




# The Joint Commission



Accreditation Program: Laboratory  
Transplant Safety


**Standard TS.03.01.01**

The organization uses standardized procedures for managing tissues.

**Elements of Performance for TS.03.01.01**

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| 1.     | The organization assigns responsibility to one or more individuals for overseeing the acquisition, receipt, storage, and issuance of tissues throughout the organization.<br>Note: Responsibility for this oversight involves coordinating efforts to provide standardized practices throughout the organization. An organization may have a centralized process (one department responsible for the ordering, receipt, storage, and issuance of tissue throughout an organization) or a decentralized process (multiple departments responsible for the ordering, receipt, storage, and issuance of tissue throughout the organization).                                                 | <b>A</b>                                                                                     |
| 2.     | (D) The organization develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of tissues. (See also TS.03.02.01, EP 5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>A</b>                                                                                     |
| 3.     | The organization confirms that tissue suppliers are registered with the U.S. Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.<br>Note: This element of performance does not apply to autologous tissue- or cellular-based products considered tissue for the purposes of these standards but classified as medical devices by the FDA.<br>Footnote: For U.S. Food and Drug Administration (FDA) registration, the supplier registration status may also be checked annually by using the FDA's online database: <a href="http://www.fda.gov/cber/tissue/tissregdata.htm">http://www.fda.gov/cber/tissue/tissregdata.htm</a> .     | <b>A</b>                                                                                     |
| 4.     | The organization coordinates its acquisition, receipt, storage, and issuance of tissues throughout the organization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>A</b>                                                                                     |
| 5.     | The organization follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  <b>A</b> |
| (M) 6. | (D) The organization documents the receipt of all tissues. (See also TS.03.02.01, EPs 3 and 6)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>C</b>                                                                                     |
| (M) 7. | (D) The organization verifies at the time of receipt that package integrity is met and transport temperature range was controlled and acceptable for tissues requiring a controlled environment. This verification is documented. (See also TS.03.02.01, EP 6)<br>Note 1: If the distributor uses validated shipping containers, then the receiver may document that the shipping container was received undamaged and within the stated time frame.<br>Note 2: Tissues requiring no greater control than "ambient temperature" (generally defined as the temperature of the immediate environment) for transport and storage would not need to have the temperature verified on receipt. | <b>C</b>                                                                                     |
| (M) 8. | (D) The organization maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures. (See also TS.03.02.01, EP 5)<br>Note 1: Types of tissue storage include room temperature, refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen storage.<br>Note 2: Tissues requiring no greater control than "ambient temperature" (defined as the temperature of the immediate environment) for storage would not require temperature monitoring.                                                                                                                                               | <b>C</b>                                                                                     |







**KEY:** **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply; **(M)** indicates Measure of Success if needed; **(D)** indicates that documentation is required





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| 9.  | The organization continuously monitors the temperature of refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues.<br>Note 1: Continuous temperature recording is not required but may be available with some continuous temperature monitoring systems.<br>Note 2: For tissue stored at room temperature, continuous temperature monitoring is not required.                                                                                                                                                                            | <b>A</b>                                                                                     |
| 10. | Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues at a controlled temperature have functional alarms and an emergency back-up plan.<br>Note: For tissue stored at room temperature, alarm systems are not required.                                                                                                                                                                                                                                                                                                                |  <b>A</b> |
| 11. | The organization complies with state and/or federal regulations when it acts as a tissue supplier.<br>Note: The U.S. Food and Drug Administration (FDA) considers the routine policy or practice of shipping tissue to another facility as distribution which requires FDA registration. Returning unused tissue back to the tissue supplier is not considered distribution and does not require FDA registration.<br>Footnote: Please refer to the following Web site: <a href="http://www.fda.gov/cber/tissue/tisreg.htm">http://www.fda.gov/cber/tissue/tisreg.htm</a> . | <b>A</b>                                                                                     |

### Standard TS.03.02.01

The organization traces all tissues bi-directionally.

#### Elements of Performance for TS.03.02.01

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| 1.                                                                                |  The organization's records allow any tissue to be traced from the donor or tissue supplier to the recipient(s) or other final disposition, including discard, and from the recipient(s) or other final disposition back to the donor or tissue supplier. |  <b>A</b> |
|  | 2.  The organization identifies, in writing, the materials and related instructions used to prepare or process tissues.                                                                                                                                   | <b>C</b>                                                                                     |
|  | 3.  The organization documents the dates, times, and staff involved when tissue is accepted, prepared, and issued. (See also TS.03.01.01, EP 6)                                                                                                           | <b>C</b>                                                                                     |
| 4.                                                                                | The organization documents in the recipient's clinical record the tissue type and its unique identifier.                                                                                                                                                                                                                                   | <b>A</b>                                                                                     |
| 5.                                                                                | The organization retains tissue records on storage temperatures, outdated procedures, manuals, and publications for a minimum of 10 years. If required by state and/or federal laws, organizations may have to retain tissue records longer than 10 years. (See also TS.03.01.01, EPs 2 and 8)                                             | <b>A</b>                                                                                     |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

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| 6. | The organization retains tissue records for a minimum of 10 years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest). If required by state and/or federal laws, organizations may have to retain tissue records longer than 10 years. Records are kept on all of the following:<br>- The tissue supplier<br>Note: For medical devices, the manufacturer may be the tissue supplier.<br>- The original numeric or alphanumeric donor and lot identification<br>- The name(s) of the recipient(s) or the final disposition of each tissue<br>- The expiration dates of all tissues<br>(See also TS.03.01.01, EPs 6 and 7)                                                                                                                                                 | <b>A</b> |
| 7. | The organization completes and returns tissue usage information cards requested by the tissue supplier.<br>Footnote: According to the Health Insurance Portability and Accountability Act (HIPAA) regulations regarding protected health information, "A covered entity may disclose protected health information for public health activities or other purposes to a person subject to the jurisdiction of the Food and Drug Administration (FDA) for the following purposes:<br>- To track products if the disclosure is made to a person required or directed by the FDA to track the product<br>- To enable product recalls, repairs or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems" (Refer to 45 CFR 164.512(b)(iii)(B) and (C)) | <b>A</b> |

**Standard TS.03.03.01**

The organization investigates adverse events related to tissue use or donor infections.

**Elements of Performance for TS.03.03.01**

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| 1. | <b>D</b> The organization has a written procedure to investigate tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue.                                                                            | <b>A</b>          |
| 2. | The organization investigates tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue. (See also IC.01.03.01, EP 3)                                                                                  | <b>A</b>          |
| 3. | As soon as the organization becomes aware of a post-transplant infection or other adverse event related to the use of tissue, it reports the infection or adverse event to the tissue supplier.                                                                                             | <b>3</b> <b>A</b> |
| 4. | The organization sequesters tissue whose integrity may have been compromised or that is reported by the tissue supplier as a suspected cause of infection.                                                                                                                                  | <b>3</b> <b>A</b> |
| 5. | The organization identifies and informs tissue recipients of infection risk when donors are subsequently found to have human immunodeficiency virus (HIV), human T-lymphotropic virus-I/II (HTLV-I/II), viral hepatitis, or other infectious agents known to be transmitted through tissue. | <b>3</b> <b>A</b> |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required