and the written agreement/contract (if applicable).

Show the administrative relationships on your bank's organizational chart.

**B1.500 Multi-Facility Tissue Banking**

N/A

Are the responsibilities between the tissue bank and the contracting facility(ies) clearly documented and available for review? Yes  No  N/A

How do you ensure the contracting facility(ies) comply with AATB *Standards*?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**B1.510 Written Agreements/Contracts**

Does the bank have a written agreement/contract with each organization that performs or for whom they perform donor screening/acceptability services, tissue retrieval, processing, or distribution? Yes  No  N/A

Do banks that determine donor suitability develop and maintain policies and procedures that clearly describe donor records deemed relevant to their operations?

Yes  No  N/A

Does the contract with the tissue bank include the following:

- Nature of the relationship Yes  No  N/A
- Division of tasks performed Yes  No  N/A
- Division of issues of liability Yes  No  N/A
- Specific responsibilities of each party Yes  No  N/A
- Summary of the protocols and procedures relating to the service provided Yes  No  N/A
- Reference to *AATB Standards as applicable* Yes  No  N/A
- Requirement to have a Medical Director Yes  No  N/A
- Requirement to share information in a timely fashion Yes  No  N/A

Review the contract(s)

**Bl.521 Inspections/Audits of Other Facilities**

Do you ensure that all other tissue banking organizations under contract, agreement, or other arrangement, performing activities/services for you, comply with AATB *Standards*, federal regulations, and applicable state and/or local laws, before executing a contract or agreement with them?

Yes  No  N/A

Is a paper audit, on-site audit, and/or inspection conducted of activities performed for you by other tissue banking organizations?

Yes  No  N/A

Are audits/inspections of non-AATB-accredited banks performed at least biennially and is documentation maintained?

Yes  No  N/A

Are audits/inspections of AATB-accredited banks performed periodically, and is documentation maintained?

Yes  No  N/A

What do you do if you are lead to believe that the entity performing activities/services for you may no longer be in compliance with *AATB Standards*, federal regulations, applicable state and/or local laws?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Do you terminate the agreement/contract if it is determined that the entity will not comply with requirements?

Yes  No  N/A

Review audit schedule and audits/inspections for those entities who provide activities/services to you?

**B2.000 FUNCTIONAL COMPONENTS OF A TISSUE BANK**

**B2.100 Tissue Bank Director**

**B2.110 Qualifications**

**B2.120 Tissue Bank Director Responsibilities**

**B2.121 General**

**B2.122 Personnel**

Is there a current organizational chart delineating the functions of each staff member within the organization? Yes  No  N/A

Review the organizational chart.

Are the job descriptions documented and current? Yes  No  N/A

✓ Randomly select two job descriptions.

Name of Staff \_\_\_\_\_  
Job Description \_\_\_\_\_  
Last review date \_\_\_\_\_

Name of Staff \_\_\_\_\_  
Job Description \_\_\_\_\_  
Last review date \_\_\_\_\_

Does the Director attend an AATB meeting or workshop at least once every three years, obtain at least 15 CEUs/CMEs, and is this documented? Yes  No  N/A

**B2.123 Implementation and Evaluation of Donor Suitability Assessment Criteria and of all Technical Policies and Procedures**

Is the Director or designee responsible for reviewing and approving all technical policies and procedures? Yes  No  N/A

How is the review and approval accomplished?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

How does the Director ensure compliance with all applicable federal, state, and/or local laws and/or regulations?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Are standard procedures prepared by another organization utilized by the bank? Yes  No  N/A

How do you verify that these procedures are consistent with, and at least as stringent as, AATB *Standards*?  
\_\_\_\_\_  
\_\_\_\_\_

**B2.124 Quality Assurance Program**

Is an annual internal audit/review performed and documented to ensure compliance with current SOPs, federal, state, and/or local laws and/or regulations and *AATB Standards*? Yes  No  N/A

Who performs the annual audit/review?  
\_\_\_\_\_

Is the STAR used as the internal audit form? Yes  No  N/A

If no, when was your audit form approved by the AATB? \_\_\_\_\_

- Review the most recent internal audit.
- Review the audit schedule.

Date of last audit \_\_\_\_\_

**B2.200 Medical Director** N/A

**B2.210 Qualifications**

Does the tissue bank have a Medical Director who is a licensed physician in the United States or abroad? Yes  No  N/A

Medical Director name \_\_\_\_\_

Is the Medical Director's license current? Yes  No  N/A

Does the Medical Director attend an AATB meeting or workshop at least once every three years, obtain at least 15 CMEs/CEUs, and is this documented? Yes  No  N/A

**B2.220 Responsibilities**

**B2.221 Donor Suitability Criteria**

Has the Medical Director reviewed and approved the donor suitability criteria? Yes  No  N/A

Does the Medical Director evaluate and determine each donor's acceptability prior to release of cells and/or tissue? Yes  No  N/A

How does the facility ensure that all SOPs that are medical in nature are reviewed and approved by the Medical Director?  
\_\_\_\_\_  
\_\_\_\_\_

**B2.222 Adverse Outcomes**

Has the Medical Director established policies and procedures regarding investigating and documenting adverse outcomes? Yes  No  N/A

Are corrective actions documented? Yes  No  N/A

Are final summary reports reviewed and approved by the Medical Director? Yes  No  N/A

**B2.300 Technical Staff** N/A

**B2.310 Qualifications**

How do you ensure that staff has the appropriate education, experience, and training to perform assigned tasks?

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**B2.320 Responsibilities**

Are the duties of each staff member described in a written job description?

Yes  No  N/A

**B2.400 Quality Assurance Program**

Does the tissue bank maintain a quality assurance program?

Yes  No  N/A

What function(s) is(are) the quality assurance department currently performing?

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**B2.410 Staff Qualifications**

Is an individual, not directly responsible for the performance of operations, responsible for the quality systems review?

Yes  No  N/A

To whom does this individual report?

Name \_\_\_\_\_ Title \_\_\_\_\_

What are this person's responsibilities?

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**B2.420 Staff Responsibilities**

Do Quality Assurance Program personnel have responsibility for assuring compliance with SOPM and regulatory requirements?

Yes  No  N/A

How do Quality Assurance Program personnel ensure compliance with SOPM and regulatory requirements?

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What quality system review process is established to approve or reject donor cells and/or tissue?

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Review quality system review of donor tissue procedure.

**AATB STANDARDS SECTION C  
RECORDS MANAGEMENT**

N/A

**C1.000 RECORDS MANAGEMENT**

N/A

**C1.100 Records Management – General**

How do you ensure that required records are maintained and that they are accurate and complete?

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**C1.120 Electronic Records**

Are records maintained electronically? Yes  No  N/A

If yes, how do you ensure data integrity is maintained and information is available?

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Can electronic records be printed as a hard copy? Yes  No  N/A

**C1.200 Availability for Inspection**

Are donor records (including electronic records) readily available for inspection? Yes  No  N/A

**C1.300 Retention**

What is the record retention policy?

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How are archived records stored?

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Is this an environment that will preserve the records? Yes  No  N/A

Are they stored according to applicable laws and regulations? Yes  No  N/A

**C1.400 Traceability**

Is a unique donor identifier assigned? Yes  No  N/A

How does the tissue bank ensure that tissue is traceable to the consignee and back to the bank distributing the tissue to you?

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Are cells and/or tissue consigned to a non-accredited entity? Yes  No  N/A

If yes, how do you ensure that the non-accredited entity complies with requirements of Section C in the AATB *Standards for Tissue Banking*?

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**C1.500 Revisions**

Does the procedure regarding revisions include the following requirements:

- A single line is drawn through altered text. Yes  No  N/A
- Revisions are initialed and dated by the individual making the revision. Yes  No  N/A
- Additions to completed records are initialed and dated by the person making the addition. Yes  No  N/A

**C2.000 CONSTRUCTION OF RECORDS**

N/A

Are donor charts assembled in a uniform manner? Yes  No  N/A

Are relevant medical records reviewed for completeness and accuracy before release of cells and/or tissue? Yes  No  N/A

Are records in English, or if in another language, translated into English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document? Yes  No  N/A

How do you ensure that you do not utilize documentation related to consent/ authorization or donor risk assessment that are obtained by unauthorized parties?

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Are authorized parties identified in agreements and are personnel performing these functions qualified, trained, and competent? Yes  No  N/A

Review record construction procedures.

Are autologous tissue records maintained in a separate log, or if incorporated into general records, maintained in such a manner that the autologous tissue may not be released for non-autologous use? Yes  No  N/A

Do cardiac records meet the general criteria and also include:

- ABO/Rh if available Yes  No  N/A
- Date/time of asystole Yes  No  N/A
- Date/time of retrieval of heart (time when subjected to cold rinse solution) Yes  No  N/A
- Date/time subsection of cardiac allograft tissue to disinfection solution Yes  No  N/A
- Start & stop times when tissue subjected to disinfection solution Yes  No  N/A
- Date/time when preservation began and when placed in the final container Yes  No  N/A

Do vascular records meet the general criteria and also include:

- ABO/Rh if available Yes  No  N/A
- Date/time of asystole Yes  No  N/A
- Date/time vascular tissues subjected to perfusion solution Yes  No  N/A
- Date/time vascular tissues placed in transport solution and subjected to wet ice temperatures Yes  No  N/A
- Date/time of subjection of vascular tissue to disinfection solution Yes  No  N/A
- Start and stop times when tissue subjected to disinfection solutions Yes  No  N/A
- Date/time when preservation began and when placed in the final container Yes  No  N/A

**AATB STANDARDS SECTION J  
GENERAL OPERATIONS**

N/A

**J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)**

N/A

**J1.100 Purpose and Design**

Is there a documented system governing the format for and control over policies/procedures? Yes  No  N/A

Review document system procedure.

**J1.200 Contents**

Are the facility's SOPM contents complete? (See J1.200 list of SOPM contents). Yes  No  N/A

Review the SOPM for completeness.

**J1.300 Implementation**

Does the tissue bank have a standard method for handling deviations from written protocol? Yes  No  N/A

**J1.400 Modifications**

When procedures are modified, are modifications approved by the Director or Medical Director? Yes  No  N/A

Prior to implementing new procedures, is training provided to staff? Yes  No  N/A

Is the nature and date of the procedure change identified on the cover sheet or other associated document? Yes  No  N/A

**J1.500 References**

How does the facility ensure that copies of publications cited in support of policies or procedures are maintained at the tissue bank?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**J1.600 Annual Review**

Is an annual review of policies and procedures performed and documented by appropriate individuals? Yes  No  N/A

Who performs the review?  
\_\_\_\_\_  
\_\_\_\_\_

Review SOPs for last review date. \_\_\_\_\_  
(Last review date)

**J1.700 Staff Access and Review**

Are pertinent and current procedures/policies available to applicable employees at all times? Yes  No  N/A

Where are the designated locations for these policies and procedures?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

How are employees updated/trained on changes to procedures?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**J1.800 Inspections**

Is the SOPM made available for inspection upon request by the AATB or authorized regulatory agencies? Yes  No  N/A

**J1.900 Archives**

Is there a master list or equivalent control system identifying the current revision status of documents in order to preclude the use of obsolete documents? Yes  No  N/A

Is a file of archived SOPs maintained in historical sequence for 16 years after discontinuation? Yes  No  N/A

Do the archived procedures indicate the dates that each procedure was in use? Yes  No  N/A

Review the archive system.

✓ Randomly review two archived procedures

Procedure reviewed \_\_\_\_\_ Procedure reviewed \_\_\_\_\_

**J2.000 TECHNICAL AND QUALITY ASSURANCE STAFF – TRAINING/CONTINUING EDUCATION**

N/A

**J2.100 Training**

Does the tissue bank maintain and administer a new employee orientation program? Yes  No  N/A

Is there a training program to train technical and QA Staff regarding applicable federal and state regulations, AATB Standards, and internal procedures?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Does training for technical and QA staff include:

SOPM

Yes  No  N/A

Technical training

Yes  No  N/A

QA

Yes  No  N/A

Computer?

Yes  No  N/A

Review the attendance list of the last technical staff training session.

\_\_\_\_\_

- Review employee records for evidence of continuing education and competency testing.

### J2.200 Competency

Is the technical staff required to demonstrate specific levels of competency? Yes  No  N/A

How do staff demonstrate competency?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### J2.300 Continuing Education

What continuing education is offered to staff?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### J2.400 Training Records

- ✓ Randomly select two training files for review of the following contents:

- Training checklist
- Description of functions employee is authorized and trained to perform
- Documentation of training to applicable SOPs
- Annual review of policies and procedures
- Annual attendance for hazardous materials training / safety training (where applicable)
- Any continuing education records

Name of Staff \_\_\_\_\_

Position \_\_\_\_\_

Date of Hire \_\_\_\_\_

Name of Staff \_\_\_\_\_

Position \_\_\_\_\_

Date of Hire \_\_\_\_\_

## J3.000 SAFETY PRACTICES

N/A

### J3.100 Work Environment

Are safety procedures included in the SOPM or in a separate safety manual, which is referenced in the SOPM?

Yes  No  N/A

**J3.200 Procedures**

Does the safety program include the following:

- Instructions for contacting emergency personnel Yes  No  N/A
- Evacuation routes and procedures in the event of fire or natural disaster Yes  No  N/A
- Procedures for the management of worker injury Yes  No  N/A
- Incident report procedures (record of medical care received, management notification, and actions to prevent recurrence.) Yes  No  N/A
- Universal Precaution training Yes  No  N/A
- Maintenance of MSDS (Material Safety Data Sheets) Yes  No  N/A
- Storage, handling, and utilization of hazardous materials Yes  No  N/A
- Cleaning biohazard us spills Yes  No  N/A

**J3.300 Hazardous Materials Training**

Is the training program designed to inform employees about chemical, biological, and radioactive hazards of the workplace as well as the use of personal protection devices? Yes  No  N/A

**J3.400 Universal Precautions**

Are universal precautions implemented and enforced? Yes  No  N/A

**J3.500 Immunization**

Is the Hepatitis B vaccination offered to those employees whose job related responsibilities involve potential exposure to blood-borne pathogens? Yes  No  N/A

What is the protocol if an employee is exposed to Hepatitis B?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**J3.600 Hazardous Waste Disposal**

What is the standard protocol for disposal of hazardous waste?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

How do you ensure hazardous waste is disposed of in accordance with applicable federal, state, and local regulations in a manner to minimize environmental impact and exposure of personnel?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**J4.000 FACILITIES**

N/A

**J4.100 General**

Is the facility (physical plant) arranged to meet operational needs? Yes  No  N/A

Are the premises:

Well maintained Yes  No  N/A

Clean Yes  No  N/A

Is there adequate:

Plumbing Yes  No  N/A

Drainage Yes  No  N/A

Lighting Yes  No  N/A

Ventilation Yes  No  N/A

Space Yes  No  N/A

**J4.200 Designated Space**

Are critical procedures listed below performed in designated areas?

Processing Yes  No  N/A

Quarantine storage Yes  No  N/A

Labeling Yes  No  N/A

Storage of distributable inventory Yes  No  N/A

Quality assurance/control functions Yes  No  N/A

Receipt and storage of containers Yes  No  N/A

Container labels Yes  No  N/A

Supplies and reagents Yes  No  N/A

Storage of medical waste Yes  No  N/A

Irradiation and other sterilization procedures Yes  No  N/A

Final product inspection and distribution Yes  No  N/A

Record storage Yes  No  N/A

**J4.210 Routine Cleaning**

Does the facility perform retrieval, processing, preservation or other activities where there is potential for cross-contamination or exposure to blood-borne pathogens?

Yes  No  N/A

Is routine, scheduled, documented cleaning performed?

Yes  No  N/A

**J4.300 Environmental Monitoring**

Have environmental monitoring procedures been implemented? Yes  No  N/A

How are the environmental monitoring activities documented and trended?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

What is the classification of the rooms used for retrieval, processing, and/or preservation? (airborne particulate cleanliness class)  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

*Please Note: The following questions are focused at a contamination control program. If a contamination control program is not instituted, proceed to section J5.000 – Equipment.* N/A

What methods are used for sampling? (particulate air sampling: non-viable vs. viable, surface cultures, RODAC touch plates)  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Is there a protocol for investigation and/or corrective action at pre-determined alert and action levels?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Review environmental monitoring program.

**J4.400 Security**

Is adequate security provided? Yes  No  N/A

**J5.000 EQUIPMENT**

N/A

**J5.100 Selection**

How does the facility ensure that equipment is appropriately sized, designed, and located to facilitate use, cleaning and maintenance?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**J5.200 Operation**

Is equipment operated according to manufacturer’s recommendations? Yes  No  N/A

**J5.300 Qualification and Maintenance**

What routine maintenance/inspection is performed on the retrieval instruments?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Are equipment maintenance files maintained? Yes  No  N/A

Are these files subject to a QA audit/review? Yes  No  N/A

**J5.310 Requalification/Recalibration**

Following repairs or system upgrades, is equipment requalified and/or recalibrated? Yes  No  N/A

**J5.400 Decontamination/Sterilization**

Is equipment for sterilizing materials used in cells and/or tissue retrieval, processing, or packaging designed, qualified, maintained, and utilized to ensure adequate function? Yes  No  N/A

How does the facility ensure equipment functions as intended?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Do you recover and/or process dura mater, vertebral bodies, and/or ocular tissue? Yes  No  N/A

If yes, are instruments used to recover and/or process this tissue removed or destroyed if involved in tissue from a donor known or suspected of having a prion-associated disease? Yes  No  N/A

**J5.500 Storage Unit Identification**

Is each unit used for storage of cells and/or tissue identified to facilitate monitoring of temperature and location of in-process quarantine and distribution inventory? Yes  No  N/A

**AATB STANDARDS SECTION K  
QUALITY ASSURANCE**

N/A

**K1.000 QUALITY ASSURANCE PROGRAM**

N/A

Dose the bank maintain a Quality Assurance (QA) program? Yes  No  N/A

**K1.100 Basic Elements**

Are the following elements included in the QA Program, where appropriate?

- 1) Quality Control functions
    - a) **Environmental monitoring** (J4.300) Yes  No  N/A
    - b) **Equipment and facility inspections** - Performance and documentation in maintenance records/logs of periodic equipment and facility inspections (J5.300 Qualification and Maintenance) Yes  No  N/A
    - c) **Supply and reagent review** - Performing acceptability determinations of supplies and reagents (E1.300 Supplies and Reagents) Yes  No  N/A
    - d) **Equipment monitoring** - review records for maintenance within specified tolerance limits) (J5.300 Qualification and Maintenance) Yes  No  N/A
    - e) **In-process control** - inspection and monitoring (C1.100 – Records Management, General, E1.800- Processing and Preservation Records) Yes  No  N/A
    - f) Monitoring laboratory performance, if applicable Yes  No  N/A
  - 2) **Validation** (shipping container validation) (D5.800 Transportation of Tissue to Processing Center) Yes  No  N/A
  - 3) **Corrective action administration**, (K4.000 Investigation) Yes  No  N/A
  - 4) **QA review** - donor screening, retrieval, and processing records (F1.100 Donor Suitability Review) Yes  No  N/A
  - 5) **Audit performance** (K5.500 Audits) Yes  No  N/A
  - 6) **Error, accident, complaint, adverse outcome, and recall administration** - documentation, and review (K4.000 Investigations) Yes  No  N/A
  - 7) **Labeling controls** - all brochures, pamphlets, and promotional materials (C1.000 Records Management) Yes  No  N/A
  - 8) **Documentation maintenance** - master SOPM, master list of labels, records of names, signatures, initials or identification codes and inclusive dates of employment, reports and conclusions of process validation and equipment qualification studies, records of supply and reagent acceptance, and archived documents (K1.100) Yes  No  N/A
  - 9) **Training** – evaluation of training of personnel and, where possible, the competency of personnel (J2.100 Training, K5.000 Audits) Yes  No  N/A
- Information Sharing** – process for sharing information with other Tissue banks that have recovered and/or received cells and/or Tissues from the same donor Yes  No  N/A

**K1.200 Qualification, Verification, and Validation Requirements**

Are protocols developed, implemented, and documented for the qualification, verification, and validation of significant components? Yes  No  N/A

Who determines which elements will be qualified, verified, or validated?

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**K1.210 Validation of Shipping Containers**

Are qualification studies performed for cryopreserved cardiac and vascular tissue transportation devices and temporary storage methods to ensure required temperatures are maintained?

Yes  No  N/A

**K1.220 Validation Procedures - Packaging and Freezing Protocols**

Are packaging and freezing protocols validated?

Yes  No  N/A

**K2.000 QUALITY CONTROL PROGRAM**

N/A

Is there a quality control program?

Yes  No  N/A

Are the appropriate QC procedures defined?

Yes  No  N/A

**K2.100 Proficiency Testing**

Is appropriate proficiency testing performed?

Yes  No  N/A

What happens if there is poor performance on proficiency testing?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**K4.000 INVESTIGATIONS**

N/A

Does the tissue bank maintain a corrective action procedure?

Yes  No  N/A

What circumstances require corrective action?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Who is responsible for the final review of completed corrective action(s)?

\_\_\_\_\_

Review corrective action procedure. Procedure number \_\_\_\_\_

**K4.100 Errors and Accidents**

How are internal nonconformances reported?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Who is responsible for the investigation into reported nonconformances?

\_\_\_\_\_

Who is responsible for the final review of reported nonconformances?

\_\_\_\_\_

**K4.200 Complaints**

Does the tissue bank maintain a customer complaint system Yes  No  N/A

How are customer complaints documented?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Review customer complaint system and files.

**K4.300 Adverse Outcomes**

Are all reported or suspected adverse outcomes that are potentially related, directly or indirectly, to an allograft investigated thoroughly and expeditiously? Yes  No  N/A

**K4.310 Notifications**

In accordance with applicable federal, state, and local regulations, are confirmed cases of transmissible disease in a recipient reported in writing in a timely fashion to public health authorities, organ retrieval organizations, and appropriate tissue banks? Yes  No  N/A

How do you ensure the reporting to appropriate individuals/entities of confirmed cases of transmissible disease?

\_\_\_\_\_  
\_\_\_\_\_

**K5.000 AUDITS**

**Reference K5.000 Audits**

Are there policies and procedures (P & P) regarding the scope and frequency of internal and external audits? Yes  No  N/A

Cite P&P# \_\_\_\_\_

How do you ensure that these P&Ps are followed?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Does the QA program review donor information for completeness before review by the Medical Director? Yes  No  N/A

Review the donor information evaluation procedures.

**K6.000 COMPUTER/DATA PROCESSING CONTROLS**

N/A

**K6.100 Authorized Access**

How does the facility ensure general access to computer systems is limited to authorized personnel?

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How does the facility ensure changes in master production and control records or other records, are instituted only by authorized personnel?

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**K6.200 Error Reduction**

Is automated data processing used for decision making in processing? Yes  No  N/A

If yes, are there adequate procedures implemented to prevent inaccurate input or output and programming errors? Yes  No  N/A

**K6.300 Backup Files**

Are backup files maintained? Yes  No  N/A

**K6.400 Security**

How does the facility ensure the safety of back up data?

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**AATB STANDARDS SECTION M  
TISSUE DISTRIBUTION INTERMEDIARIES**

N/A

**M1.000 TISSUE DISTRIBUTION INTERMEDIARIES - GENERAL**

N/A

(An agent who acquires and stores distributed cells and/or tissue for further distribution and performs no other tissue banking activities.)

Do you acquire distributed cells and/or tissue for storage and further distribution? Yes  No  N/A

How do you ensure appropriate policies and procedures are implemented to ensure traceability?

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**M2.000 STORAGE**

N/A

**M2.100– Storage - General**

How does the facility ensure conformance with distributing bank guidelines?

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**M2.200 – Equipment**

Are refrigerators maintained, calibrated, and monitored? Yes  No  N/A

Review QC procedures for refrigerator maintenance, calibration, and monitoring.

✓ Randomly select maintenance records for a refrigerator.

Is the information complete? Yes  No  N/A

Is the maintenance schedule maintained? Yes  No  N/A

Maintenance log reviewed: \_\_\_\_\_

Procedure numbers \_\_\_\_\_

**M2.300 – Labeling**

How does the facility ensure cells and/or tissue is not relabeled or the label altered?

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**M3.000 DISTRIBUTION – GENERAL**

N/A

- Review the procedures for receipt of cells and/or tissue orders, unit selection, final container and/or package inspection, shipping, and transportation of cells and/or tissue for transplantation.

Are procedures current and complete?

Yes  No  N/A

**M3.100 Tissue Distribution Restrictions**

How does the facility ensure requests for cells and/or tissue are received from appropriate sources?

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**M3.200 Transfer of Tissue to Other Banks/Dispensing Services**

How do you ensure all appropriate documentation is forwarded with the cells and/or tissue?

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**M3.300 Requests for Donor Status and Tissue Processing Information**

How do you ensure donor information is released according to standards and your SOPM?

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**M3.400 Distribution Records**

Do you maintain appropriate distribution records?

Yes  No  N/A

How does the facility ensure appropriate information is documented in the distribution records (see standard M3.400)?

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**M3.500 Tissue Disposal**

How does the facility ensure cells and/or tissue is disposed of in such a manner as to minimize hazards to staff and the environment?

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Is documentation of notification of the final disposition of cells and/or tissue recorded?

Yes  No  N/A

**M4.000 PACKAGING AND SHIPPING**

N/A

**M4.100 Tissue Storage Environment**

Are specific environmental conditions required for storing tissue? Yes  No  N/A

How does the facility ensure environmental conditions are maintained during transit?

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**M4.200 Validation and Packaging Expiration**

Do cells and/or tissue to be shipped require specific environmental conditions other than ambient temperature? Yes  No  N/A

If yes, was the validation study for determining the capability of the transport container to maintain environmental conditions documented? Yes  No  N/A

Review the validation procedure. Procedure number \_\_\_\_\_

**M4.300 Quality Control**

If required, is quality control monitoring of shipping and packaging containers performed? Yes  No  N/A

Where are the QC checks documented?

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**M4.400 Final Inspection**

Is a thorough and appropriate final inspection performed for each package? Yes  No  N/A

Review procedure(s). Procedure number \_\_\_\_\_

**M4.500 Transportation**

How is the mode of transportation of cells and/or tissue selected?

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**M5.000 RETURN OF TISSUE**

N/A

Does the facility accept returned cells and/or tissue? Yes  No  N/A

If yes, how does the facility ensure the requirements in M5.000 are followed?

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Review the return of tissue procedure. Procedure number \_\_\_\_\_

**M6.000 Recalls**

N/A

**M6.100 Recall Records**

Is recall information appropriately documented? Yes  No  N/A

Is all required information included in the documentation?

- Reason for recall Yes  No  N/A
- Steps taken to retrieve recalled tissue Yes  No  N/A
- Documentation of all recall communication Yes  No  N/A
- Quarantining steps Yes  No  N/A
- Final disposition of cells and/or tissue Yes  No  N/A
- Corrective actions recommended and implemented Yes  No  N/A
- Documentation of review Yes  No  N/A

How long is recall information retained?

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Is AATB notified of recalls within 15 days? Yes  No  N/A

Review the recall procedure. Procedure number \_\_\_\_\_

**M7.000 RECORDS**

N/A

Does the tissue dispensing service record all steps in the process so that all steps can be clearly traced? Yes  No  N/A

How long are records maintained? \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**M7.100 Tissue Receipt Records**

Does each cells and/or tissue specimen have a tissue identification number? Yes  No  N/A

Do records contain the appropriate information as indicated in this standard?

- Name and address of tissue supplier Yes  No  N/A
- Description of cells and/or tissue and quantity received Yes  No  N/A
- Date of cells and/or tissue receipt Yes  No  N/A
- Condition of cells and/or tissue upon receipt Yes  No  N/A
- Expiration date of cells and/or tissue (if applicable) Yes  No  N/A

**M7.200 Distribution Records**

When cells and/or tissue is transferred to another facility is all appropriate information recorded?

Yes  No  N/A

How does the facility ensure all appropriate information is recorded?

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**M8.000 ADVERSE OUTCOMES**

N/A

Are reports of adverse outcomes, transmitted disease, or other complications reported to the supplier of the cells and/or tissue in a timely fashion?

Yes  No  N/A

## AATB ACCREDITATION POLICIES

### AATB Accreditation Policies

1. How does the bank ensure compliance with AATB Accreditation Policies?

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2. Does the tissue bank ensure that AATB is notified of the following reportable events, within the required number of days:

Contrary events (e.g., warning letters, recall notices, deviation reports, changes in licensure, etc.)

Yes  No  N/A

Major operational changes (e.g., move, change in Director, Medical Director, QA Director, scope of operations, facilities, name, dissolution of the tissue bank, etc.).

Yes  No  N/A

3. Does the tissue bank ensure that AATB is notified when the bank moves or adds locations?

Yes  No  N/A

4. How does the bank ensure that reported events contain the required information?

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5. Does the bank provide a copy of any 483s (or equivalent document) received with corrective action within two weeks of submitting the response to FDA (or equivalent organization)?

Yes  No  N/A