### ST - E0000 - Initial Comments

**Title**  Initial Comments

**Type**  Memo Tag

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

### ST - E0001 - Eligibility

**Title**  Eligibility

**Type**  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>The agency is in substantial compliance with the requirements established in Chapter 381, F.S., and Ch.59A-1, F.A.C., for an eye bank license.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

### ST - E0002 - Eligibility

**Title**  Eligibility

**Type**  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>The eye bank license is posted in a conspicuous place.</td>
<td>Surveyor shall verify that the current license 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 license is optional, as long as the printed information is visible and shows no signs of alteration.</td>
</tr>
<tr>
<td>Ch.59A-1.004(7), F.A.C.</td>
<td></td>
</tr>
</tbody>
</table>
### ST - E0003 - Organizational Standards

**Title**: Organizational Standards

**Type**: Standard

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

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

#### 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.

### ST - E0004 - Agency Staffing

**Title**: Agency Staffing

**Type**: Standard

#### Regulation Definition
The eye bank has an agency director pursuant to Ch. 59A-1.005(1)(a)2., F.A.C.

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

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

### ST - E0005 - Agency Staffing

**Title**: Agency Staffing

**Type**: Standard

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

1. all procedures and policies which are developed and

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

1. Surveyor shall review documentation for evidence that the agency director reviews procedures and policies.
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. coordination of daily operations of the agency;
Ch. 59A-1.005(1)(a)2.b., F.A.C.

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

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

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.

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

Title Agency Staffing

Type Standard

Regulation Definition
The eye 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

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.
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.

### ST - E0007 - Agency Staffing

**Title** Agency Staffing

**Type** Standard

**Regulation Definition**
The medical director shall have demonstrated an expertise in external eye disease, corneal surgery, research or teaching in cornea and external disease. If the medical director has not served a corneal fellowship, the eye bank shall have and document a consulting relationship with an ophthalmologist who has.

Ch.59A-1.005(47)(a), F.A.C.

### ST - E0008 - Agency Staffing

**Title** Agency Staffing

**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 are on file to ensure that personnel are qualified for designated positions pursuant Chapter 483, Part IV, Personnel, F.S.
Aspen State Regulation Set: E 1.00 Eyebanks

ST - E0009 - Agency Staffing

Title Agency Staffing

Type Standard

**Regulation Definition**

A supervisory eye bank technician is the individual responsible for the daily operation of the eye bank laboratory. The supervisory eye bank technician shall ensure compliance with these standards for the eye bank laboratory. Each eye bank processing laboratory must have at least one certified technician in a supervisory role.

Ch.59A-1.005(47)(b)1., F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

ST - E0010 - Agency Staffing

Title Agency Staffing

Type Standard

**Regulation Definition**

An eye bank technician shall be trained in acquisition, evaluation, and distribution of eye tissue for transplantation.

Ch.59A-1.005(47)(b)2., F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.
### Type: Standard

#### Regulation Definition

A procurement technician shall be proficient in screening and retrieval of the eye tissue.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Ch.59A-1.005(47)(b)3., F.A.C.

#### ST - E0012 - Agency Staffing

**Title** Agency Staffing

#### Regulation Definition

The eye bank shall provide an orientation program for each new technician and the employee’s participation shall be documented.

**Interpretive Guideline**

Ch.59A-1.005(48(a), F.A.C.

#### ST - E0013 - Agency Staffing

**Title** Agency Staffing

#### Regulation Definition

The eye bank provides educational opportunities such as in-service training programs, attendance at meetings, seminars, and workshops for all technical personnel, including laboratory supervisors, at a frequency that is defined and reasonable for the size and needs of the technical staff.

**Interpretive Guideline**
Aspen State Regulation Set: E 1.00 Eyebanks

Ch.59A-1.005(48)(b), F.A.C.

ST - E0014 - Agency Policies

Title Agency Policies

Type Standard

**Regulation Definition**

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

Interpretive Guideline

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

ST - E0015 - Agency Policies

Title Agency Policies

Type Standard

**Regulation Definition**

The agency has job descriptions for each employee and position.

Interpretive Guideline

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

ST - E0016 - Agency Policies

Title Agency Policies

Type Standard

**Regulation Definition**
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.

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.

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.

3. Obsolete revised procedures are retained separately to maintain a historical sequence.

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

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.

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.

6. Copies of the agency's policies and procedures shall be available to surveyors for the AHCA for inspection upon request.
Ch. 59A-1.005(1)(a)6.e., F.A.C.

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

**ST - E0017 - Records**

**Title** Records

**Type** Standard

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

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

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

**ST - E0018 - Records**

**Title** Records

**Type** Standard

**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.

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

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

**ST - E0019 - Records**

**Title** Records
Aspen State Regulation Set: E 1.00 Eyebanks

**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 contractor 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 - E0020 - Records

**Title**  
Records

**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.

### Interpretive Guideline

Compliance with this standard is essential for certification.

Surveyor shall review documentation for evidence that records identify the person performing the work, including the dates of various entries, test results, and interpretation of the results.

### ST - E0021 - Records

**Title**  
Records

**Type**  
**Standard**

### Regulation Definition

All records shall be legible and indelible and shall
Aspen State Regulation Set: E 1.00 Eyebanks

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.

ST - E0022 - Records

Title  Records

Type  Standard

**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 - E0023 - Records

Title  Records

Type  Standard

**Regulation Definition**

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.

Compliance with this standard is essential for certification.
Aspen State Regulation Set: E 1.00 Eyebanks

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

**ST - E0024 - Records**

**Title**  Records

**Type**  Standard

**Regulation Definition**

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.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

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

**ST - E0025 - Records**

**Title**  Records

**Type**  Standard

**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.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Ch.59A-1.005(1)(b)7, F.A.C.
ST - E0026 - Records

**Title** Records

**Type** Standard

**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

c. control and test results.

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

**Interpretive Guideline**

ST - E0027 - Records

**Title** Records

**Type** Standard

**Regulation Definition**
All of these records are retained for ten years after distribution of organs or tissues and 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 - E0028 - Community Involvement & Education
### ST - E0029 - Community Involvement & Education

**Title**  Community Involvement & Education  

**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.  

### ST - E0030 - Community Involvement & Education

**Title**  Community Involvement & Education  

**Type**  Standard  

**Regulation Definition**  
Each OPO, tissue bank and eye 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.
Aspen State Regulation Set: E 1.00 Eyebanks

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.

<table>
<thead>
<tr>
<th>ST - E0031 - Community Involvement &amp; Education</th>
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<tbody>
<tr>
<td><strong>Title</strong></td>
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<tr>
<td><strong>Type</strong></td>
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</table>

**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.

<table>
<thead>
<tr>
<th>ST - E0032 - Safety &amp; Environmental Control</th>
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<tbody>
<tr>
<td><strong>Title</strong></td>
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<td><strong>Type</strong></td>
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</table>

**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.

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

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Surveyor shall review evidence that safety procedures and policies are posted or readily available to all personnel.
<table>
<thead>
<tr>
<th>Title</th>
<th>Safety &amp; Environmental Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Standard</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Title</th>
<th>Safety &amp; Environmental Control</th>
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</thead>
<tbody>
<tr>
<td>Type</td>
<td>Standard</td>
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</table>

**Regulation Definition**


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

**Interpretive Guideline**

Surveyor shall review OSHA requirements, and if there appears to be non-compliance, refer immediately to OSHA.
### Aspen State Regulation Set: E 1.00 Eyebanks

**Title** Facilities & Equipment

**Type** Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities are designated for the specialized purposes for which they are to be used and shall be maintained in a clean and orderly manner.</td>
<td>Ch.59A-1.005(3)(a), F.A.C.</td>
</tr>
</tbody>
</table>

**ST - E0036 - Facilities & Equipment**

**Title** Facilities & Equipment

**Type** Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>All instruments and equipment are subjected to regularly scheduled maintenance and calibration. All temperature measuring devices must be calibrated against U.S. Bureau of Standards certified thermometers.</td>
<td>Ch.59A-1.005(3)(a), F.A.C.</td>
</tr>
</tbody>
</table>

**ST - E0037 - Facilities & Equipment**

**Title** Facilities & Equipment

**Type** Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerators and freezers used for the storage of tissues shall have monitors. Each agency shall have</td>
<td>Ch.59A-1.005(3)(a), F.A.C.</td>
</tr>
</tbody>
</table>

Compliance with this standard is essential for certification.

Surveyor shall review for evidence of documented maintenance records.

Compliance with this standard is essential for certification.
established procedures to follow in the event of electrical failure.

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

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

### Regulation Definition

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

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

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

### Regulation Definition

Each eye bank shall have an adequate stable electrical source and a sufficient number of grounded electrical outlets for operating laboratory equipment. Laminar flow hoods or similar piece of equipment shall be available for sterile processing.

Ch.59A-1.005(53)(b), F.A.C.

<table>
<thead>
<tr>
<th>Title</th>
<th>Facilities &amp; Equipment</th>
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<tr>
<td>Type</td>
<td>Standard</td>
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</table>
Aspen State Regulation Set: E 1.00 Eyebanks

**Type**  
Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td>Each eye bank shall have a refrigerator with a device for recording temperature variations. Temperature variations shall be recorded daily and remain within the range of 2 degrees to 6 degrees C. These records shall be kept for a minimum of ten years. The refrigerator shall be maintained for the exclusive use of donor related material and shall contain clearly defined and labeled areas for all tissue stored, i.e., quarantined tissue, surgical tissue awaiting distribution, and research tissue.</td>
<td></td>
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</table>

Ch.59A-1.005(53)(c), F.A.C.

**Title**  
Facilities & Equipment

**Type**  
Standard

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<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td>In the event of power failure, there shall be established policies and procedures for action to be taken, which may include an emergency power supply to maintain essential refrigeration.</td>
<td></td>
</tr>
</tbody>
</table>

Ch.59A-1.005(53)(d), F.A.C.

**Title**  
Facilities & Equipment
Aspen State Regulation Set: E 1.00 Eyebanks

<table>
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<tr>
<th>Type</th>
<th>Standard</th>
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</thead>
</table>

**Regulation Definition**

| No sterilized instruments, supplies, and reagents, such as corneal preservation medium for surgical tissues, shall be used beyond the expiration date for surgical tissues. |
| Compliance with this standard is essential for certification. |

Ch.59A-1.005(53)(e), F.A.C.

**ST - E0043 - Facilities & Equipment**

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard</th>
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</thead>
</table>

**Regulation Definition**

| Satellite eye banks that retrieve, process, and distribute tissue shall have a technician and be supervised by and have access to a qualified medical director or designee. Such satellite eye bank shall be inspected by surveyors for the AHCA as part of the certification process for the parent eye bank. |
| Compliance with this standard is essential for certification. |

Ch.59A-1.005(54), F.A.C.

**ST - E0044 - Ethical Standards**

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard</th>
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</thead>
</table>

**Regulation Definition**

| The eye bank has written policies to avoid conflicts of interest. |
| Compliance with this standard is essential for certification. |
ST - E0045 - Ethical Standards

Title Ethical Standards

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.

ST - E0046 - Quality Assurance

Title Quality Assurance

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.

Compliance with this standard is essential for certification.

ST - E0047 - Quality Assurance
Title Quality Assurance

Type Standard

**Regulation Definition**

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.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

ST - E0048 - Quality Assurance

Title Quality Assurance

Type Standard

**Regulation Definition**

The QA program shall include ongoing monitoring and evaluation of its activities, identification of problems, and plans for corrective action.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

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

ST - E0049 - Quality Assurance

Title Quality Assurance

Type Standard

**Regulation Definition**

The QA procedures and records shall be reviewed at

**Interpretive Guideline**

Surveyor shall review documentation for:

Ch.59A-1.005(1)(a)2.f., F.A.C.
Aspen State Regulation Set: E 1.00 Eyebanks

least annually and shall provide the basis for the development of the QA program.

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 - E0050 - Quality Assurance

Type Standard

Title Quality Assurance

Interpretive Guideline

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 tissues(s) to the source OPO, tissue bank or eye bank, which in turn shall forward the adverse reaction information to the AHCA.

ST - E0051 - Performance Standards

Type Standard

Title Performance Standards

Interpretive Guideline

Each eye bank shall demonstrate proficiency in all aspects of eye banking by annually retrieving, processing, and distributing at least 100 corneas for penetrating keratoplasty and provide the AHCA with documentation of its performance.

Compliance with this standard is essential for certification.
### ST - E0052 - Performance

**Title** Performance

**Type** Standard

**Regulation Definition**
The eye bank has a policy for the physical inspection of the donor and examination and documentation of the prospective donor's available medical record or death investigation.

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

Ch.59A-1.005(49)(b), F.A.C.

### ST - E0053 - Performance

**Title** Performance

**Type** Standard

**Regulation Definition**
Review of all available records on each donor is performed by an individual who is qualified by profession, education and training to do so, and who is familiar with the intended use of the tissue.

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

Ch.59A-1.005(49)(c), F.A.C.

### ST - E0054 - Informed Consent

**Title** Informed Consent

**Type** Standard
### Regulation Definition

Agency personnel shall be trained regarding obtaining and documenting consent for donation.

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

| Title         | Informed Consent
<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Type</td>
<td>Standard</td>
</tr>
</tbody>
</table>

### Interpretive Guideline

Consent shall be obtained from each donor, next of kin, or other designated legal entity in order of priority and availability pursuant to s. 765.512, F.S.

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

<table>
<thead>
<tr>
<th>ST - E0056 - Informed Consent</th>
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</table>

### Regulation Definition

A copy of the original signed consent form or record of telephone consent shall be retained in the agency's donor record.

Ch.59A-1.005(7)(a)5., F.A.C.

<table>
<thead>
<tr>
<th>ST - E0057 - Informed Consent</th>
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<tr>
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### ST - E0058 - Donor Compensation

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<tr>
<th>Title</th>
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<th>Type</th>
<th>Standard</th>
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### ST - E0059 - Sale Of Anatomical Matter

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<tr>
<th>Title</th>
<th>Sale Of Anatomical Matter</th>
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</table>

### Regulation Definition

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.

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

### Interpretive Guideline

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

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

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

### Interpretive Guideline

Sale of one of a pair or organs (such as an eye or kidney) by a living donor for financial compensation is

<table>
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<tr>
<td>Compliance with this standard is essential for certification.</td>
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</tbody>
</table>
Aspen State Regulation Set: E 1.00 Eyebanks

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.

ST - E0060 - Donor Selection

Title  Donor Selection

Type  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye tissue from donors with the following shall not be used for penetrating keratoplasty, lamellar keratoplasty, patch grafts, epikeratoplasty or any other type of surgery:</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>

1. death of unknown cause;

2. death from central nervous system diseases of unknown etiology;

3. Creutzfeldt-Jacob disease;

4. subacute sclerosing panencephalitis;

5. progressive multifocal leukoencephalopathy;

6. congenital rubella;

7. Reye's syndrome;

8. active viral encephalitis of unknown origin;

9. active septicemia (bacteremia, fungemia, viremia);

10. active bacterial or fungal endocarditis;
11. active viral hepatitis;

12. rabies;

13. intrinsic eye disease;
   a. retinoblastoma;
   b. malignant tumors of the anterior ocular segment;
   c. active ocular or intraocular inflammation: conjunctivitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis;
   d. congenital or acquired disorders of the eye which preclude a successful outcome for the intended use, e.g., a central donor corneal scar for an intended penetrating keratoplasty, keratoconus, and eratoglobus;
   e. pterygia or other superficial disorders of the conjunctiva or corneal surface involving the central optical area of the corneal button.
   f. exceptions are that tissue with local eye disease affecting the corneal endothelium may be used for epikeratoplasty, patch grafts, and scleral transplant surgery, and tissue with local eye disease affecting the corneal endothelium or previous ocular surgery that does not compromise the corneal stroma may be used for lamellar keratoplasty or patch grafts.

14. prior intraocular or anterior segment surgery:
   a. refractive corneal procedures, e.g., radial keratotomy, lamellar inserts, etc.;
b. laser photoablation surgery;

c. if corneas are used from donors who have had prior anterior segment surgery (e.g., cataract, intraocular lens, glaucoma filtration), the corneas shall be screened by specular microscopy and meet the eye bank’s endothelial standards as determined by the medical director; and

d. laser surgical procedures such as argon laser trabeculoplasty, retinal and panretinal photoagulation do not necessarily preclude use for penetrating keratoplasty but should be cleared by the medical director;

15. active leukemia;

16. active disseminated lymphomas;

17. hepatitis B surface antigen positive donors;

18. recipients of human pituitary-derived growth hormone (pit-hGH) during the years from 1963 -- 1985;

19. HIV seropositive donors;

20. acquired immunodeficiency syndrome (AIDS);

21. children (under 13 years old) and infants of mothers with AIDS or a high risk of HIV infection;

22. high risk for HIV infection based on the FDA Guidance Concerning Application of Testing and High Risk Criteria for HIV and Hepatitis for Banked Human Tissue, incorporated herein by reference;

23. HTLV infection;
24. active syphilis;

25. hepatitis C seropositive donors.

Ch.59A-1.005(50)(a)1.-25., F.A.C.

ST - E0061 - Donor Selection

Title  Donor Selection

Type  Standard

**Regulation Definition**

The eye bank has a policy that tissue from donors meeting the criteria in EBS 059 shall not be used for epikeratoplasty or other surgery with the exception that tissue with local eye disease affecting the corneal endothelium (e.g., aphakia, iritis) is acceptable for use. Interval of time from donor's death to preservation of eye tissue may be extended.

Ch.59A1.005(50)(b), F.A.C.

**ST - E0062 - Donor Testing**

Title  Donor Testing

Type  Standard

**Regulation Definition**

Culturing of eye bank donor eyes is recommended. However, the responsibility for determining the need of culturing shall reside with the transplanting surgeon.

Ch.59A-1.005(51)(a), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.
ST - E0063 - Donor Testing

Title  Donor Testing

Type  Standard

Regulation Definition
Eye banks may elect to perform corneal-scleral rim cultures at the time of the corneal preservation in tissue culture medium. Positive culture reports shall be reported to the receiving surgeon or recipient eye bank.

Interpretive Guideline
Compliance with this standard is essential for certification.

Ch.59A-1.05(51)(a)1., F.A.C.

ST - E0064 - Donor Testing

Title  Donor Testing

Type  Standard

Regulation Definition
Each eye bank shall recommend culturing of the corneal-scleral rim for corneal transplantation, or a piece of sclera for scleral implantation at the time of surgery. Positive culture results in cases of postoperative infection shall be reported to the eye bank that processed the tissue.

Interpretive Guideline

Ch.59A-1.005(51)(a)2., F.A.C.

ST - E0065 - Donor Testing

Title  Donor Testing
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**Aspen State Regulation Set: E 1.00 Eyebanks**

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard</th>
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</table>

**Regulation Definition**

| Each eye bank shall have an HIV screening program using FDA-approved tests, pursuant to 10D-93.073, F.A.C., for all donors of surgically designated tissue. A negative screening test shall be documented prior to release of tissue for transplantation. |
| Compliance with this standard is essential for certification. |

**Interpretive Guideline**

| Surveyor shall verify that the laboratory has been issued a current license under Chapter 483, Part I, F.S. Non-compliance with this section mandates referral to the Laboratory Licensure Section, Agency for Health Care Administration. |

Ch.5A-1.005(51)(b)1., F.A.C.

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**ST - E0066 - Donor Testing**

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard</th>
</tr>
</thead>
</table>

**Regulation Definition**

| Eye tissue 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, incorporated herein by reference. |
| Compliance with this standard is essential for certification. |

**Interpretive Guideline**

| |

Ch.59A-1.005(51)(b)2., F.A.C.

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**ST - E0067 - Donor Testing**

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard</th>
</tr>
</thead>
</table>

**Regulation Definition**

| Each eye bank shall have a hepatitis B screening program using an FDA-approved test, pursuant to |
| Compliance with this standard is essential for certification. |

**Interpretive Guideline**

| |

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## Aspen State Regulation Set: E 1.00 Eyebanks

<table>
<thead>
<tr>
<th>10D-93.073, F.A.C., for hepatitis B surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation.</th>
<th>Surveyor shall verify that the laboratory has been issued a current license under Chapter 483, Part I, F.S. Non-compliance with this section mandates referral to the Laboratory Licensure Section, Agency for Health Care Administration.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ch.59A-1.005(51)(c), F.A.C.</td>
<td>ST - E0068 - Donor Testing</td>
</tr>
<tr>
<td><strong>Title</strong> Donor Testing</td>
<td><strong>Type</strong> Standard</td>
</tr>
<tr>
<td><strong>Regulation Definition</strong> Each eye bank shall have a hepatitis C screening program using an FDA-approved test, pursuant to 10D-93.073, F.A.C., for hepatitis C surface antigen for all donors of surgically designated tissue. A negative screening test or neutralization or confirmatory test must be documented prior to release of tissue for transplantation.</td>
<td><strong>Interpretive Guideline</strong> Compliance with this standard is essential for certification.</td>
</tr>
<tr>
<td></td>
<td>Surveyor shall verify that the laboratory has been issued a current license under Chapter 483, Part I, F.S. Non-compliance with this section mandates referral to the Laboratory Licensure Section, Agency for Health Care Administration.</td>
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<tr>
<td>Ch.59A-1.005(51)(d), F.A.C.</td>
<td>ST - E0069 - Donor Testing</td>
</tr>
<tr>
<td><strong>Title</strong> Donor Testing</td>
<td><strong>Type</strong> Standard</td>
</tr>
<tr>
<td><strong>Regulation Definition</strong> If donor screening for HTLV has been performed, a negative screening test shall be obtained and documented prior to release of tissue for transplantation.</td>
<td><strong>Interpretive Guideline</strong> Compliance with this standard is essential for certification.</td>
</tr>
<tr>
<td></td>
<td>Surveyor shall verify that the laboratory has been issued a current license under Chapter 483, Part I, F.S. Non-compliance with this section mandates referral to the Laboratory Licensure Section, Agency for Health Care Administration.</td>
</tr>
</tbody>
</table>
Aspen State Regulation Set: E 1.00 Eyebanks

Ch.59A-1.005(51)(e), F.A.C. Health Care Administration.

ST - E0070 - Donor Testing

Title Donor Testing

Type Standard

Regulation Definition
If the screening test for syphilis is performed and is positive, a negative confirmatory test shall be obtained and documented prior to release of tissue for transplantation.

Interpretive Guideline
Compliance with this standard is essential for certification.

Surveyor shall verify that the laboratory has been issued a current license under Chapter 483, Part I, F.S. Non-compliance with this section mandates referral to the Laboratory Licensure Section, Agency for Health Care Administration.

ST - E0071 - Donor Information Documentan

Title Donor Information Documentan

Type Standard

Regulation Definition
Donor screening forms and copies of medical charts, medical examiner, or coroner review forms and gross autopsy results, if performed, shall be completed and retained on all donated eye tissue as part of the donor record. Until the final written autopsy report becomes available, documentation of verbal reports of autopsy findings are acceptable.

Interpretive Guideline
Compliance with this standard is essential for certification.

ST - E0072 - Donor Information Documentation

Title Donor Information Documentation
Aspen State Regulation Set: E 1.00 Eyebanks

**ST - E0073 - Donor Information Documentation**

**Type**  Standard

**Regulation Definition**
The eye bank has a report form for retaining donor and recipient information. This form includes the following minimum information:

1. eye bank identification number unique to each tissue graft;
2. name of eye bank;
3. location of eye bank;
4. phone number;
5. type of preservation;
6. age of donor;
7. cause of death;
8. type of preservation granted;
9. organ identification number;
10. eye bank identification number;
11. identification of eye bank clinical staff;
12. identification of eye bank research staff;
13. identification of eye bank management staff;
14. identification of eye bank finance staff;
15. identification of eye bank legal staff;
16. identification of eye bank human resources staff;
17. identification of eye bank marketing staff;
18. identification of eye bank administrative staff;
19. identification of eye bank technical staff;
20. identification of eye bank support staff;
21. identification of eye bank volunteer staff;
22. identification of eye bank board of directors;
23. identification of eye bank governing board;
24. identification of eye bank management;
25. identification of eye bank board of trustees;
26. identification of eye bank advisory board;
27. identification of eye bank advisory committee;
28. identification of eye bank advisory panel;
29. identification of eye bank advisory council;
30. identification of eye bank advisory board.

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

Ch.59A-1.005(52)(b), F.A.C.
8. death date and time;
9. enucleation or in situ retrieval date and time;
10. preservation date and time;
11. slip lamp report;
12. specular microscopy, if performed;
13. name of enucleator/evaluator/technician;
14. name of surgeon receiving tissue;
15. recipient identification;
16. utilization of non-transplantable tissue;
17. all serological or microbiological tests performed; and
18. adverse reaction, when reported.

Ch.59A-1.005(52)(c)1.-18., F.A.C.

ST - E0074 - Retrieval & Processing Procedures

Title Retrieval & Processing Procedures

Type Standard

Regulation Definition
The eye bank's policies and records indicate that the ultimate responsibility for personnel to perform enucleation rests with the agency director and the medical director.

Interpretive Guideline
Compliance with this standard is essential for certification.
ST - E0075 - Retrieval & Processing Procedures

Type: Standard

Title: Retrieval & Processing Procedures

**Regulation Definition**
Removal of the corneal-scleral rim shall be performed using sterile technique by individuals specifically trained in in situ retrieval and facility-based removal of the corneal-scleral segment.

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

ST - E0076 - Retrieval & Processing Procedures

Type: Standard

Title: Retrieval & Processing Procedures

**Regulation Definition**
Eye bank shall use a corneal storage medium which has been used and stored according to the manufacturer's recommendations. The manufacturer's recommendations must be retained and made available for inspection by surveyors for the AHCA.

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

Surveyor reviews documentation for manufacturer's recommendation for storage and usage of the medium available in the laboratory.

ST - E0077 - Retrieval & Processing Procedures

Title: Retrieval & Processing Procedures
### Aspen State Regulation Set: E 1.00 Eyebanks

**ST - E0078 - Retrieval & Processing Procedures**

**Type**: Standard  

**Regulation Definition**

Eye banks employing long-term preservation of corneal tissue, such as organ culturing, shall carefully document the procedure in their procedures manual, and adhere to strict aseptic technique.

Ch.59A-1.005(55)(d), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

**ST - E0079 - Retrieval & Processing Procedures**

**Type**: Standard  

**Regulation Definition**

Eye banks that store whole eyes for lamellar or refractive keratoplasty shall employ aseptic practices using one of the preservation methods given in the eye banks's procedures manual. The selected preservation method shall be documented in the eye bank's own procedure manual.

Ch.59A-1.005(55)(e), F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.
Aspen State Regulation Set: E 1.00 Eyebanks

bank's own procedures manual.

Ch.59A-1.005(55)(f)1., F.A.C.

ST - E0080 - Retrieval & Processing Procedures

Type  Standard

**Regulation Definition**
An expiration date for use of tissue shall be indicated based on the container capability and factors documented or recommended by the eye bank.

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

Ch.59A-1.005(55)(f)2., F.A.C.

ST - E0081 - Retrieval & Processing Procedures

Type  Standard

**Regulation Definition**
Corneal preservation shall occur as soon as possible after death and within the time frame determined by the medical director as defined by the agency's policies and procedures. All time intervals (i.e., time of death to the time of enucleation and preservation) shall be recorded for each donor.

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

Ch.59A-1.005(55)(g), F.A.C.

ST - E0082 - Retrieval & Processing Procedures

Title  Retrieval & Processing Procedures
### Aspen State Regulation Set: E 1.00 Eyebanks

**Type**  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td>Procedures for eye maintenance shall be described in the eye bank's policies and procedures. Each individual eye bank's procedure is left to the discretion of the medical director and shall be clearly documented and adhered to.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
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Ch.59A-1.005(55)(h), F.A.C.

**ST - E0083 - Retrieval & Processing Procedures**

**Title**  Retrieval & Processing Procedures

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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<tbody>
<tr>
<td>Prior to distribution of tissue for transplantation, the medical director or designee has reviewed and documented the medical and laboratory information in accordance with criteria established in this rule.</td>
<td>Compliance with this standard is essential for certification.</td>
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Ch.59A-1.005(55)(i), F.A.C.

**ST - E0084 - Retrieval & Processing Procedures**

**Title**  Retrieval & Processing Procedures

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td>Review of records indicate that the medical director or designee has signed off on records that were reviewed.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>
If donor tissue provided for purposes other than surgery, e.g., research, practice surgery, etc., and if that donor tissue is not screened for HIV, hepatitis, or syphilis, a label indicating that screening for HIV-antibody, hepatitis B, hepatitis C, or syphilis has not been carried out or stating "Potentially Hazardous Biological Material" shall be attached to the container used for the donor tissue storage and transport.

Ch.59A-1.005(55)(j), F.A.C.

ST - E0085 - Retrieval & Processing Procedures

Title  Retrieval & Processing Procedures

Type  Standard

**Regulation Definition**

Each agency shall have 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.

**RegSet.rpt**

The transplanting surgeon has ultimate responsibility for determining the suitability of the tissue for transplantation.

Ch.59A-1.005(56), F.A.C.
Aspen State Regulation Set: E 1.00 Eyebanks

ST - E0087 - Tissue Evaluation

Title  Tissue Evaluation

Type  Standard

Regulation Definition
The corneal-scleral segment shall be initially examined grossly for clarity, epithelial defects, foreign objects, contamination, and scleral color (e.g., jaundice).

Interpretive Guideline
Compliance with this standard is essential for certification.

Ch.59A-1.005(56)(a), F.A.C.

ST - E0088 - Tissue Evaluation

Title  Tissue Evaluation

Type  Standard

Regulation Definition
The cornea shall be examined for epithelial and stromal pathology and in particular endothelial disease. Enucleated whole globes are to be examined in the laboratory prior to distribution and corneal procurement. After corneal procurement, the corneal-scleral rim is evaluated by slit lamp biomicroscopy, even if the donor eye has been examined with the slit lamp prior to procurement of the corneal-scleral rim, to ensure that damage to the corneal endothelium or surgical detachment of Descemet's membrane did not occur.

Interpretive Guideline
Compliance with this standard is essential for certification.

Ch.59A-1.005(56)(b), F.A.C.

ST - E0089 - Tissue Storage
Aspen State Regulation Set: E 1.00 Eyebanks

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<th>Title</th>
<th>Tissue Storage</th>
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<tr>
<td>Type</td>
<td>Standard</td>
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</table>

**Regulation Definition**

All surgical tissue shall be stored in quarantine until negative serology results have been documented, pursuant to 10D-93.073, F.A.C.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Ch.59A-1.005(57)(a), F.A.C.

<table>
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<tr>
<th>ST - E0090 - Tissue Storage</th>
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<tr>
<th>Title</th>
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<td>Type</td>
<td>Standard</td>
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</table>

**Regulation Definition**

All tissue shall be stored at a temperature appropriate to the method of preservation used.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Ch.59a-1.005(57)(b), F.A.C.

<table>
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<tr>
<th>ST - E0091 - Labeling</th>
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<tbody>
<tr>
<td>Title</td>
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<td>Type</td>
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</table>

**Regulation Definition**

A sufficient area of the container shall remain unobstructed to permit inspection of the contents.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Ch.59A-1.005(58)(a), F.A.C.
ST - E0092 - Labeling

Title  Labeling

Type  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each corneal or scleral tissue shall be clearly and indelibly labeled to include, at least, the following:</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
<tr>
<td>1. name of source eye bank;</td>
<td></td>
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<tr>
<td>2. tissue identification number;</td>
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</tr>
<tr>
<td>3. type of tissue;</td>
<td></td>
</tr>
<tr>
<td>4. date and time of donor's death;</td>
<td></td>
</tr>
<tr>
<td>5. date and time of corneal-scleral preservation; and</td>
<td></td>
</tr>
<tr>
<td>6. expiration date for scleral tissue.</td>
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</tbody>
</table>

Ch.59A-l.005(58)(b)1.-6., F.A.C.

ST - E0093 - Labeling

Title  Labeling

Type  Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement shall accompany the tissue stating that:</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
<tr>
<td>1. the tissue is intended for single patient application only and that it is not to be considered sterile and that</td>
<td></td>
</tr>
</tbody>
</table>

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Aspen State Regulation Set: E 1.00 Eyebanks

the FDA therefore recommends culturing or reculturing; and

2. the tissue was procured from a donor who was non-reactive when tested for HIV-1 and HIV-2 antibodies, hepatitis B surface antigen (HBsAg), and hepatitis C antibody (HCV) using a test approved by the FDA and follows provision of 10D-93.073, F.A.C.

Ch.59A-1.005(58)(b)7.a.-b., F.A.C.

ST - E0094 - Packaging

Title Packaging

Type Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each tissue is individually packaged and sealed with a shrink wrap.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
<tr>
<td>The shrink wrap covers the cap and half the vial.</td>
<td></td>
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</tbody>
</table>

Ch.59A-1.005(57)(a), F.A.C.

ST - E0095 - Packaging

Title Packaging

Type Standard

<table>
<thead>
<tr>
<th>Regulation Definition</th>
<th>Interpretive Guideline</th>
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</thead>
<tbody>
<tr>
<td>The tissue shall be packed in a water proof container with wet ice, so as to maintain the temperature of the tissue at an acceptable level. Packing is done so that the package insert and tissue label do not become wet. Special instructions shall be included on the package insert.</td>
<td>Compliance with this standard is essential for certification.</td>
</tr>
</tbody>
</table>
Aspen State Regulation Set: E 1.00 Eyebanks

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

ST - E0096 - Packaging

Title  Packaging

Type  Standard

**Regulation Definition**

A package insert form shall accompany the tissue for transplantation. This form shall include the following:

1. recommended storage temperature with specific emphasis on DO NOT FREEZE;

2. that the surgeon shall check for integrity of the seal and immediately report to the eye bank any evidence of possible tampering;

3. that color change per the manufacturer's guidelines may indicate a change in pH, in which case the tissue shall not be used and a report made immediately to the eye bank;

4. whether pre-surgical microbiological cultures were performed by the eye bank, including the advisement that culture of the donor rim and sclera shall be performed at the time of surgery; and

5. the form shall also advise the receiving surgeon that the tissues are delivered with no warranty as to the merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging if the tissue is suitable for use.

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

**Interpretive Guideline**

Compliance with this standard is essential for certification.
<table>
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<tr>
<th>Title</th>
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<tbody>
<tr>
<td>ST - E0097 - Tissue Distribution System Fair &amp; Equitable</td>
<td>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. Compliance with this standard is essential for certification. Ch.59A-1.005(19), F.A.C.</td>
</tr>
<tr>
<td>ST - E0098 - Adverse Reaction Policy</td>
<td>The eye bank has an adverse reaction policy. Compliance with this standard is essential for certification. Ch.59A-1.011(1), F.A.C.</td>
</tr>
<tr>
<td>ST - E0099 - Look Back Procedures</td>
<td></td>
</tr>
</tbody>
</table>
# Aspen State Regulation Set: E 1.00 Eyebanks

## ST - E0100 - Recall Procedures

**Title** Recall Procedures

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<thead>
<tr>
<th>Type</th>
<th>Standard</th>
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**Regulation Definition**

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.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Ch.59A-1.005(14), F.A.C.

## ST - E0101 - HIV Testing And Notification

**Title** HIV Testing And Notification

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<thead>
<tr>
<th>Type</th>
<th>Standard</th>
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**Regulation Definition**

Each eye 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.

**Interpretive Guideline**

Compliance with this standard is essential for certification.

Ch.59A-1.005(15), F.A.C.
Aspen State Regulation Set: E 1.00 Eyebanks

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 Ch. 10D-93.073, F.A.C.

Compliance with this standard is essential for certification.

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

ST - E9999 - Final Observations

Title Final Observations

Type Memo Tag

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