### ST - T0000 - Initial Comments

<table>
<thead>
<tr>
<th>Rule</th>
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<tr>
<td>Memo Tag</td>
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</table>

#### Regulation Definition

The agency is in substantial compliance with the requirements established in Chapter 381, F.S., and 59A-1, F.A.C., for a tissue bank certificate.

#### Interpretive Guideline

Compliance with this standard is essential for certification.

### ST - T0001 - Eligibility

<table>
<thead>
<tr>
<th>Rule</th>
<th>Type</th>
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<tbody>
<tr>
<td>Standard</td>
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</table>

#### Regulation Definition

The agency is in substantial compliance with the requirements established in Chapter 381, F.S., and 59A-1, F.A.C., for a tissue bank certificate.

#### Interpretive Guideline

Compliance with this standard is essential for certification.

### ST - T0002 - Eligibility

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<th>Rule</th>
<th>Type</th>
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<tbody>
<tr>
<td>Standard</td>
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</table>

#### Regulation Definition

The tissue bank license is posted in a conspicuous place.

#### Interpretive Guideline

Surveyor shall verify that the current certificate is posted/hung in an area accessible to the public (bulletin board, wall, etc.). Access can be limited to a reception area, waiting room or offices as long as the public can access the area. Access is to be allowed at least during normal awake/business hours, 9-5, seven days a week. Framing, laminating the certificate is optional, as long as the printed information is visible and shows no signs of alteration.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0003 - Eligibility

Title  Eligibility
Rule
Type  Standard

**Regulation Definition**
The agency has clearly defined its purpose.

**Interpretive Guideline**
Surveyor shall review documentation for evidence that clearly states the purpose of the agency. There should be documented information regarding whether the agency is an independent operation or part of another institution.

Ch. 59A-1.005(1)(a), F.A.C.

ST - T0004 - Agency Staffing

Title  Agency Staffing
Rule
Type  Standard

**Regulation Definition**
The tissue bank has an agency director pursuant to

**Interpretive Guideline**
Compliance with the standard is essential for certification.

Ch. 59A-1.005(1)(a)2., F.A.C.

ST - T0005 - Agency Staffing

Title  Agency Staffing
Rule
Type  Standard

**Regulation Definition**
The agency director's job description clearly indicates that he is responsible for:

**Interpretive Guideline**
Compliance with this standard is essential for certification.
Aspen State Regulation Set: T 1.01 Tissue Banks

1. all procedures and policies which are developed and maintained under his supervision.  
   Ch. 59A-1.005(1)(a)2., F.A.C.

2. all administrative operations including, but not limited to, compliance with these standards.  
   Ch. 59A-1.005(1)(a)2.a., F.A.C.

3. coordinating daily operations of the agency.  
   Ch. 59A1.005(1)(a)2.b., F.A.C.

4. implementing the policies of the board of directors or advisory board.  
   Ch. 59A-1.005(1)(a)2.b., F.A.C.

5. prescribing technically acceptable means for procuring, processing, quality control, storage, and distribution of tissue.  
   Ch. 59A-1.005(1)(a)2b, F.A.C.

6. ensuring that technical staff maintain competency through training courses and technical meetings or other educational programs.  
   Ch. 59A-1.005(1)(a)2.d., F.A.C.

7. appointing technical staff with capabilities and training appropriate to their function.  
   Ch.59A-1.005(1)(a)2.g., F.A.C.

1. Surveyor shall review documentation for evidence that the agency director reviews procedures and policies.

6. Surveyor shall review records for evidence that the employee is qualified by training and experience for the scope of activities being pursued, e.g., physician, cryobiologist, geneticist or scientist in a medical discipline.
## Aspen State Regulation Set: T 1.01 Tissue Banks

### Regulation Definition

The tissue bank has a licensed physician medical director, licensed to practice medicine and surgery in the state in which the agency is incorporated. Florida-based agencies must have a medical director licensed to practice medicine and surgery in Florida. The medical director provides supervision to coordinators and all other staff who assist in the medical management of donors.

Ch.59A-1.005(1)(a)3., F.A.C.

### Interpretive Guideline

Compliance with this standard is essential for certification.

Surveyor shall review the records for documentation that the medical director or designee is always available in person or by telephone to provide medical direction or consultation.

### ST - T0007 - Agency Staffing

#### Title
Agency Staffing

#### Rule
Type Standard

#### Regulation Definition

The agency director shall appoint technical staff and be responsible for ensuring that staff have capabilities and training appropriate to their function.

Ch.59A-1.005(1)(a)2.g., F.A.C.

#### Interpretive Guideline

Compliance with this standard is essential for certification.

Surveyor shall review documentation for evidence that employment applications, continuing education, certificates, and copies of licenses or certifications are on file to ensure that personnel are qualified for designated positions pursuant to Chapter 483, Part IV, Personnel, F.S.

### ST - T0008 - Agency Staffing

#### Title
Agency Staffing

#### Rule
Type Standard

#### Regulation Definition

All supervisory or senior technical personnel are certified in tissue banking by a recognized organization (e.g., the

#### Interpretive Guideline

Compliance with this standard is essential for certification.
### Aspen State Regulation Set: T 1.01 Tissue Banks

American Association of Tissue Banks).

Ch.59A-1.005(33)(b), F.A.C.

#### ST - T0009 - Agency Policies

<table>
<thead>
<tr>
<th>Title</th>
<th>Agency Policies</th>
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<tbody>
<tr>
<td>Rule</td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Standard</td>
</tr>
</tbody>
</table>

**Regulation Definition**

Each agency director shall have a working relationship with medical examiner offices in the agency's service area.

Ch. 59A-1.005(1)(a)4., F.A.C.

#### ST - T0010 - Agency Policies

<table>
<thead>
<tr>
<th>Title</th>
<th>Agency Policies</th>
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<tbody>
<tr>
<td>Rule</td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Standard</td>
</tr>
</tbody>
</table>

**Regulation Definition**

The agency has job descriptions for each employee and position.

Ch.59A-1.005(1)(a)5., F.A.C.

#### ST - T0011 - Agency Policies

<table>
<thead>
<tr>
<th>Title</th>
<th>Agency Policies</th>
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<tbody>
<tr>
<td>Rule</td>
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<td>Type</td>
<td>Standard</td>
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</table>

**Regulation Definition**

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RegSet.rpt
### Aspen State Regulation Set: T 1.01 Tissue Banks

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Job descriptions, including scope of activities, specific responsibilities, and reporting relationships for all personnel shall be established by written personnel policies and procedures approved by the agency director. Ch. 59A-1.005(1)(a)5., F.A.C.</td>
<td>Surveyor shall review documentation for copies of activities, specific responsibilities and reporting relationships that are established by written personnel policies approved by the director or designee.</td>
</tr>
<tr>
<td>1. Each agency shall maintain policies and procedures which detail all aspects of retrieval, processing, testing, storage, and distribution practices. Ch. 59A-1.005(1)(a)6., F.A.C.</td>
<td></td>
</tr>
<tr>
<td>2. Each of these procedures shall be reviewed and affirmed in writing annually by the agency director or designee. Modifications of standard procedures and development of new procedures shall be approved by the agency director or designee. Ch. 59A-1.005(1)(a)6.a., F.A.C.</td>
<td></td>
</tr>
<tr>
<td>3. Obsolete revised procedures are retained separately to maintain a historical sequence. Ch. 59A-1.005(1)(a)6.b, F.A.C.</td>
<td></td>
</tr>
<tr>
<td>4. Copies of the agency's policies and procedures shall be available to the staff at all times. Technical staff are required to state in writing that they have read and understand the manual. Ch. 59A-1.005(1)(a)6.c., F.A.C.</td>
<td></td>
</tr>
<tr>
<td>5. Copies of procedures from published literature cited by reference shall be attached or are in bibliography in an appendix to the procedures manual. Ch. 59A-1.005(a)6.d., F.A.C.</td>
<td></td>
</tr>
<tr>
<td>6. Copies of the agency's policies and procedures shall be available to surveyors for the AHCA for inspection upon</td>
<td></td>
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</tbody>
</table>
Aspen State Regulation Set: T 1.01 Tissue Banks

request.
Ch. 59A-1.005(1)(a)6.e., F.A.C.

7. Procedures shall be sufficiently detailed and unambiguous.
Ch.59A-1.005(1)(a)6.f., F.A.C.

<table>
<thead>
<tr>
<th>Title</th>
<th>Records</th>
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<tbody>
<tr>
<td>Rule</td>
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<tr>
<td>Type</td>
<td>Standard</td>
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</tbody>
</table>

**Regulation Definition**

Donor and recipient records shall be accurate, complete and confidential, pursuant to s. 455.241, F.S.

Ch.59A-1.005(1)(b)1., F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

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<td>Rule</td>
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<td>Type</td>
<td>Standard</td>
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</table>

**Regulation Definition**

Donor record confidentiality shall not preclude access by surveyors for the AHCA when conducting an inspection or investigation pursuant to 59A-1.009(1)(a),(b),(c), F.A.C., and the medical examiner for cases which fall within the medical examiner's jurisdiction, as established under s. 406.05, F.S.

Ch. 59A-1.005(1)(b)1., F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0014 - Records

Title  Records

Rule

Type  Standard

Regulation Definition

Donor medical records and a final hard copy of the results of all laboratory tests shall be reviewed and affirmed in writing by the medical director, designees, or medical contractee to ensure suitability of the donated organ(s) or tissue(s) for the intended application.

Ch.59A-1.005(1)(b)1., F.A.C.

Interpretive Guideline

ST - T0015 - Records

Title  Records

Rule

Type  Standard

Regulation Definition

Documentation shall be concurrent with the performance of each activity in the retrieval, preparation, testing, storage, and distribution of organs and tissues in such a manner that all activities can be clearly traced.

Ch.59A-1.005(1)(b)2., F.A.C.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0016 - Records

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<thead>
<tr>
<th>Title</th>
<th>Records</th>
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<tr>
<td>Rule</td>
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<tr>
<td>Type</td>
<td>Standard</td>
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</table>

**Regulation Definition**

All records shall be legible and indelible and shall identify the person performing the procedures/tasks. The record shall include dates of entries and test results. The expiration period assigned to specific categories of processed tissues is to be recorded in the agency's policies and procedures.

Ch.59A-1.005(1)(b)2., F.A.C.

**Interpretive Guideline**


ST - T0017 - Records

<table>
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<th>Title</th>
<th>Records</th>
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<td>Rule</td>
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<td>Type</td>
<td>Standard</td>
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</table>

**Regulation Definition**

Records shall be as detailed as necessary for a clear understanding of each activity and shall be available for inspection by surveyors for the AHCA when conducting an inspection or investigation pursuant to 59A-1.009(1)(a),(b),(c), F.A.C., upon request and within the bounds of medical-legal confidentiality, pursuant to s. 455.241, F.S.

Ch.59A-1.005(1)(b)3., F.A.C.
### ST - T0018 - Records

**Title**  Records  
**Rule**  
**Type**  Standard  

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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<tbody>
<tr>
<td>Each organ and tissue and any components derived therefrom shall be assigned, in addition to generic designation, one unique identification number which shall serve as a lot number to identify the material from retrieval through distribution and utilization.</td>
<td></td>
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</tbody>
</table>

Ch.50A-1.005(1)(b)4., F.A.C.

### ST - T0019 - Records

**Title**  Records  
**Rule**  
**Type**  Standard  

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records shall identify the donor, document the pathological and microbiological evaluation of the donor, verify laboratory conditions under which the tissue is retrieved, processed, tested, and stored, if applicable, and indicate the disposition of the transplanted organ or tissue.</td>
<td></td>
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</table>

Ch.59A-1.005(1)(b)5., F.A.C.
## Aspen State Regulation Set: T 1.01 Tissue Banks

### ST - T0020 - Records

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<td>Rule</td>
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<td>Type</td>
<td>Standard</td>
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</table>

#### Regulation Definition

Maintenance and certification records, if applicable, on facilities, instruments, and equipment, including their monitors, shall be maintained. These records indicate dates of inspection, name of facility, and performance evaluations. Each agency shall include in its procedures manual, the monitoring, inspection and cleaning procedures and schedules for each piece of equipment.

Ch.59A-1.005(1)(b)7, F.A.C.

### ST - T0021 - Records

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<td>Rule</td>
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<td>Type</td>
<td>Standard</td>
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</table>

#### Regulation Definition

Documented cleaning schedules for laboratory equipment shall be maintained. Records of function checks requiring interpretation of findings must include the interpretation. Records must include:

- a. temperature in incubators when in use;
- b. spore lot number and expiration date used for autoclave function check; and
Aspen State Regulation Set: T 1.01 Tissue Banks

c. control and test results.

Ch.59A-1.005(1)(b)7.a.-c., F.A.C.

ST - T0022 - Records

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<th>Records</th>
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<tr>
<td>Rule</td>
<td>Standard</td>
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**Regulation Definition**

All of these records are retained by the tissue bank for ten years after distribution of tissues and shall be available for AHCA inspection.

Ch.59A-1.005(1)(b)9., F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

ST - T0023 - Records

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<th>Title</th>
<th>Records</th>
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<tbody>
<tr>
<td>Rule</td>
<td>Standard</td>
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</table>

**Regulation Definition**

Responses from transplant centers which identify adverse reactions attributable to allografts shall be maintained. The records of the tissue banks shall be opened to inspection by the AHCA at a mutually convenient time.

Ch.59A-1.005(38)(a), F.A.C.
### Aspen State Regulation Set: T 1.01 Tissue Banks

<table>
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<td>Type</td>
<td>Standard</td>
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</table>

#### ST - T0024 - Records

**Regulation Definition**

A tissue bank, when sending tissue to a hospital or surgeon, must request in writing that the transplanting surgeon report allograft-related complications to the tissue bank's medical director. Records of adverse reactions and all related follow-up documentation shall be maintained for a period of ten years.

Ch.59A-1.005(38)(d), F.A.C.

#### ST - T0025 - Records

**Regulation Definition**

A record of all unprocessed, processed, and distributed tissues shall be maintained.

Ch.59A-1.005(38)(e), F.A.C.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0026 - Records

Title  Records
Rule
Type  Standard

Regulation Definition

The records shall include all information on the donor including laboratory reports, autopsy reports, a clinical history, a tissue procurement record, and related material. The records of the permission to procure the tissue are kept permanently. A final summary statement is written by the physician responsible for the quality assurance of the allografts which he or she has made available to the transplant surgeon.

Ch.59A-1.005(39), F.A.C.

Interpretive Guideline

Compliance with this standard is essential for certification.

ST - T0027 - Tissue Tracking

Title  Tissue Tracking
Rule
Type  Standard

Regulation Definition

Each tissue and any components derived therefrom are assigned, in addition to generic designation, one unique tissue identification number which shall serve as a lot number to identify the material during all steps from retrieval through distribution and utilization. Donor number and lot number shall be the same.

Ch.59A-1.005(45), F.A.C.

Interpretive Guideline

Compliance with this standard is essential for certification.
## ST - T0028 - Community Involvement & Education

**Title** Community Involvement & Education  
**Rule**  
**Type** Standard

### Regulation Definition

Each tissue bank shall assist hospitals in establishing and implementing protocols for making routine inquiries about organ and tissue donations by potential donors.

Ch.59A-1.005(5)(a), F.A.C.

### Interpretive Guideline


## ST - T0029 - Community Involvement & Education

**Title** Community Involvement & Education  
**Rule**  
**Type** Standard

### Regulation Definition

Each agency shall maintain documentation, that shall be available for review by surveyors for the AHCA, of educational services provided to the community, health care professionals and hospitals in the agency's service area.

Ch.59A-1.005(5)(b), F.A.C.

### Interpretive Guideline


## ST - T0030 - Community Involvement & Education

**Title** Community Involvement & Education  
**Rule**  
**Type** Standard
Aspen State Regulation Set: T 1.01 Tissue Banks

**Regulation Definition**

Documentation of education of professionals shall be maintained. Documentation of donor hospital policies, procedures, characteristics and donor related activities shall be kept. Written agreements between the hospital and the agency shall document these activities.

Ch.59A-1.005(5)(c), F.A.C.

**Interpretive Guideline**

**Title** Community Involvement & Education

**Rule**

**Type** Standard

**Regulation Definition**

Each agency shall produce or have available literature and media items that will provide education for donation of organs, tissues, or eyes. Each agency shall be responsible for establishing and assisting in the dissemination of these materials.

Ch.59A-1.005(5)(d), F.A.C.

**Interpretive Guideline**

**Title** Safety & Environmental Control

**Rule**

**Type** Standard

**Regulation Definition**

The agency director shall establish written procedures and instructions for action in case of emergency or exposure to...
communicable disease, chemical and biological hazard. Surveyor shall review evidence that safety procedures and policies are posted or readily available to all personnel.

Ch.59A-1.005(2), F.A.C.

### ST - T0033 - Safety & Environmental Control

**Title** Safety & Environmental Control

**Rule**

**Type** Standard

**Regulation Definition**

Human waste items are disposed so as to minimize any hazard to personnel or the environment. Dignified and proper disposal procedures are used to obviate recognizable human remains. Any organs or tissues from a donor whose blood test for HIV or hepatitis, pursuant to s. 381.0041, F.S., that are confirmed as positive by confirmatory testing shall be destroyed, treated, or disposed, in accordance with s. 381.0098, F.S., Chapter 403 Part IV, F.S., and 10D-104, F.A.C.

Ch.59A-1.005(2)(a), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

### ST - T0034 - Safety & Environmental Control

**Title** Safety & Environmental Control

**Rule**

**Type** Standard

**Regulation Definition**

The tissue bank complies with Occupational Safety and Health Administration (OSHA) rules 29 Code of Federal Regulations (CFR) Part 1910.1030, 1991. These rules establish requirements for minimizing exposure to Hepatitis, HIV, and

**Interpretive Guideline**

Surveyor shall review OSHA requirements, and if there appears to be non-compliance, refer immediately to OSHA.
Aspen State Regulation Set: T 1.01 Tissue Banks

other blood-borne pathogens.
Ch.59A-1.005(2)(b), F.A.C.

<table>
<thead>
<tr>
<th>Title</th>
<th>Facilities &amp; Equipment</th>
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<tbody>
<tr>
<td>Rule</td>
<td></td>
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<td>Type</td>
<td>Standard</td>
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</table>

Regulation Definition | Interpretive Guideline
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Facilities are designated for the specialized purposes for which they are to be used and shall be maintained in a clean and orderly manner.
Ch.59A-1.005(3)(a), F.A.C.

<table>
<thead>
<tr>
<th>Title</th>
<th>Facilities &amp; Equipment</th>
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<tr>
<td>Rule</td>
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<td>Type</td>
<td>Standard</td>
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Regulation Definition | Interpretive Guideline
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All instruments and equipment are subjected to regularly scheduled maintenance and calibration.
Ch.59A-1.005(3)(a), F.A.C.

Compliance with this standard is essential for certification.
Surveyor shall review for evidence of documented maintenance records.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0037 - Facilities & Equipment

Title Facilities & Equipment
Rule
Type Standard

**Regulation Definition**
All temperature measuring devices must be calibrated against U.S. Bureau of Standards certified thermometers. Refrigerators and freezers used for the storage of tissues shall have monitors. Each agency shall have established procedures to follow in the event of electrical failure.

Interpretive Guideline
Compliance with this standard is essential for certification.

Ch.59A-1.005(3)(a), F.A.C.

ST - T0038 - Facilities & Equipment

Title Facilities & Equipment
Rule
Type Standard

**Regulation Definition**
A security system or physical configuration is provided to prevent entry of unauthorized persons.

Interpretive Guideline

Ch.59A-1.005(3)(b), F.A.C.

ST - T0039 - Facilities & Equipment

Title Facilities & Equipment
Rule
Type Standard
### Aspen State Regulation Set: T 1.01 Tissue Banks

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td>If a tissue bank has an operating room, it shall be reserved for the retrieval of</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
<tr>
<td>cadaveric tissue on a 24-hour basis. Such an operating room shall conform to</td>
<td>Surveyor shall view the operating room to ensure the presence of air filtration,</td>
</tr>
<tr>
<td>standard operating room requirements under 59A-3, F.A.C.</td>
<td>stainless steel furniture, washable walls, etc.</td>
</tr>
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<td></td>
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<tr>
<td>Ch.59A-1.005(41)(a), F.A.C.</td>
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#### ST - T0040 - Facilities & Equipment

<table>
<thead>
<tr>
<th>Title</th>
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<tr>
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<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td>Environmental monitoring procedures shall be established and periodic sampling of</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
<tr>
<td>air, drains, surfaces, and water faucets shall be documented.</td>
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<td></td>
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<tr>
<td>Ch.59A-1.005(41)(b), F.A.C.</td>
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#### ST - T0041 - Ethical Standards

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<th>Ethical Standards</th>
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<tr>
<td>Rule</td>
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<td>Type</td>
<td>Standard</td>
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<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>The tissue bank has written policies to avoid conflicts of interest.</td>
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<tr>
<td>Ch.59A-1.005(4)(a), F.A.C.</td>
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</tbody>
</table>
ST - T0042 - Ethical Standards

Title Ethical Standards
Rule
Type Standard

Regulation Definition
In the event that services other than obtaining referral or consent are provided to the procuring agency, that procuring agency may make arrangements to pay expenses incurred for services rendered. Reimbursement to the individual shall not be in conflict with the personnel policies of the primary employer.

Ch.59A-1.005(4)(b), F.A.C.

ST - T0043 - Quality Assurance

Title Quality Assurance
Rule
Type Standard

Regulation Definition
Tests and procedures are available for measuring, assaying, or monitoring properties of tissue essential to the evaluation of their safety and usefulness, e.g., hepatitis B surface antigen (HBsAg), human immunodeficiency virus HIV-1 and HIV-2 antibodies, and hepatitis C virus (HCV) antibody.

Ch.59A-1.005(1)(a)2.e., F.A.C.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0044 - Quality Assurance

Title  Quality Assurance
Type  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any clinical laboratory tests performed within a certified OPO, tissue bank or eye bank must comply with Chapter 483, F.S., and the Clinical Laboratories Improvement Act of 1988 (CLIA-88), as applicable.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

Surveyor shall review records for documentation that all tests listed in TBS 043 are followed and recorded in the agency's permanent records.

Ch.59A-1.005(1)(a)2.e., F.A.C.

ST - T0045 - Quality Assurance

Title  Quality Assurance
Type  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>The QA program shall include ongoing monitoring and evaluation of its activities, identification of problems, and plans for corrective action.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

Ch.59A-1.005(1)(a)2.f., F.A.C.

ST - T0046 - Quality Assurance

Title  Quality Assurance
Type  Standard
Aspen State Regulation Set: T 1.01 Tissue Banks

**Regulation Definition**

The QA procedures and records shall be reviewed at least annually and shall provide the basis for the development of the QA program.

Ch.59A-1.005(1)(a)2.f., F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

1. evidence of signed reviews by the agency director; and

2. evidence that modifications of standard procedures and development of new procedures are approved and signed by the director or designee.

---

**ST - T0047 - Quality Assurance**

**Title**
Quality Assurance

**Rule**

**Type**
Standard

**Regulation Definition**

The agency's quality assurance program shall include a method for the transplanting surgeon to report adverse reactions from the transplantation of organ(s) and tissue(s) to the source OPO, tissue bank or eye bank, which in turn shall forward the adverse reaction information to the AHCA.

Ch.59A-1.005(13), F.A.C.

**Interpretive Guideline**

---

**ST - T0048 - Informed Consent**

**Title**
Informed Consent

**Rule**

**Type**
Standard

**Regulation Definition**

Personnel records indicate that agency personnel are trained in obtaining and documenting consent for donation.
### ST - T0049 - Informed Consent

**Title** Informed Consent  
**Rule**  
**Type** Standard  

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent shall be obtained from the donor, next of kin, or other designated legal entity in order of priority and availability according to 765.512, F.S.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

Ch.59A-1.005(7)(a)2., F.A.C.

### ST - T0050 - Informed Consent

**Title** Informed Consent  
**Rule**  
**Type** Standard  

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>A copy of the original signed consent form or record of telephone consent shall be retained in the agency's donor record.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

Ch.59A-1.005(7)(a)3., F.A.C.

### ST - T0051 - Informed Consent

**Title** Informed Consent  
**Rule**  
**Type** Standard  

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Compliance with this standard is essential for certification.</td>
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</tbody>
</table>

Ch.59A-1.005(7)(a)5., F.A.C.
Permission to obtain organs and tissues from donors by informed consent shall be as defined in 59A-1.003, F.A.C., and shall be documented in writing. The consent form shall include the organs and tissues for which permission is granted (e.g., bone from the upper or lower extremities or bone from below the waist). Information provided shall be written or spoken in language understandable to the donor or the donor's next of kin.

Ch.59A-1.005(7)(b)1., F.A.C.

Permission to retrieve organs and tissues from non-living donors shall be sought from next of kin in order of legal precedence as required by s. 765.512, F.S. In cases falling under the provisions of Chapters 406 and 765, F.S., the permission of the medical examiner or appropriate designee shall be obtained prior to the procurement of any organ(s) and tissue(s).

Ch.59A-1.005(7)(b)2., F.A.C.

Compliance with this standard is essential for certification.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0053 - Compensation For Donors

Title Compensation For Donors
Rule
Type Standard

Regulation Definition
Monitory compensation other than reimbursement of donor-related expenses is prohibited.

Ch.59A-1.005(9), F.A.C.

Interpretive Guideline
Compliance with this standard is essential for certification.

ST - T0054 - Sale Of Anatomical Matter

Title Sale Of Anatomical Matter
Rule
Type Standard

Regulation Definition
Sale of one of a pair or organs (such as an eye or kidney) by a living donor for financial compensation is illegal under Public Law 98-507, s. 301; 42 United States Code s. 274e; and Chapter 873, F.S.

Ch.59A-1.005(10), F.A.C.

Interpretive Guideline
Compliance with this standard is essential for certification.

ST - T0055 - Donor Selection

Title Donor Selection
Rule
Type Standard
Tissues with evidence of infectious disease are conditions which shall preclude distribution for transplantation. The following is a list of examples of commonly encountered conditions which preclude donation of tissues:

1. Infectious diseases such as:
   a. septicemia (demonstrable) at time of death;
   b. systemic mycoses;
   c. meningitis or encephalitis;
   d. active systemic viral disease or past history of chronic viral disease;
   e. active tuberculosis or history of tuberculosis;
   f. active hepatitis; and
   g. active syphilis or anatomically demonstrable syphilitic lesions.

2. Bacterial infections such as:
   a. pyelonephritis;
   b. peritonitis;
   c. pneumonia (other than non-confluent bronchopneumonia);
   d. bacterial endocarditis; e. osteomyelitis; and
   f. other potential transmittable bacterial diseases.

3. Malignancies - individuals with malignancies arising anywhere in the body shall be excluded from the donor pool. Any exceptions shall be approved by the medical director.

4. Collagen and immune complex diseases:
   a. rheumatoid arthritis;
   b. systemic lupus erythematosis;
   c. polyarteritis nodosa;
   d. sarcoidosis;

Compliance with this standard is essential for certification.
Aspen State Regulation Set: T 1.01 Tissue Banks

e. myasthenia gravis; and

f. acute rheumatic fever.

5. Severe trauma - patients who have a tracheotomy or have been on a respirator for over 96 hours and have evidence of infection, multiple open wounds, or wounds to the abdomen are excluded from the donor pool.

6. Transfused donor:
   a. Tissues from a donor who has been transfused shall comply with the FDA Guidance Concerning the Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue.

   b. The decision as to whether or not an individual who received a blood transfusion(s) six months or less before death should serve as a tissue donor is a medical judgment. Therefore, the responsibility of accepting tissue from transfused donors rests with the medical director or physician designee. In making such a decision, factors such as information obtained on retesting of blood donors, testing of organ donor recipients, etc., shall be taken into account.

7. A potential donor who has chronic blood transfusions shall be eliminated from the donor pool.

8. Recipients of organ transplants are not eliminated because of the transplant per se, but are carefully evaluated because of the drug therapy they receive and the disease processes they might have.

9. Donors receiving chronic corticosteroid drugs shall be eliminated as bone donors because of the effect on bone.
Aspen State Regulation Set: T 1.01 Tissue Banks

Other drugs in therapeutic doses, which might reside in the tissues, may eliminate the donor from the donor pool.

10. Toxic exposure sufficient to affect tissue procured and an unknown but suspicious medical history shall constitute a reason for rejecting a donor.

Ch.59A-1.005(34)(c)1.-10., F.A.C.

ST - T0056 - Donor Selection

<table>
<thead>
<tr>
<th>Title</th>
<th>Donor Selection</th>
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<tbody>
<tr>
<td>Rule</td>
<td></td>
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<tr>
<td>Type</td>
<td>Standard</td>
</tr>
</tbody>
</table>

**Regulation Definition**

If scant medical history is available, as in the case of a sudden death, a documented attempt shall be made to acquire information beyond what is available before these tissues can be released. In the event that additional information or records cannot be found, the medical director shall determine if these tissues are suitable for release for transplantation and document the release of in the donor's medical record.

Ch.59A-1.005(34)(a), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

ST - T0057 - Donor Selection

<table>
<thead>
<tr>
<th>Title</th>
<th>Donor Selection</th>
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<tbody>
<tr>
<td>Rule</td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Standard</td>
</tr>
</tbody>
</table>

**Regulation Definition**

HIV testing is required under 10D-93.073, F.A.C. Potential

**Interpretive Guideline**

Compliance with this standard is essential for certification.
Aspen State Regulation Set: T 1.01 Tissue Banks

Donors falling into a high-risk group shall be eliminated from the donor pool. This includes high-risk behavior groups and high-risk ethnic or geographic groups, pursuant to 59A-1.005(11)(a), F.A.C., and the partners of the above groups, as well as intravenous recreational drug users.

Surveyor shall review documentation for evidence that the tests were performed by a laboratory licensed under Chapter 483, Part I, F.S. Surveyor shall review documentation for evidence that the U.S. Public Health Service current criteria for exclusion of high risk donors are followed.

Ch. 59A-1.005(34)(b), F.A.C.

Title Donor Testing
Rule
Type Standard

**Regulation Definition**

The tissue bank provides for the following serology studies on donors:

1. HBsAg;
2. HIV-1 and HIV-2 antibodies;
3. HCV;
4. HBcAb;
5. FDA-licensed HTLV test;
6. STS -- confirmed. Tissue from donors with positive (confirmed) test are not used for transplantation; and
7. Rh determination -- provide information cautioning about possibility of sensitization.

Compliance with this standard is essential for Ch. 59A-1.005(1)(a)2.e., F.A.C. and 59A-1.005(35), F.A.C.

Surveyor shall review documentation for evidence that the tests were performed by a laboratory licensed under Chapter 483, Part I, F.S. If there appears to be non-compliance, refer to the Laboratory Unit, Agency for Health Care Administration.

Ch. 59A-1.005(1)(a)2.e., F.A.C. and 59A-1.005(35), F.A.C.

7. Not applicable to heart valves and saphenous veins.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0059 - Donor Testing

Title  Donor Testing

Rule

Type  Standard

**Regulation Definition**

Prior to transplantation, the medical director, designees, or medical contractee states in writing in the donor record that the current medical history, postmortem examination and laboratory test results together with the available previous medical history, are sufficient to indicate that the donor was acceptable for tissue donation.

Ch.59A-1.005(35)(b), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for Ch. 59A-1.005(1)(a)2.e., F.A.C. and 59A-1.005(35), F.A.C.

ST - T0060 - Donor Testing

Title  Donor Testing

Rule

Type  Standard

**Regulation Definition**

Each tissue bank shall have microbiological laboratory policies and procedures which ensure allograft safety. Documentation of adherence to these policies and procedures is required.

Ch.59A-1.005(36), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for Ch. 59A-1.005(1)(a)2.e., F.A.C. and 59A-1.005(35), F.A.C.

Surveyor shall review documentation for compliance with Chapter. 483, Part I, F.S. If there appears to be non-compliance, refer to the Laboratory Licensing Section, Agency for Health Care Administration.
The agency has a policy regarding autopsy. This policy includes, but is not limited to:

1. A gross external and, if applicable, internal examination of any area of the donor altered by the retrieval shall be performed and dictated or otherwise recorded by the procuring person(s) at the time of the removal of tissues from the cadaveric donor.

2. A written report of these findings is immediately prepared and delivered to the person(s) responsible for the autopsy of the donor. This report contains a notation of all normal as well as itemization of all abnormal pathological findings found during the gross examination of the donor.

3. Whenever a full medical autopsy of the donor was not subsequently performed by a medical examiner, the tissue bank obtained a full medical autopsy by other means.

4. The tissue bank shall affix a copy of the autopsy report to the donor record.

5. The medical director or designees may exercise a waiver of an autopsy on a case-by-case basis and shall justify and document that waiver in the donor's medical record.

Ch.59A-1.005(37), F.A.C.
ST - T0062 - Donor Testing

Title  Donor Testing
Rule
Type  Standard

**Regulation Definition**
The time limitation for tissue retrieval shall be 24 hours if the cadaver is refrigerated and 15 hours if the cadaver is unrefrigerated.

Ch.59A-1.005(40), F.A.C.

**Interpretive Guideline**
Tissue recovery must commence within the stated timeframes of the Rule. If tissue recovery is not complete at 24 hours (refrigerated) or 15 hours (un-refrigerated), tissue recovery does not need to be terminated.

ST - T0063 - Donor Testing

Title  Donor Testing
Rule
Type  Standard

**Regulation Definition**
If tissues are retrieved using aseptic techniques, methods shall be consistent with standard operating room practice.

Ch.59A-1.005(42)(a), F.A.C.

**Interpretive Guideline**
Compliance with this standard is essential for certification.

ST - T0064 - Donor Testing

Title  Donor Testing
Rule
Type  Standard
Aspen State Regulation Set: T 1.01 Tissue Banks

### Regulation Definition

Tissue banks employing ethylene oxide (ETO) for sterilization of tissues, chambers of freeze-dryers, instruments or equipment must monitor occupational exposure to ethylene oxide. Semi-annual reports of ETO monitoring must be kept for 30 years.

Ch.59A-1.005(42)(b), F.A.C.

### Interpretive Guideline

Compliance with this standard is essential for certification.

### ST - T0065 - Donor Testing

**Title** Donor Testing  
**Rule**  
**Type** Standard

#### Regulation Definition

Tissue shall be processed into specimens appropriate for clinical use. The specific methods employed may vary with each type of tissue and with the manner in which it has been procured, but each type of tissue shall be prepared according to written tissue bank procedures.

Ch.59A-1.005(42)(c), F.A.C.

#### Interpretive Guideline

Compliance with this standard is essential for certification.

### ST - T0066 - Donor Testing

**Title** Donor Testing  
**Rule**  
**Type** Standard

#### Regulation Definition

Sterile bone and tissue allografts shall be packaged in minimum room class 1000 environments. Certification of

#### Interpretive Guideline

Compliance with this standard is essential for certification.
conformance, issued by outside agencies, must attest that the room meets cleanliness requirements for class 1000 or less of FED-STD-209D. Such certification must be obtained every 12 months. If processing is performed in laminar flow hoods, and not in clean rooms, the latter must be similarly certified every 12 months. Adequate supplies must be available, and there must be adequate space for equipment.

Ch.59A-1.005(42)(d), F.A.C.

**ST - T0067 - Donor Testing**

**Title** Donor Testing

**Rule**

**Type** Standard

**Regulation Definition**

The tissue bank has a policy for the reconstruction of the body which is integral to maintaining the dignity of the donor.

Ch.59A-1.005(12), F.A.C.

**ST - T0068 - Donor Information Documentation**

**Title** Donor Information Documentation

**Rule**

**Type** Standard

**Regulation Definition**

The records include all information on the donor including laboratory reports, autopsy reports, a clinical history, a tissue procurement record, and related material. The records of the permission to procure the tissue are kept permanently. A final

**Interpretive Guideline**

Compliance with this standard is essential for certification.
summary statement is written by the physician responsible for the quality assurance of the allografts which he makes available to the transplant surgeon.

Ch.59A-1.005(39), F.A.C.

### ST - T0069 - Labeling

**Title**  Labeling  
**Rule**  
**Type**  Standard

**Regulation Definition**

Visual inspection -- A sufficient area of the container is unobstructed when the label has been affixed to the container to permit inspection of the contents of freeze dried tissue allografts. Tissues that are vacuum sealed shall be spark tested prior to disposition.

Ch.59A-1.005(43)(a), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Surveyor shall select at random containers with freeze-dried tissue stored under vacuum and subject these containers to a spark test

### ST - T0070 - Labeling

**Title**  Labeling  
**Rule**  
**Type**  Standard

**Regulation Definition**

Container label -- Containers shall be labeled so as to identify the following:

1. name of the product;

2. name and address of the tissue bank;

**Interpretive Guideline**

Compliance with this standard is essential for certification.
3. tissue identification number; and

4. expiration date, if applicable.

Ch.59A-1.005(43)(b)1.-4., F.A.C.

---

ST - T0071 - Labeling

**Title** Labeling

**Rule**

**Type** Standard

---

**Regulation Definition**

Shipping label -- Packages shall be labeled so as to identify the:

1. identification of human tissue;

2. name and address of tissue bank;

3. name of facility to which tissue is being shipped;

4. recommended storage temperature; and;

5. special instructions indicated by the particular product, e.g., DO NOT FREEZE.

Ch.59A-1.005(43)(c)1.-5., F.A.C.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0072 - Packaging

Title Packaging
Rule
Type Standard

**Regulation Definition**
Shipping shall maintain sterility of the contents and maintain integrity of the appropriate container.

Ch.59A-1.005(44), F.A.C.

**Interpretive Guideline**
Compliance with this standard is essential for certification.

Surveyor shall visibly inspect several packaged bone and tissue allografts using a magnifying glass to determine if these may contain any foreign matter and to determine the adequacy of washing.

ST - T0073 - Packaging

Title Packaging
Rule
Type Standard

**Regulation Definition**
Package insert - All tissues are accompanied by a package insert which contains instructions for proper storage and reconstitution when appropriate. Specific instructions are enclosed with tissues requiring special handling. Such instructions minimally include:

1. presence of known sensitizing substances;
2. type and estimated amount of antibiotics added during processing;
3. source of the tissue (when it is a factor in safe administration);

**Interpretive Guideline**
Compliance with this standard is essential for certification.
Aspen State Regulation Set: T 1.01 Tissue Banks

4. all donor test results and laboratory procedures (including an autopsy if performed) on the donor;

5. secondary sterilization procedure, if utilized;

6. any chemical agent that may cause a change; and

7. all preservation and the concentration of the preservation used in the processing of tissue allografts, if utilized.

Ch.59A-1.005(44)(b)1.-7., F.A.C.

ST - T0074 - Distribution System Fair And Equitable

Title  Distribution System Fair And Equitable
Rule
Type  Standard

Regulation Definition
Each agency shall establish and document a system of distribution that is just, equitable, and fair to all patients served by the agency. Documentation of distribution (date of requests for, offer of, and delivery of organs and tissues) shall be available for examination by authorized individuals, including surveyors for the AHCA. Access to organs and tissues shall be provided without regard to recipient sex, age, religion, race, creed, color or national origin.

Ch.59A-1.005(19), F.A.C.

Interpretive Guideline
Compliance with this standard is essential for certification.

Surveyor shall review records for evidence that there is a documented system of distribution that is just, equitable, and fair to all patients served by the tissue bank. Documentation of distribution shall include the date of request for, offer of, and delivery of tissues.

Ch.59A-1.005(19), F.A.C.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0075 - Adverse Reaction Policy

Title Adverse Reaction Policy

Rule

Type Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>The tissue bank has an adverse reaction policy.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

Ch.59A-1.011(1), F.A.C.

ST - T0076 - Recall Procedures

Title Recall Procedures

Rule

Type Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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<tbody>
<tr>
<td>A written procedure shall exist for recall of organs or tissues or notification of recipient agencies of the possibility of contamination, defects in processing, preparation or distribution, or other factors affecting suitability of the tissue for their intended application. Procedures for documenting the steps in recall shall be included in the agency's policies and procedures.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

Surveyor shall review sampling of random records to ensure that the recipient's physician and/or transplantation center are identified sufficiently to accomplish a notification or recall should such become necessary.

Ch.59A-1.005(14), F.A.C.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T0077 - Look Back Procedures

Title  Look Back Procedures
Rule
Type  Standard

**Regulation Definition**

Each tissue bank shall have procedures for notifying the transplanting agency or physicians that they may have received infected tissues. Documentation of look back procedures shall be included in the agency's policies and procedures.

Ch.59A-1.005(15), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

ST - T0078 - HIV Testing And Notification

Title  HIV Testing And Notification
Rule
Type  Standard

**Regulation Definition**

Notification of HIV test results to donors and recipients of organs, tissues, and eyes in this state shall be in accordance with s. 381.0041, F.S., and 10D-93.073, F.A.C.

Ch.59A-1.005(16), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.
Aspen State Regulation Set: T 1.01 Tissue Banks

ST - T9999 - Final Observations

Title  Final Observations
Rule
Type  Memo Tag

<table>
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<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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