AABB Standards

1.3 Policies, Processes, and Procedures

Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these BB/TS Standards are satisfied. All such policies, processes, and procedures shall be in writing or captured electronically and shall be followed.

1.3.1 The medical director shall approve all medical and technical policies, processes, and procedures.

1.3.2 Any exceptions to policies, processes, and procedures warranted by clinical situations shall require justification and pre-approval by the medical director on a case-by-case basis.

Similar Standards

AATB

L1.000 Tissue Dispensing Services - General

Medical, dental, and hospital facilities, and physician offices that are Tissue Dispensing Services shall establish policies and procedures regarding cells and/or tissue receipt, storage, and final disposition to ensure the safety and traceability of cells and/or tissue from receipt through clinical use, transfer, or destruction.

CAP

TRM.30900

Is there a mechanism for the transfusion service medical director or designee to approve and document deviations from standard operating procedures?

The Joint Commission

Hospital Standard PC.17.10

Laboratory Standard QC.5.300

The organization uses standardized procedures to acquire, receive, store, and issue tissues. Does the hospital develop, maintain, and follow procedures to:

EP 1 Assign responsibility for overseeing the tissue program throughout the hospital, including storage and issuance activities?

EP 2 Validate that source facilities who supply tissues are licensed by state agencies and/or registered as a tissue establishment with the FDA?

EP 3 Coordinate tissue ordering, receipt, storage, and issuance throughout the hospital?

EP 4 Transport, handle, store, and use tissue according to the source facilities’ or manufacturers’ written directions?

EP 5 Log in all incoming tissue?

EP 6 Maintain continuous temperature monitoring of storage refrigerators and freezers?

EP 7 Maintain daily records to show that tissues were stored at the required temperatures?
EP 8  [Ensure] storage equipment has functional alarms and emergency back-up?

EP 9  Comply with state and/or federal regulations when acting as a source facility that supplies tissues?

EP 10  Verify at receipt that package integrity is met and transport temperature range was controlled and acceptable?

<table>
<thead>
<tr>
<th>Accrediting Organization</th>
<th>AATB</th>
<th>CAP</th>
<th>The Joint Commission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>L1.000 Tissue Dispensing Services - General</td>
<td>TRM.30900</td>
<td>PC.17.10/QC.5.300 EPs 1-10</td>
</tr>
</tbody>
</table>

**Explanation: Standard 1.4**

Not only are tissue products subject to a tissue establishment’s internal disasters (including environmental disasters that affect the facility directly, such as power failures, storm damage, etc), but they also often become what is needed in an external disaster (not affecting the facility directly). Alternative tissue storage areas should be available and an inventory management system should be created for use in the event of a disaster. Emergency operation plans need to be defined and directional.

**AABB Standards**

1.4 Emergency Preparedness

The blood bank or transfusion service shall have emergency operation policies, processes, and procedures to respond to the effects of internal and external disasters.

**Similar Standards**

**AATB**

Section E Processing, Preservation, Quarantine, and Storage

E4.150 Emergency Transfers

Policies and procedures shall be developed for the emergency transfer of cells and/or tissue to designated alternative storage facilities and for alternative monitoring methods in the event of mechanical failure or loss of coolant. These shall include specification of Tolerance Limits or temperatures and time limits after which the initiation of the emergency transfer is required. Actions to be taken when limits have been exceeded shall also be specified in the SOPM.
**SELF-ASSESSMENT: 1. ORGANIZATION**

**Standards**

**AABB**

1.0 Organization  
The blood bank or transfusion service shall have a structure that clearly defines and documents the parties responsible for the provision of blood, components, tissue, derivatives, and services and the relationship of individuals responsible for key quality functions.

**AATB**

Similar to AABB 1.0 - 1.2:  
Similar to AABB 1.3:  
Similar to AABB 1.4:  

**CAP**

Similar to AABB 1.0 - 1.2:  
Similar to AABB 1.3:  

**The Joint Commission**

Similar to AABB 1.0 - 1.2:  
Similar to AABB 1.3:  
Similar to AABB 1.4:  

**Checklist**

Objective  
To describe the framework of the tissue dispensing service as it exits within the organization, including responsible individuals and emergency plans.

| ABB Standards  
(Similar Standards or Related Notes in Italics) | Supporting Documents  
(Policies, Procedures, Charts, Forms, etc) | Compliant?  
Yes Partly No |
|---|---|---|
| 1.0 Organization  
- Identify where the tissue dispensing services exist in the organizational chart.  
- Identify responsible parties for the provision of tissue.  
- Describe the relationships of all personnel responsible for key quality functions.  
 **The Joint Commission:** Confirm responsibility is assigned throughout the hospital for oversight for the entire tissue program. See definition of "tissue" by The Joint Commission.  
Comments: | | |